

Assessment of a computerised decision support system for allergic rhino-conjunctivitis counselling in German pharmacy

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Abstract *Objective* In a prospective two-phase intervention study we evaluated a newly developed computerised pharmacy decision support system (PDSS) for the counselling of patients with allergic rhinitis and conjunctivitis. *Method* Community pharmacists were invited to counsel a virtual patient in a first interview. Immediately thereafter, we trained pharmacists to operate the PDSS, which they applied in a second patient interview immediately following the training. We assessed the completeness of mandatory questions asked as defined by national guidelines. *Results* Participating pharmacists ($n = 50$, 78% female, mean age 34 [IQR: 27–40] years, 8 [2–14.5] years of practical experience, 32% specialised in community pharmacy) asked considerably more mandatory questions to confirm appropriateness of self-medication with 7 (5.25–9; 78%) from 9 questions compared to 2 (1–3; 22%) without PDSS (median; $P < 0.001$). In particular, using the PDSS more than doubled mandatory questions (9/12, 6.25–10; 75% vs. 4/12, 3–5; 33%; $P < 0.001$) relevant for appropriate drug selection. *Conclusion* Pharmacists omitted many questions mandatory to assess whether self-

medication is appropriate. Using the newly developed PDSS more than doubled the number of mandatory questions asked. The results suggest that the PDSS is ready for evaluation of its impact in real patients.

Keywords Allergic rhinitis · Clinical pharmacy · Information systems · Community pharmacy services · Computer systems · Conjunctivitis · Decision support systems · Drug information services · Rhinitis

Impact on practice statements

- A newly developed PDSS was effective in increasing the number of mandatory questions asked to assess appropriateness of self-medication to treat allergic rhinoconjunctivitis.
- Time requirements to handle the PDSS are moderate suggesting that using the system would be feasible in pharmacy practice.

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Introduction

Allergic diseases have a prevalence of about 20% in adults [1] and an increase of 10% was found in lifetime prevalence over the last 40 years [2]. To treat symptoms of allergy self-medication is common. Insufficient allergy control, however, can result in disease progression and allergies are often associated with an increased risk for bronchial asthma [3]. Pharmacists should therefore carefully distinguish between harmless symptoms and indicators of asthma or infection that require referral to a physician.

For this purpose, guidelines dealing with typical counselling situations in pharmacies were designed but counselling quality is poor [4] and guidelines are not rigorously implemented in daily routine. Pharmacy decision support systems (PDSS) governing e.g. drug–drug interaction and drug–allergy checking have been used in pharmacy information systems for several decades [5, 6]. More training, however, about software capabilities coupled with the addition of more advanced decision support features is demanded in the literature including also research on PDSS use by practising pharmacists [5, 6]. We are not aware of any specific algorithm-based electronic tool governing allergy treatment in primary care settings for pharmacies.

Aim of the study

We intended to develop a PDSS for the counselling of patients with allergic rhino-conjunctivitis in community pharmacies and to evaluate its impact on the appropriateness of self-medication and treatment recommended by the pharmacist.

Method

Participants and setting: We consecutively invited pharmacists with practical experience in community pharmacy of at least half a year from our voluntarily participating teaching pharmacies ($n = 9$) around our department to participate in this study. No further inclusion or exclusion criteria were applied. All invited pharmacists participated in the study.

Computerised PDSS

We developed a web-based PDSS for allergic rhino-conjunctivitis counselling in a five-step procedure. First, a clinical pharmacist developed an algorithm that included mandatory questions according to current guidelines on self-medication of the Federal Union of German Associations of Pharmacists, Berlin (available from: http://www.abda.de/fileadmin/assets/Praktische_Hilfen/Handlungsanweisungen/Information_und_Beratung_Selbstmedikation/LL_Info_und_Beratung_Selbstmedikation.pdf). Second, another clinical pharmacist checked the algorithm for appropriateness and suitability in practice. Third, medical computer scientist programmed the tool. Fourth, a clinical pharmacologist checked the content of the system. Finally, community pharmacists pre-tested the system for its suitability and their feedback prompted five technical modifications to improve user interface and practical handling of the PDSS. These pharmacists did not take part in the main study. The PDSS followed the counselling procedure recommended for community pharmacies by the Federal Union of German Associations of Pharmacists and consisted of sections on (1) opening the conversation, (2) limitations of self-medication, (3) evaluation of patient's self-diagnosis (Fig. 1), (4) choice of active ingredient including brand and counselling on its appropriate use. In each step, check boxes or radio buttons were offered to document the answers to mandatory questions. Hyperlinks complemented these checklists that offered algorithm-based decision support for drug selection as well as detailed information about special patient groups. The PDSS contained all mandatory questions according to Table 1 and additionally informed about

