Pharmaceutical care, the future of pharmacy

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5
RESULTS OF PHARMACEUTICAL CARE IN ASTHMA, THE TOM STUDY

The TOM study into the effects of pharmaceutical care in asthma patients with moderate asthma was carried out between the beginning of 1995 and the end of 1997, according to the description in Chapter 3 of this dissertation.

The intervention group received education about asthma, drug and non-drug management and the self-management of asthma over a period of 24 months. Compliance with a preventive drug regimen was regularly discussed. In the mean time the pharmacist evaluated the drug use and possible drug-related problems and gave suggestions for improvement to the patient. When necessary the pharmacist made recommendations to the physicians regarding pharmacotherapy. In this chapter some of the results of the TOM study are presented and discussed. For the analysis the following data sources were available:

- the intake data and evaluations (after 6, 12 and 24 months) by the pharmacists;
- the replies to questionnaires which were sent to intervention and reference patients at the start of the projects and after 6, 12 and 24 months;
- drug-prescription data of the intervention and reference patients, from the computers of the participating pharmacists.

The data on knowledge about diseases have been evaluated differently from the OMA data (see Chapter 4) to explore different possibilities for data evaluation and presentation.

Like in the OMA study, not all patients answered all parts of all questionnaires, therefore the evaluated numbers per item (and per paragraph) may differ from the total population. An additional problem when analysing the data for this project was that the number of patients at intake and the number of patients who fully concluded the study was relatively low compared to the power calculations.

Most data were entered and analysed using SPSS, version 7.5. Drug data were entered into an Access database, and analysed with the help of SPSS, Excel and Dbase V. Unless otherwise stated, a difference was assumed to be significant at a level of 95% probability or higher. Most comparisons of means have been made with the help of the Student t test, in the appropriate format as offered by SPSS. If other tests have been used this is explicitly mentioned in the text.

As in the previous chapter, both the Intention To Treat as the Per Protocol have been used, depending on the character and availability of the data.

5.1 THE POPULATION, INCLUSION AND DROP-OUT

For the TOM-study 527 asthma patients with mild to medium severe asthma and aged 20-45, consented by telephone to take part in the study. However, 74 of these patients did not sign the informed consent form, did not return the baseline questionnaire, or proved not to be
within the age limit at intake. Some were not included because the intervention pharmacy dropped out before the whole intake procedure was finalised (2 pharmacies).

During the study a high percentage of the population dropped out, especially in the intervention group. The reasons for dropping out of the TOM study were difficult to assess. Usually the patients did not attend their meetings with the pharmacist, or did not return their questionnaires to the research centre without further explanation. The available reasons for drop out have nevertheless been analysed. Table 5.1 shows the composition of the study-population, and the drop-out numbers during the project.

### Table 5.1 Study population TOM and drop-out

<table>
<thead>
<tr>
<th></th>
<th>Intervention</th>
<th>Internal reference</th>
<th>External reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients at intake</td>
<td>191</td>
<td>157</td>
<td>105</td>
</tr>
<tr>
<td>Drop out during study</td>
<td>121 (63.4%)</td>
<td>28 (17.8%)</td>
<td>24 (22.9%)</td>
</tr>
<tr>
<td>Patients at end of the study</td>
<td>70</td>
<td>129</td>
<td>81</td>
</tr>
</tbody>
</table>

In the intervention group the initial drop out, between the 0-assessment and the first evaluation was 28.5%, another 22.8% dropped out between the first and second assessment. At the end of the study we received 100 patient-assessments from the pharmacists, however, only 70 of those patients also returned the final questionnaire. Some other characteristics of the patient groups at intake can be found in table 5-2.

Although the frequency of pharmacy visits shows a remarkable difference between the intervention and both reference groups, this difference is not significant. The difference in familiarity with the pharmacist is significant (Student t test), which can be explained by the different ways the intervention and external reference pharmacists were recruited (see Chapter 3).

