Title: What do patients need to know? A study to assess patients' satisfaction with information about medicines.

Abstract

Objectives This study aimed to determine the information needs and reported adherence of patients prescribed medicines for chronic conditions in those who have received a community pharmacy advanced service and those who have not.

Methods A questionnaire was constructed using validated tools to measure medication information satisfaction and adherence together with questions eliciting information regarding the use of pharmacy services and demographic characteristics. This questionaire was distributed from four community pharmacies to a convenience sample of 400 patients as they collected their medicines. Patients were eligible if prescribed more than one regular medicine and attending the pharmacy for longer than three months. The questionnaire was returned directly to the university.

Key Findings 232 (58%) questionnaires were returned. All respondents desired further information about their prescribed medicines, particularly about potential medication problems. Dissatisfaction centred on side effects, interactions and certain medicine characteristics such as how long it will take to act. Satisfaction with information about medicines and adherence were significantly greater in a subgroup reporting that they had received an advanced pharmacy service e.g. medicine use review.

Conclusion Patients who had received an advanced service reported greater adherence and satisfaction with medicine related information. This was a small, observational study, using a convenience sample of four pharmacies; in order to draw definitive conclusions, a larger study with participants randomised to receive an advanced service is required.

Introduction

The World Health Organisation has stated that patients not-adhering to prescribed recommendations for medicines for chronic conditions can lead to poor outcomes and increased medicines wastage and health resource utilisation[1]. Reasons for non-adherence are often subcategorised into intentional and unintentional causes[2]. Unintentional non-adherence occurs when practical barriers such as poor dexterity or memory impair the individual's ability to take their medicines as prescribed. Intentional non-adherence occurs when perceptual barriers such as beliefs, concerns and expectations lead a patient to make a conscious decision to deviate from the prescriber's recommendations. Often patient behaviour is an amalgam of unintentional and intentional factors and thus current adherence research is largely focussed on complex interventions to target both practical and perceptual

barriers.(3) Conversely, routine healthcare provision is dominated by practical behaviour change techniques such as simplifying dosage regimens and providing adherence aids or education(4) which have demonstrated marginal adherence enhancing effects.(5)

A positive relationship between patient satisfaction with information received and adherence is, however, consistently reported.(6) The Satisfaction with Information about Medicines Scale(6) acknowledges that patients have differing information needs; some patients with an internal locus of control and thus a belief that their own actions can influence the outcomes from their prescribed medication may desire detailed information regarding their prescribed medicine whilst others in response to detailed information may feel distressed and adopt coping strategies e.g. making a conscious decision not to take the medicine resulting in reduced adherence.(7)

An essential component of United Kingdom community pharmacy services is provision of the medicines related information necessary for a patient to adhere to their prescribed medicine. In 2005, the UK government introduced two advanced community pharmacy services to support patient adherence by providing appropriate patient information regarding medicines. These services, termed medicine use review (MUR) and new medicines service (NMS), include information provision and adherence assessment as key elements and guide practitioners to ask whether the patient is experiencing any problems or concerns with taking their medicines. There is, however, no comprehensive training or guidance for pharmacists regarding how such problems might be effectively addressed and therefore this may be leading to a one-size-fits-all approach to conducting services with many pharmacists conducting reviews on patients that may not require them and providing information that the patient does not require (8-11). Some MUR studies have demonstrated a positive impact on medicines knowledge, patient confidence and an improvement in disease outcomes.(12-17). There has, however, been criticism of both the MUR and NMS from within pharmacy and other professional groups such as general practitioners regarding the extent to which they successfully support patient medication adherence.(8-10, 18, 19) In particular there is evidence to show that pharmacists may be conducting MURs simply to achieve targets set by the companies which they work for, rather than based on patient need (11, 18, 20).

An exploration of patient satisfaction with medicines related information received, adherence and whether any variation exists between patients who have and have not received an advanced service may provide greater clarity regarding the extent to which essential and advanced community pharmacy services are fulfilling the needs of patients. Therefore, the

aim of this study is to determine the information needs and reported adherence of patients prescribed medicines for chronic conditions in those who have received a community pharmacy advanced service and those who have not.An additional objective of the study is to explore the relationship between adherence and information satisfaction.

Method

Ethical approval for this final year pharmacy student project was obtained from the University of East Anglia Faculty of Medicines and Health Research Ethics Committee.