Fig. 1 Graphical user interface of the part of the pharmacy decision support system (PDSS) that supports the assessment of a patient's self-diagnosis of allergic rhinitis and conjunctivitis

1 Opening conversation » 2 Limitations of self medication » 3 Self diagnosis » 4 Counselling

Self diagnosis

1. Frequency of symptoms
☒ seasonal

2. Duration of symptoms
☒ more than 4 days per week

3. Cardinal symptoms

☒ Sneezing	☐ Streaming eyes	☒ Cough
☐ Red skin	☐ Nasal obstruction	

4. Accompanying symptoms

☐ Sore throat	☐ Itchy skin	☐ Mouth breathing
☒ Itchy eyes	☒ Eyelid edema	☐ Red eyes

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Table 1 Questions addressed by the interview without (pre-intervention) and with (post-intervention) using a PDSS ($n = 50$ community pharmacists)

Criterion	Pre-intervention (without PDSS)	Post-intervention (with PDSS)	<i>P</i> value
A Evaluation of appropriateness of self-medication			
A1 Medication for the patient himself?	40 (80%)	49 (98%)	0.008
A2 Allergy as self-diagnosis?	36 (72%)	49 (98%)	<0.001
A3 Prescribed medication by GP/specialists?	27 (54%)	42 (84%)	<0.001
A4 Can symptoms of common cold (e.g. sore throat) be excluded?	4 (8%)	31 (62%)	<0.001
A5 Can symptoms of sinusitis (e.g. facial pain) be excluded?	2 (4%)	35 (70%)	<0.001
A6 Bloody and sanious sputum (to exclude infections or other severe diseases requiring referral to a GP)?	5 (10%)	38 (76%)	<0.001
A7 Symptoms occurred after contact to a person with the same symptoms (infection, common cold, or other serious diseases requiring referral to a GP)?	1 (2%)	23 (46%)	<0.001
A8 Mild or high fever (infection requiring referral to a GP)?	1 (2%)	33 (66%)	<0.001
A9 Acute dyspnoea (asthma requiring referral to a GP)?	8 (16%)	38 (76%)	<0.001
B Assessment of symptoms guiding appropriate drug selection			
B1 Frequency of symptoms?	25 (50%)	41 (82%)	<0.001
B2 Duration of symptoms?	26 (52%)	39 (78%)	0.012
B3 Nasal obstruction?	16 (38%)	39 (78%)	<0.001
B4 Sneezing?	36 (72%)	48 (96%)	0.003
B5 Mouth breathing?	3 (6%)	18 (36%)	0.001
B6 Cough?	6 (12%)	32 (64%)	<0.001
B7 Sore throat?	4 (8%)	28 (56%)	<0.001
B8 Itchy eyes?	33 (66%)	46 (92%)	0.004
B9 Red and streaming eyes?	26 (52%)	45 (90%)	<0.001
B10 Eyelid edema?	3 (6%)	23 (46%)	<0.001
B11 Itchy skin (except of nose and eyes)?	0 (0%)	27 (54%)	NA
B12 Skin redness (except of nose and eyes)?	7 (14%)	29 (58%)	<0.001
C Recommendations on how to use a nasal spray appropriately			
C1 Was the chosen drug appropriate (as to active ingredient and preparation)?	44 (88%)	48 (96%)	0.221
C2 Was information provided on how long, when, and how the drug should be administered?	39 (78%)	48 (96%)	0.008
C3 Was information about adverse drug reactions provided?	11 (24%)	18 (36%)	0.181
C4 Was information about drug interactions provided?	11 (22%)	16 (32%)	0.359
C5 Was information about contraindications provided?	1 (2%)	10 (20%)	0.008
D Recommendations on how to use eye drops appropriately			
D1 Was the chosen drug appropriate (as to active ingredient and preparation)?	42 (84%)	45 (90%)	0.371
D2 Was information provided on how long, when, and how the drug should be administered?	36 (72%)	44 (88%)	0.013
D3 Was information about adverse drug reactions provided?	11 (22%)	15 (30%)	0.423
D4 Was information about drug interactions provided?	9 (18%)	13 (26%)	0.480
D5 Was information about contraindications provided?	2 (4%)	8 (16%)	0.114

PDSS computerised pharmacy decision support system, GP general practitioner, NA not assessable, NS not significant ($P > 0.05$)

the proper administration of complex drug preparations using pictures and flow charts.