### Table 5-2 Characteristics of TOM study population at intake

<table>
<thead>
<tr>
<th></th>
<th>Intervention</th>
<th>Int. Ref.</th>
<th>Ext. Ref</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of pharmacies</td>
<td>16</td>
<td>17</td>
<td>13</td>
</tr>
<tr>
<td>Male (%)</td>
<td>41.4</td>
<td>32.5</td>
<td>34.3</td>
</tr>
<tr>
<td>Mean age</td>
<td>34.3</td>
<td>34.0</td>
<td>32.6</td>
</tr>
<tr>
<td>Mean score symptom domain Asthma Related Quality of Life</td>
<td>4.98 (response 99%)</td>
<td>4.92 (response 99%)</td>
<td>4.95 (response 72%)</td>
</tr>
<tr>
<td>Freq. of pharmacy visits (yearly means)</td>
<td>7.9</td>
<td>9.4</td>
<td>9.6</td>
</tr>
<tr>
<td>Familiarity with pharmacist (%)</td>
<td>48.4</td>
<td>50.6</td>
<td>35.9</td>
</tr>
<tr>
<td>Patients not visiting other pharmacies (%)</td>
<td>94.7</td>
<td>86.5</td>
<td>93.2</td>
</tr>
</tbody>
</table>
5.1.1 Analysis of dropout
The major reason for drop out was the fact that no final evaluation was performed and/or no final questionnaire was returned. This accounted for over 95% of the dropouts in all three groups. In each group one patient moved, and in the intervention group three patients (2.5%) stated that they did not feel like continuing; another 3 patients found themselves too ill to continue.

In the external reference group a relatively high proportion of women dropped out (75%), compared to the original composition of that group. The resulting groups, however, were not significantly different from each other in this respect.

There also has been some bias on the basis of the age of the patients. The mean age (at the start) of the patients who completed the study went up by 0.5-2 years. With regard of the age limits in the study (20-45), this can be ignored but it is possibly an indication that younger patients had more difficulties to adhere to the study and attend the evaluation sessions.

5.1.2 Discussion and conclusion on the population in the study
The intervention, internal and external reference patients in the TOM study did not show significant differences at the beginning of the study, which might influence the results. The mean score for the symptom domain of the Asthma Quality of Life Questionnaire also showed that the severity of the asthma of the included patients is the same. The external reference group is less familiar with their pharmacist than the intervention or the internal reference group. For the study itself and the interpretation of the results this has only minor consequences because satisfaction data about the pharmacist were only evaluated if the patients knew the pharmacist.

If dropout rates are compared, then the relative high rate of the intervention group is striking but not much can be said about the reasons for drop out in the TOM study. It appeared that there was not enough motivation left at the end of the study to fill out the final evaluation by the pharmacists and for the patients to fill out and return the final questionnaire. The intervention pharmacists reported that it often took a great deal of effort to even make an appointment with the patients included into the study. Most of the patients were at work during the daytime and not inclined to visit the pharmacist in the evening. But another reason could be that the patients found that they had learned enough to handle their own asthma after a limited number of consultations, and did not need to see the pharmacist anymore.

There is no reason to assume that the slight increase in the age of the remaining patients at the end of the study will influence results.

In general the intervention and reference population showed no important differences at intake and that no selection bias occurred which could influence the outcomes of the TOM study.

5.2 Quality of life
Because the main objective of pharmaceutical care is to influence patient quality of life, in this study a generic (the SF36) and a disease specific asthma questionnaire (the Asthma Quality of Life Questionnaire, AQLQ) were used (see Chapter 3 for the selection
arguments). After 24 months the intervention patients were also asked in a self-completed questionnaire if they felt better because of the received care during the TOM project.

5.2.1 Method

All intervention and reference patients received the mail version of the SF36 and the AQLQ at baseline and after 6, 12 and 24 month. Both questionnaires were administered by mail, with pharmacist and research centre independent telephone support, 3-5 days after reception of the questionnaire, by a marketing research organisation. The results were entered into SPSS, and domain scores were calculated. Scores of the SF-36 were compared according to the SF-36 manual with the help of SPSS, ver 7.5. Scores for the AQLQ were compared according to the procedures described by Juniper et al.\(^1\). The four domains for evaluation of the latter questionnaire are: activity limitations, symptoms, emotional function and exposure to environmental stimuli.