A convenience sample of five community pharmacies (three independents and two supermarkets) was invited using email with a follow-up phone call to ascertain willingness to participate. All pharmacies expressed an interest in participation and were visited, the study requirements described and verbal consent obtained from the pharmacy manager.

During an eight week period, staff employed by each participating pharmacy identified all patients attending the pharmacy whilst the student was present if they met the following criteria: prescribed more than one regular medicine for a long term condition (similar criteria to the MUR service), aged 18 years or over and receiving medication dispensed by the pharmacy for at least three months. Pharmacy staff approached all eligible patients to avoid selection bias, briefly introduced the survey and indicated the recruiting student's presence. Patients expressing an interest in participation approached the student who provided further information about the service evaluation, a patient information leaflet, questionnaire and envelope for pre-paid return to the university. A complementary pen was provided to enhance the likelihood of response(21). Patients were able to complete the questionnaire in the pharmacy or take it home to complete at a later date. Consent was assumed from return of a completed questionnaire either by post or in person.

The questionnaire comprised the validated Satisfaction with Information about Medicines Scale (SIMS) (6) and Morisky Measure of Adherence Score (MMAS-4) (22) to explore the primary outcomes together with questions to describe respondent demographic characteristics and use of pharmacy services.

The 17 item SIMS invites patients to rate the information received regarding their prescribed medicines. It was validated in patients receiving more than one medicine for more than two months for a variety of chronic conditions. It was chosen as this closely matches the MUR inclusion criteria and is focused on the level of satisfaction with regard to different aspects of

information about medicines. The tool contains two categories: the first nine questions relate to medicine's actions and usage e.g. what the medicine is for and how long it takes to work, whilst questions 10 to 17 examine potential problems with the medicine e.g. the likelihood of experiencing side effects and what to do if a patient misses a dose. The options of the information received being "about right" or "none needed" are assigned a score of 1 and "too much", "too little" or "none received" is scored as 0. Scores therefore range from 0-17 with higher scores indicating greater satisfaction. (6)

The MMAS-4(23) comprises four 'yes'/'no' questions generating a score of one to four, where a score of four indicates self-reported full adherence and scores of one to three signify partial adherence. Both questionnaires ask patients to reflect on information provided for all of their medicines.

The patient information leaflet and questionnaire comprised a brief description of MUR and NMS. Respondents were then asked whether they had received an MUR or NMS in the previous year and space was provided for any thoughts on the services. Space was also provided for any further comments or thoughts.

Piloting (which took place in a separate pharmacy from those in the main study) with 20 patients yielded a low response rate of 45% so the questionnaire information was amended to further emphasise that respondents are anonymous, in line with the literature (24).

In the main study, a target of 100 recruited patients per pharmacy was set. Recruiting students each attended one of the four pharmacies for consecutive full days (9am-6pm) until 100 patients had been recruited. This was a convenience sample with a target number of patients to approach that would be achievable within the timespan of the project whilst providing the evaluation with enough data to draw sensible conclusions.

Descriptive statistics were used to report the demographic data. SIMS was analysed both as a score out of 17 and as the two subscales; these data were reported as a mean (95% confidence interval) or median (interquartile) as appropriate depending upon whether the data were normally distributed or skewed respectively. MMAS-4 scores were dichotomised into 'adherent' and 'partially adherent'. Logistic regression analysis was used to examine whether receipt of an advanced service was associated with self-reported adherence. The following factors directly related to experience of the advanced service: pharmacy service provider, frequency of access to the pharmacist and SIMS score were also included as independent variables. The choice of dichotomisation for SIMS Action Usage and SIMS

Potential Problem was based on exploratory data analysis which revealed a clear change-point or jump in the relationship between the log-OR and SIMS scores. The choice of cut-point was based on visual inspection of when the adherence rate changed greatly between two SIMS scores. A simple content analysis was performed on the 'additional comments' responses. All tests were carried out at the 5% level of significance.