Study design

This prospective intervention study included two interviews separated by a teaching session. We conducted the

interview in community pharmacies with all information sources usually consulted for patient counselling at hand. In the first part, pharmacists were asked to counsel a patient on the appropriate treatment for allergic rhinitis and conjunctivitis. For a standardised counselling procedure, advanced pharmacy students ($n = 3$) posed as pseudo-patients. To ensure reliability, communication skills were

trained in an interactive 90-min training addressing counselling situations in the community pharmacy. To assess pharmacists' individual best practice, we informed them in advance about the fact that the counselling will be evaluated in a test scenario and not in a real patient. The participating pharmacists, however, were not informed about the counselling topic beforehand. Appropriate recommendation and counselling by pharmacists were considered as a correct response to the scenario, hence no referral to a general practitioner was required. Immediately after this baseline assessment, the student trained the pharmacists how to operate the PDSS. This teaching session consisted of a theoretical explanation of the PDSS and a practical training to operate the system and without commenting on the pharmacists' performance during the first interview. Training took 5 min per participant and was immediately followed by a second interview that used the same scenario. Hence, the design enabled a high internal validity because the counselling quality of each participant was assessed two times with and without the PDSS. Because no patient was involved in the study, no ethical approval was required. All pharmacists and pharmacy students took part voluntarily and could quit their participation without giving any reasons for their decision. We evaluated all data anonymously.

Power calculation and data analysis

According to the results of a pilot study (five pharmacists not participating in the main study), in which the beta version of the PDSS was assessed, we hypothesised that without computerised support only 30% of the mandatory questions about self-medication will be asked. An increase by at least 100% (i.e. a rate of >60% after the intervention) due to the PDSS was considered clinically relevant. Assuming rates in this range, a double-sided test at a

significance level of $\alpha = 0.05$ and a sample size of 42 will provide a power of $1 - \beta = 0.80$. Data is presented as median with interquartile range (IQR), mean with 95% confidence interval (CI), or as absolute numbers or frequencies in percent. Results were analysed by McNemar test or Wilcoxon-Signed-Rank test as appropriate. A P value <0.05 was considered significant.

Results

Characteristics of participating pharmacists

Fifty community pharmacists (78% female, 32% specialised in community pharmacy) with a median age of 34 (IQR: 27–40) years and a practical experience of 8 (2–14.5) years participated in the study.

Completeness of mandatory questions

Using the PDSS, community pharmacists more often asked mandatory questions to confirm appropriateness of self-medication with a median of 7 (78%; IQR 5.25–9) out of 9 questions compared to 2/9 (22%; 1–3) in the absence of additional support ($P < 0.001$, Table 2). Pharmacists also asked more mandatory questions to identify symptoms guiding appropriate drug selection (9/12, 75%; 6.25–10) than without PDSS (4/12, 33%; 3–5, $P < 0.001$). Concerning the treatment of rhinitis with nasal sprays the participants gave more recommendations (3/5, 60%; 2–3) than before the intervention (2/5, 40%; 2–3, $P < 0.001$) whereas for eye drops performance was unchanged.

Time requirements and acceptance: The average time required for the counselling of a patient increased from 3.6 (CI 3.2–4.1) to 5.1 min (4.6–5.5; $P < 0.001$). All participating pharmacists considered the PDSS a suitable

Table 2 Fractions of mandatory questions according to guidelines that were actually asked by 50 community pharmacists in a simulated patient interview with (+) and without (–) electronic decision support

	A		B		C		D	
	Confirmation whether self-medication is appropriate?		Asking for symptoms relevant for appropriate drug selection		Recommendations on how to use a nasal spray appropriately		Recommendations on how to use eye drops appropriately	
With (+) and without (–) PDSS	–	+	–	+	–	+	–	+
Median								
(n)	2/9	8/9	4/12	9/12	2/5	3/5	2/5	2/5
(%)	22	89	33	75	40	60	40	40
Min–max (n)	0–3	2–9	1–7	2–12	0–5	0–5	0–3	0–4
P value	<0.001		<0.001		0.01		NS	

PDSS pharmacy decision support system, NS not significant ($P > 0.05$)

instrument to improve the quality of self-medication counselling in community pharmacies. Four pharmacists suggested using the PDSS as a teaching tool rather than an instrument directly implemented in patient counselling.