The list of activities offered to the patients in the AQLQ is well balanced and quite exhaustive. Therefore, if there were 1-4 missing activities amongst the first 5 questions of the questionnaire, the patient was expected to have no limitations in other activities than those mentioned and the missing scores for question 2-5 were defined as 7 (not at all limited). If no activity was mentioned at all, the scores for the first five questions were left as missing. Domain scores (means) were only calculated if not more than 75% of the scores per domain were missing, according to the indications given by the author of the questionnaire.\(^1\) Missing data for the SF36 were dealt with according to the rules given in the manual\(^2\).

Different statistical methods were applied to detect differences in the development between the intervention, internal reference and external reference patients. Internal and reference patient-groups were often merged to increase the statistical power because no clear difference between those groups could be established. Mainly one approach has been chosen for evaluation of the patients who had completed the whole study (Per Protocol, PP), because the interest of the study lies in the application of pharmaceutical care over time. Drop out analysis did not show any significance of drop out, as far as data were available.

5.2.2 Results Quality of Life

The analysis of the SF-36 data showed no significant changes in any of the domains (for detailed descriptions of the possible analysis of the results of the SF-36 see Chapter 4). In case of the AQLQ there were no significant differences between the domain scores for the intervention and the reference groups at intake (Student t test for independent samples). In both the intervention group as well as the reference group there were significant score-increases for some of the domains, but the increases in the intervention group were always larger (Student t test for paired samples, see table 5-3).

In spite of the differences between the mean increase in the intervention and reference group, the GLM procedure in SPSS 7.5 did not indicate that the increases in the domains differed significantly between the intervention and reference group.

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1. Personal information (Email received from E. Juniper, Dept. of Clinical Epidemiology & Biostatistics, McMaster University, Hamilton, Canada. 13th November 1998.)
Table 5-3  Score and score changes in TOM study, PP analysis AQLQ (n=257)

<table>
<thead>
<tr>
<th></th>
<th>Mean score 0-assessment</th>
<th>Mean increase (Δ) of score over study period (24 months)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention (n=70)</td>
<td>Reference (n=187)</td>
</tr>
<tr>
<td></td>
<td>Int.</td>
<td>Ref.</td>
</tr>
<tr>
<td>Activity</td>
<td>5.30 (sd 1.18)</td>
<td>5.19 (sd 1.14)</td>
</tr>
<tr>
<td>Symptoms</td>
<td>4.87 (sd 1.34)</td>
<td>4.92 (sd 1.17)</td>
</tr>
<tr>
<td>Emotional functioning</td>
<td>5.39 (sd 1.21)</td>
<td>5.45 (sd 1.18)</td>
</tr>
<tr>
<td>Environment stimuli</td>
<td>4.56 (sd 1.33)</td>
<td>4.62 (sd 1.26)</td>
</tr>
</tbody>
</table>

n.s. = change not significant. If p values are mentioned then the change is significant.

Of the 70 intervention patients remaining at the end of the project, 46% expressed in a questionnaire that they were feeling better or much better because of the received care. There was no clear correlation between this opinion and the changes in quality of life according to the AQLQ.

5.2.3 Discussion and conclusion of the quality of life

On the basis of the results of the AQLQ there is a clear indication, that the asthma related quality of life in the intervention group increased more than in both reference groups, although the difference was not significant at a 0.05 level. This increase was also found in the ITT analysis. The mean domain scores at the start of the project were similar, but somewhat lower than those found by van der Molen in a Dutch population with moderate asthma.

The question remains if the increase could be clinically significant. Juniper et al. described the minimal important difference in score to be 0.5, which should be consistent across the domains. There is a continuous debate on the relationship between clinical findings and quality of life and their statistical and clinical significance, so it is hard to reach clear conclusions at this stage. In another article, in which she described seven clinical symptoms, correlation of score changes with several clinical measures ranged from 0.30 to 0.6 (symptoms domain), from 0.26-0.56 (emotions domain), from 0.2 to 0.45 (activities domain) and 0.17 to 0.44 (environment domain). Apparently different issues are being measured.