Results

One pharmacy was recruited for the pilot and four separate pharmacies (two independent and two multiples/chains) were recruited for the main study. Four hundred patients were recruited from four community pharmacies in Norfolk, UK. A total of 265 questionnaires (66.3%) were returned, of which 33 (12%) were excluded from analyses because respondents reported that they received only one regular medicine, yielding an actual response rate of 232/367 (63.2%). The questionnaires were primarily returned by post with only 38 (16.4%) respondents completing the questionnaire in the pharmacy. Of the 232 repondents prescribed more than one medicine, 118 (50.9%) reported receiving an advanced service with 105 (45.3%) reporting an MUR and 51 (22%) an NMS intervention. Eleven (4.2%) respondents were unsure about whether or not they had received an advanced service and were thus excluded from the analysis comparing advanced service provision. For respondents reporting not having received an advanced service, the mean (SD) age was 65.24 (15.59) years of which 55 (48.2%) were male, 50 (43.9%) respondents reported visiting a pharmacy once per month and 38 (33.3%) visited more than once per month. 57 (50%) of respondents reported taking more than five medicines. For respondents reporting receipt of an advanced service, the mean (SD) age was 65.65 (12.89) years of which 54 (45.8%) were male. A pharmacy visit once per month was reported by 59 (50%) respondents and more than once per month by 37 (31.4%) respondents which is comparable to respondents who reported not receiving an advanced service. 53 (44.9%) respondents reported taking more than five medicines.

Table 1 and figures 1 and 2 provide a comparison of the SIMS scores for respondents reporting receipt of an advanced service compared with no advanced service. Most respondents were satisified with information received relating to the action and usage of medicines. Notable exceptions were 'How you can tell if it is working' and 'How long it will take to act'. There was, however, a widespread desire for further information regarding the potential problems of their medicines.

Insert Figure 1 and 2

The MMAS-4 was completed by 229 respondents of whom 125 (54.6%) reported that they were adherent. Table 2 summarises the relationships of potential factors associated with MMAS-4 reported adherence.

Insert Table 2

Receipt of an advanced service doubled the likelihood of adherence. No association was identified between adherence and the pharmacy providing services or frequency of pharmacy visits.

A non-linear relationship was observed from exploratory analysis of SIMS and MMAS-4 which revealed a sudden jump in odds at certain scores of SIMS. SIMS 'action and usage' was therefore grouped into scores of 0 to 8 and scores of 9 whilst SIMS 'potential problems' was grouped into scores of 0 to 6, and 7 to 8. The adjusted odds ratio from the logistic regression model showed that the odds of being adherent were marginally higher for participants reporting a high level of 'action and usage' satisfaction but not significantly related to SIMS 'potential problems'. However, there was significant interaction between the terms; participants reporting a high level of satisfaction for both 'action and usage' and 'potential problems' information items were over six times more likely to be adherent.

Analysis of respondent comments identified a general endorsement of the advanced services. Respondents who had received one of the advanced services largely felt that it had served to reassure them about their medication.

"was reassured about my concerns and questions by the pharmacist, no such talks with GP. I always approach a pharmacist now as I am confident in their approach" (223B, male)

Some respondents highlighted that it was useful to reinforce advice that had been given by the GP or to seek information that had not been obtained during the GP consultation.

"It would help to reinforce what the Dr has told you, especially on side effects." (349B, female)

"very useful as questions come up after you leave doctors and you can then ask pharmacist" (201B, female)

Two respondents noted that the information received from the pharmacist had seemed "rushed" and one person stated that the consultation had been performed "at one side of the counter".

There were some respondents for whom the service was either not appropriate or not deemed to not fit in to their medical care.

"as I understand my medication I didn't really need this facility but I'm sure it is useful for many people" (218B, female)

This respondent is acknowledging that whilst not personally required, the service may have a benefit for other people.

"neither services will be of interest to me as this is something my doctor and I review regularly. I don't think I would want to review this with a pharmacist anyway" (228B, female)

This comment suggests that the respondent already receives her information from another source and therefore she is questioning the usefulness of a duplicate service from a healthcare professional perceived to be less appropriate for the purpose.

Discussion

Patients who had received an advanced service reported greater adherence and satisfaction with medicine related information, however there were still needs for information in both groups. In general, patients appear to be largely satisfied with the information received about their prescribed medicines with no variation across different pharmacies or the frequency of visits. A desire for further information about what can be expected from a medicine in terms of how quickly it might work, how to identify efficacy and potential problems associated with prescribed medicines was demonstrated. Whilst it is not possible to demonstrate a causal link due to the observational nature of the study, the evidence supports the assumption that adequate information regarding the potential problems of a medicine is necessary in addition to the basic actions and usage of a medicine in order to achieve adherence. Pharmacists should therefore ensure that discussions with patients address information relating to side effects (including the risk of experiencing them), interactions with other medicines, what to do if a dose is missed, length of time taken to have an effect and how a patient can tell if the medicine is working.