Discussion

Our study revealed that pharmacists failed to ask many questions mandatory to confirm the appropriateness of self-medication and to choose an appropriate drug. Conversely, integration of a PDSS efficiently guiding the pharmacist through the counselling process substantially increased the number of mandatory questions actually asked in the interview. Without using the PDSS, questions most frequently not addressed concerned referral to a physician. In contrast, explanation of drug administration and adverse reactions was quite good already before the intervention indicating that pharmacists were familiar with the drugs. The use of the PDSS required an average additional time of 1.5 min per interview. This extra time appears well spent given the observed quality improvement and its potential to avoid inappropriate self-medication and inherent complications.

Especially for OTC medication, pharmacists are often the only health care professionals providing advice. At first sight, using OTC medication and avoiding of unnecessary GP consultations might save costs for health insurance funds. Delayed or missed referral to the GP, however, can cause harm to the patient if correct diagnoses are deferred and the disease progresses. Pharmacists must therefore become capable of deciding whether referral to a physician is required.

Among the methods successfully ensuring a high counselling quality for self-medication are quality circles, mystery shoppers, and closer collaboration between community pharmacists and physicians [7, 8]. Those procedures, however, are time-consuming and strongly depend on the motivation of individual participants. Moreover, mystery shopper concepts without feedback and teaching elements are geared to detect problems in the delivery of health services but are hardly useful to improve counselling quality. Simulated patient situations appear to be a more reliable method of evaluating counselling practice in pharmacies than other methods because they evaluate real conditions and are highly reproducible [9]. In contrast to frequently used questionnaire surveys in similar settings [10], our intervention did not only assess counselling quality but determined the effect of a web-based PDSS. Contrary to mystery shopper interventions, which conceal the test situation from the pharmacists, we openly informed the participants thus probably limiting the true impact of the intervention. Within our survey, participating pharmacists were not obliged to forward all information provided

by the PDSS to the patient. However, the completeness of asked questions improved, suggesting that many questions were omitted without using the PDSS.

The present study has several limitations. First, we conducted an open intervention study without an independent control group. Theoretically, there might be other reasons for improvement of the results in the second interview than the use of the PDSS. The second interview, however, immediately followed the intervention thus strongly limiting potential bias by other sources. Additionally, it is hardly possible to conduct an interview using a new PDSS in a blinded design. Because we have chosen an open design also for the first interview, it is unlikely that pharmacists deliberately withheld information in the first interview but disclosed it in the second independent of the PDSS. Moreover, because no feedback was given on the performance during the first interview its bias is likely small if present at all. Second, we used a setting in which well-educated students posed as pseudo-patients. Thereby, we ensured a good standardisation of the evaluation without any potential risk for real patients. So far, no actual patient was counselled by pharmacists using the system and therefore the performance and impact of the system on the quality of real counselling situations is yet unknown. The selected study design also precluded testing of actual referral to a general practitioner. Third, we focused on allergic rhinitis and rhino-conjunctivitis excluding further indications of self-medication or complex treatment with several co-morbidities. Conclusions are therefore limited to these simple albeit rather frequent counselling situations. Because the counselling process is rather similar in all OTC indications the results are likely similar in other areas of self-medication.

For potential long-term benefits of such systems, further investigation especially considering learning effects of the users are necessary. In addition, its impact on patient behaviour and treatment response needs evaluation, and, finally, optimal ways of integrating this knowledge into the workflow of the pharmacist must be tested. This tool seems to be suitable for either training or use in a real-life situation, which both require further testing.

Conclusion

Pharmacists frequently omitted questions essential for thorough assessment of self-medication. A newly developed computerised decision support system for allergic rhino-conjunctivitis counselling more than doubled the number of mandatory questions asked to decide whether self-medication is appropriate. This benefit required only a moderate extra effort in time. The results suggest that the PDSS is ready for evaluation of its impact in real patients.

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