In the TOM study, especially in the fields of symptoms and emotional functioning the change in the intervention group came close to 0.5, but there was also a score increase in the reference group. The increase in HRQL in both groups could be attributed to effects of illness adaptation and increased coping-capabilities of all patients, an effect that has been described by Padilla et al. Part of the increase in both groups could also be attributed to environmental differences, which are season dependent and can not be corrected for (except by including a reference group in an asthma study, as was the case here).
Nevertheless with regard to the impact of emotions and feelings involved in asthma, which are reflected by a HRQL questionnaire, according to the TOM data there is a clear indication that a patient’s quality of life improves from receiving the pharmaceutical care as described in Chapter 3. All scores went up, be it not statistically significant at a level of $p<0.05$ when compared to the reference group. This increase is especially clear in the field of symptoms, emotional function and exposure to environmental stimuli.

Apparently, the patients were not always aware of the improvement because there was no clear correlation between their opinion on their improved wellbeing and the results of the AQLQ. Since the Asthma Quality of Life questionnaire is well validated, asking patients if they are feeling better clearly is not a good way of evaluating their asthma related quality of life.

Although in previous studies it has been demonstrated that the SF-36 is a suitable instrument to identify changes in the quality of life in asthma patients, our study does not confirm these findings. The SF-36 scores in this study showed no significant changes. But according to Juniper the SF-36 is not well suited to use in longitudinal clinical trials and also correlates poorly between quality of life and clinical improvements in asthma. Therefore in the case of the longitudinal evaluation of additional care for asthma patients the SF-36 is probably not a good instrument to measure changes in the quality of life. V.d. Molen also found in his PhD-dissertation that the most sensitive instrument to measure changes in asthma status is the AQLQ, and even advises against the use of a generic instrument.

5.3 Satisfation, Content and Character of Communication, a Process Evaluation

The communication process is an important element of pharmaceutical care. During the TOM study different aspects of the communication process were studied because the major topics for the consultations were well defined: inhalation technique, drug use and self-management and because the consultation itself is even more important than in the (more diffuse) OMA project. If the communication process is optimal and important topics in the field of asthma have been discussed, then the chances for a good result are optimal. The satisfaction of the patients will partially depend on the satisfaction with the care provided during the consultations, and partially on the experienced changes in quality of life and physical improvements, which are discussed elsewhere.

5.3.1 Method

The intervention patients were questioned on the contents and the ‘emotional’ character of their communication during the consultations in the questionnaires at 6, 12 and 24 months. Not all intervention patients responded to all questionnaires. At 6 months 72.8%, at 12 months 76.4% and at 24 months 36.6% of the patients at intake responded to this section of the questionnaire.

Of the responding patients ($n=140$) one patient had not spoken with the pharmacist during the first 6 months of the study. Of the patients responding during the second round of questionnaires ($n=146$), 39 patients reported that they had not spoken with the pharmacist between the 6 and 12 month evaluations. Of the patients responding at 24
months (n=70), two patients stated that they had not spoken with the pharmacist during the previous 12 months. The given results are based upon the patients who responded that they had spoken with the pharmacist in the period concerned.

5.3.2 Results satisfaction and communication
Patients were asked to indicate how often and where they had spoken with the pharmacist. All consultations took place in the pharmacy.

During the first year the mean number of consultations (including the intake) was 3.8 (range 2-15, sd 2.1). During the last year the average frequency was 2.07 (range 1-10, sd 1.46). Figure 5-4 clarifies the distribution.

From the available data it is difficult to estimate the average time spent on consultations. According to the pharmacists, the intake took about 45 minutes (range 30-60 minutes). Consequent evaluations took 20-30 minutes (range 15-45 minutes).