The strengths of this study are the high response rate, wide ranging demographic characteristics of respondents and generally well completed questionnaires. Furthermore,

the inclusive eligibility criteria reflecting those of MURs service provision support the relevance of this evaluation. However, the study comprised a small number of pharmacies situated within a geographically confined area which limits generalisability. By only including patients taking more than one medicine for a chronic condition, this evaluation may have excluded patients that had received the new medicine service and were currently prescribed no additional medicines.

Further study design limitations are response bias introduced by the willingness to please of regular pharmacy patients and selection bias of responders who may be more adherent to their medicines and more active in healthcare decision making than non-responders. To mitigate these effects, potential participants were informed that the questionnaire would be returned to the university and that the pharmacist would not see their responses. The protocol was designed to minimise recruitment bias by pharmacy staff, however, protocol fidelity could not be determined as the research team had no access to pharmacy records in order to confirm that all potential participants had been approached. A further study limitation was the lack of data collected on those patients who were approached to participate and either didn't agree to speak to the student or didn't complete the questionnaire. This data would have allowed a comparison to be made to determine the representativeness of the sample and inform the generalisability of the conclusions.

Finally, self-reported adherence has been shown to have lower specificity compared to pill counts or electronic monitoring[25, 26]. Conversely, the reactive bias of the latter measures and higher costs mean that there is yet to be an accepted gold standard measure of adherence.[27]

The present study has demonstrated that information provision regarding action and usage of medicines is largely satisfactory excepting 'how long it will take to act' and 'how to tell if it is working'. Addressing issues related to the potential problems of medicines was frequently perceived as deficient with greater satisfaction predicting greater adherence. These pieces of information are particularly pertinent to the context of preventing intentional non-adherence by managing patient expectations of their medicine both in terms of side effects and efficacy. Even respondents who had received an advanced service identified these aspects of information as frequently suboptimal. A similar investigation of information satisfaction, in a sample of 140 in-patients, found that the medication's effect on sex life and the risk of getting side effects were the two lowest scoring items[28]. Further studies have also confirmed that information provision about medicines may be inadequate.[29, 30]

The significantly greater satisfaction with information about potential problems in patients who have received an advanced pharmacy service suggests that the MUR and NMS interventions may help in addressing some patient concerns. It may also support previous research demonstrating that MURs enhance knowledge and understanding of medicines(16, 17). However, the present study findings also indicate that MUR and NMS consultations are not addressing all of the patient's needs for information about their medicines. Recent work has shown that pharmacy services should take account of patients' perceptions of their illness (31) and this evaluation suggests that this should extend to their knowledge and beliefs about their medication.

The high completion rate of the SIMS suggests that it may be acceptable to use in routine practice to target patients in most need of an advanced service. If patients were aware of the information they were lacking it may prompt them to ask their pharmacist for advice. Such patients may also speak with their doctor who could refer the patient to the pharmacist. If the doctor was to refer patients to the pharmacist then patients may perceive the pharmacist's consultation as a more integrated part of the health service. This would also align with the comments, from respondents, about the services and the likelihood they would engage with them. Some identified that they had no need for the services as they already received information from their GP. These results concur with findings from a series of focus groups conducted in patients with diabetes (32). Previous work suggests that patients have opinions regarding the suitability of each healthcare professional for providing information and their relationship with those professionals is central to determining where they obtain it.

It cannot be assumed that the improvement in adherence is resultant of the MUR or NMS service. The greater proportion of self-reported adherence in the MUR group may be attributable to willingness to please of the patient or a selection bias introduced by whom pharmacists invite for an MUR. Although patients who had received an MUR were more satisfied with information, it was not established how satisfied patients were before receipt of the services so it cannot be conclusively stated that the service was responsible for the increased satisfaction.

There is therefore a clear need to more effectively target advanced services, particularly MURs, at those patients that need and, in particular, want them. This study provides an indication of the subjects of interest to patients that may be addressed as part of the MUR or NMS.

Conclusion

This study indicates the types of information that patients who take regular medicines may be lacking. These largely relate to the potential problems of medicines rather than their action and usage. The SIMS may be an appropriate tool to identify which patients may benefit from a community pharmacy advanced service. Despite being more satisfied with information received about medicines, the respondents who had received an advanced service had unaddressed medication information needs. This may imply that detailed, comprehensive information about potential problems should be provided during MUR and NMS consultations in addition to the actions and usage of medications.

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Table 1: comparison of SIMS score between those patients in receipt of an advanced service and those without.

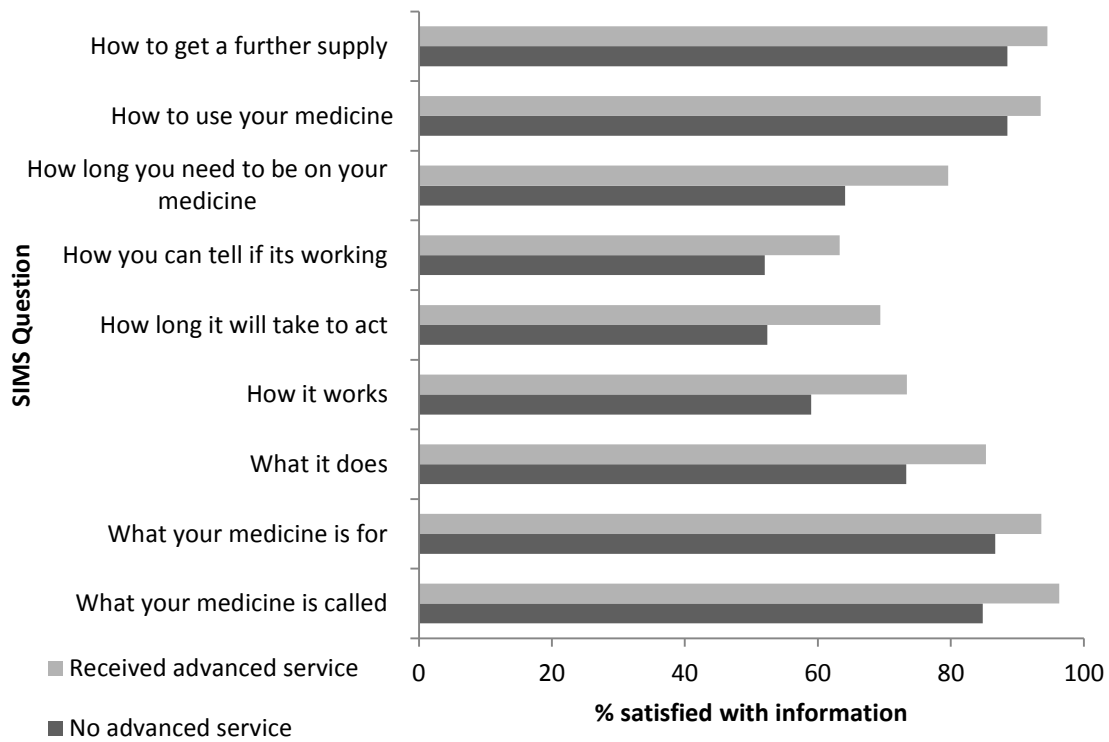| SIMS component	Measure	Advanced service	No advanced service	p-value[#]
Overall	Median (IQ)	14 (10-17)	12 (7-16)	0.001
Action and usage	Median (IQ)	8 (6-9)	7 (5-9)	0.002
Potential problems	Median (IQ)	7 (4-8)	4 (2-7)	<0.001