The patients mentioned average times per consultation ranging from 3 to 90 minutes, with a mean of approximately 28 minutes. After the first six months, most patients (60%) had only 1 consultation with the pharmacist as shown in table 7-5. This consultation was most probably the session at which the evaluation assessment was carried out. There were no differences between the individual pharmacies for the amount of time spent or the frequency of the consultations.
The intervention patients who responded and who had spoken with the pharmacist reported that they had always or mostly spoken about the topics mentioned in table 5-5. The patients mentioned no additional topics. In general women indicated less often to have spoken about all those topics than men. The difference was significant for lifestyle, hobbies, family and health/disease in general.

The topics discussed during consultation according to patients (% of responders)

<table>
<thead>
<tr>
<th>Table 5-5</th>
<th>The topics discussed during consultation according to patients (% of responders)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>6 months n=139</td>
</tr>
<tr>
<td><strong>Correct use of medicines</strong></td>
<td>82.9</td>
</tr>
<tr>
<td><strong>Action of medicines</strong></td>
<td>82.1</td>
</tr>
<tr>
<td><strong>Asthma self-management</strong></td>
<td>81.0</td>
</tr>
<tr>
<td><strong>Inhaler technique</strong></td>
<td>69.8</td>
</tr>
<tr>
<td><strong>Patients’ disease(s)</strong></td>
<td>66.7</td>
</tr>
<tr>
<td><strong>Side effects of medicines</strong></td>
<td>45.3</td>
</tr>
<tr>
<td><strong>Life style issues</strong></td>
<td>40.6</td>
</tr>
<tr>
<td><strong>Health/disease in general</strong></td>
<td>34.1</td>
</tr>
<tr>
<td><strong>Relationships with doctors</strong></td>
<td>19.6</td>
</tr>
<tr>
<td><strong>Patients’ hobbies</strong></td>
<td>13.9</td>
</tr>
<tr>
<td><strong>Family circumstances</strong></td>
<td>10.1</td>
</tr>
<tr>
<td><strong>The pharmacy</strong></td>
<td>8.7</td>
</tr>
<tr>
<td><strong>OTC</strong></td>
<td>6.6</td>
</tr>
<tr>
<td><strong>Home delivery of medicines</strong></td>
<td>3.6</td>
</tr>
</tbody>
</table>

The character of the consultations was analysed for those patients giving an opinion as outlined in table 5-6. The opinion of the intervention patients hardly changed during the project. The indicated ranges are the minimum and maximum mentioned in any of the 4 assessments. No influence of gender could be recognised on these issues.

At the final evaluation the meaningfulness is correlated (Spearman’s rho, $r_s$) with other positive opinions about the consultations, like clarifying ($r_s=0.70$), informative ($r_s=0.62$), pleasant ($r_s=0.44$) and personal ($r_s=0.41$), all $p<0.0005$. Patients who found the consultations annoying often found the consultations too long ($r_s=0.41$) or badly structured ($r_s=0.47$).

The positive opinion of the intervention patients with the new way of coaching increased slightly from 62% after 6 months to 75.7% after 24 months. The remaining 24.3% of the patients at the end indicated to be neutral. No negative opinion was expressed. If patients were asked in what period they had benefited most of the provided care, 66% said during the whole period and 27% said during the first 6 months (n=52).

Intervention patients, who had spoken with the pharmacist about medicines, were also asked for their opinions on the interest of the pharmacist for their well-being and the
privacy offered. Before the intervention 64% of the patients who expressed an opinion (n=25) thought that the pharmacist was interested in their well-being and at the end of the intervention 87% (n=52). Before the intervention 56% of the patients who expressed an opinion (n=25) thought there was enough privacy in the pharmacy, after the intervention 92% (n=52) had this opinion. In the reference group there was no important change on these opinions (see table 5-7 and 5-8).