[#]MWU; N=208

Figure 1 Scores for action and usage subscale of SIMS for those that have and have not received an advanced service
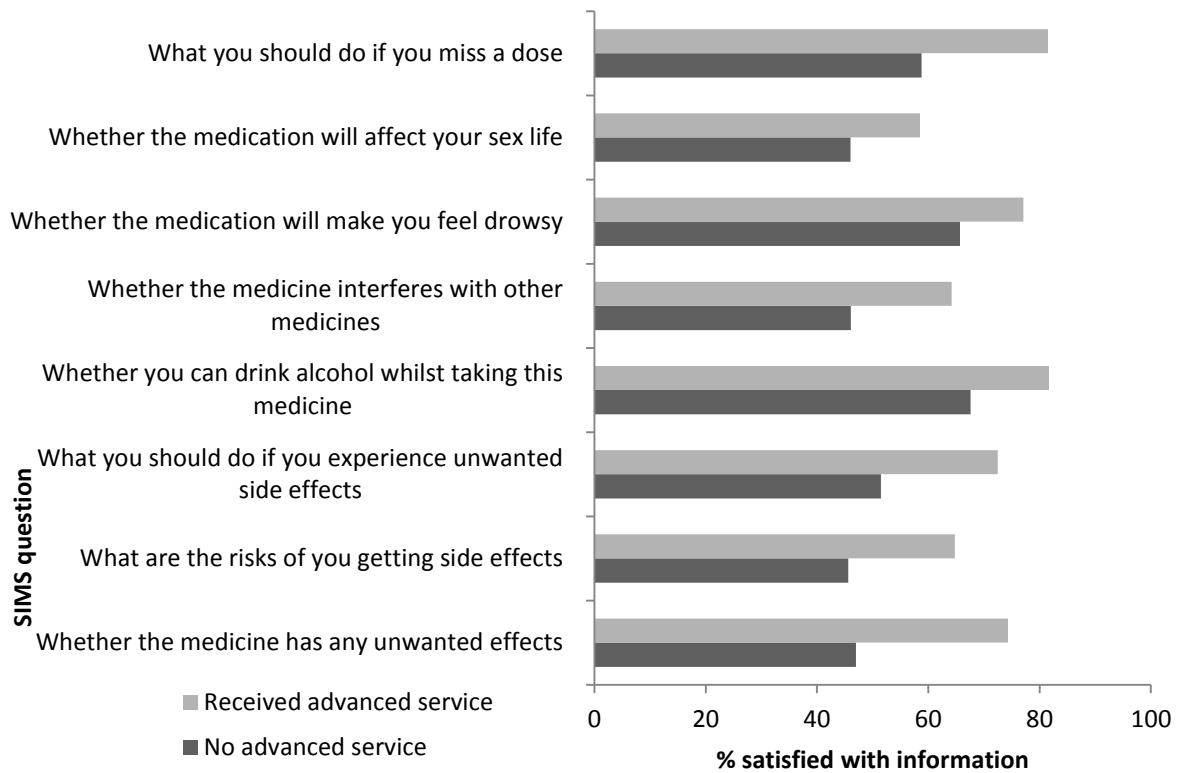
Figure 2 Score for the potential problems subscale of SIMS for those that have and have not received an advanced service

Table 2: Association between factors and self-reported adherence

Factor	Partially adherent (n=104)	Adherent (n=125)	Univariate p-value	Adjusted OR (95% CI)[3]	Adjusted p-value[3]
Pharmacy providing the service			0.086[1]		
Pharmacy 1	19	39 (67.2)		1.81 (0.75,4.37)	0.19
Pharmacy 2	27	29 (51.8)		0.94 (0.38,2.3)	0.889
Pharmacy 3	27	33 (55.0)		1.62 (0.7,3.78)	0.263
Pharmacy 4	31	24 (43.6)		1	N/A
Pharmacy visit frequency			0.245[1]		
<once per month	39	34 (46.6)		1	N/A
Once per month	46	63 (57.8)		1.54 (0.77,3.1)	0.226
>once per month	19	28 (59.6)		1.91 (0.8,4.55)	0.143
Self-reported receipt of advanced service			**0.001[1]**		
No	63	48 (34.8)		1	N/A
Yes	41	77 (65.3)		2.34 (1.21,4.53)	**0.012**
SIMS 'action and usage (median/IQR)	7 (5-9)	9 (6-9)	**0.0063[2]**		
SIMS 'action and usage' group			**<0.001[1]**		
0-8	73	55 (42.97)		1	
9	29	63 (68.48)		1.04 (0.32,3.44)	0.946
SIMS 'potential problems' (median/IQR)	5 (3-7)	7 (3-8)	**0.009[2]**		
SIMS 'potential problems' group			**0.001**		
0-6	65	53 (44.9)		1	
7-8	30	63 (67.7)		0.48 (0.14,1.6)	0.232
Interaction between SIMS 'potential problems' and 'action and usage'	NA	NA		6.82 (1.2,38.56)	**0.03**

[1] Chi-squared/Fisher's exact test; [2] Wilcoxon Rank-sum test; [3] Based on a multivariable logistic regression model adjusting for all other factors in the table.