<table>
<thead>
<tr>
<th>Suggested character of consultation</th>
<th>Range of patients sometimes or always agreeing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Too long</td>
<td>4-7%</td>
</tr>
<tr>
<td>Useless</td>
<td>5-12%</td>
</tr>
<tr>
<td>Badly structured</td>
<td>6-10%</td>
</tr>
<tr>
<td>Annoying</td>
<td>6-7%</td>
</tr>
<tr>
<td>Too short</td>
<td>10-15%</td>
</tr>
<tr>
<td>Professional</td>
<td>60-70%</td>
</tr>
<tr>
<td>Pleasant</td>
<td>80-86%</td>
</tr>
<tr>
<td>Personal</td>
<td>84-86%</td>
</tr>
<tr>
<td>Clarifying</td>
<td>89-97%</td>
</tr>
<tr>
<td>Friendly</td>
<td>94-99%</td>
</tr>
<tr>
<td>Meaningful</td>
<td>97-100%</td>
</tr>
</tbody>
</table>

Table 5-7 Opinion on enough privacy in the pharmacy and response rates in TOM study

<table>
<thead>
<tr>
<th>Privacy</th>
<th>Intervention</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Before study</td>
<td>56%</td>
<td>6%</td>
</tr>
<tr>
<td>End of study</td>
<td>92%</td>
<td>6%</td>
</tr>
</tbody>
</table>

Table 5-8 Opinion on the pharmacists’ interest in the wellbeing of the patient and response rates in TOM study

<table>
<thead>
<tr>
<th>Interest</th>
<th>Intervention</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Before study</td>
<td>64%</td>
<td>12%</td>
</tr>
<tr>
<td>End of study</td>
<td>87%</td>
<td>0%</td>
</tr>
</tbody>
</table>

The increase in the reference group was in both cases clearly due to an increased positive opinion of the internal reference group. The numbers of responding patient were, however, to low to justify further statistical analysis on this aspect.
5.3.3 Discussion and conclusion of the satisfaction and process evaluation

It is difficult to assess how often patients and pharmacists spoke with each other. Apart from the first 6 months after the intake, most patients saw the pharmacist at least once every 6 months. In spite of this low frequency, patients had almost similar opinions about the character of the consultation at all three assessments, and are quite positive. Although their questionnaires were directly returned to the research centre, social desirability may explain part of this positive attitude. If patients did not like the consultations, they found them too long, useless or not so friendly.

Medicines and their use in asthma, including inhaler technique and self-management appeared to be the major topics which patients remembered to discuss during the consultations. These topics remained approximately the same throughout the project. This might partially be explained by the fact that during the evaluations the content of the consultation was largely dictated by the evaluation questionnaire and that the pharmacists were asked by the research team to focus on inhaler technique and self-management.

Only the patients’ diseases, and health and disease in general were more frequently discussed between 6 and 12 months. This indicates that such subjects apparently need more understanding between the partners in pharmaceutical care before they can be discussed.

During the study it became also more clear to the intervention patients that the pharmacist had an interest in their wellbeing and that there was enough privacy for consultations. In the reference group there was also a slight increase, but based upon much lower numbers because the patients in those groups had less contact with the pharmacist. In this respect there was an indication that the internal reference pharmacists (e.g. the pharmacists in the other pharmaceutical care study) performed increasingly better than the pharmacists in the external reference group, although the frequency of contacts with the pharmacists did not increase.

In general it is clear that patients liked the consultations (even when they dropped out), which is also reflected by the high satisfaction about the care provided. Based upon the fact that satisfaction in both the ITT and PP analysis were similar throughout the project, there is no indication that more patients with a negative or neutral opinion about the provided care dropped out of the project than patients with a positive opinion.

5.4 Knowledge about asthma and related diseases

An assessment was made of the possible knowledge changes in relation to asthma and related diseases during the TOM study at intake, after 6 and after 24 months. The planned 12 months assessment was omitted because during project evaluation sessions the assessments about knowledge proved to be quite a burden on the participating pharmacists (and patients).

The structure of the knowledge questionnaire was similar to the one used in the OMA study (see Chapter 3). Because of the structure of the knowledge questionnaire and the fact that the questionnaire would give raise to discussion and was therefore part of the intervention, only data from intervention patients were collected. To avoid influencing the knowledge in the reference patients, they did not complete knowledge questionnaires.
Fully completed 0-month knowledge questionnaires were obtained from 190 participants in the TOM study. From 100 participants we received the 0-assessment and either the 6 months assessment and/or the 24 months assessment. These participants were included into the analysis. The final number of evaluated knowledge questionnaires at 24 months was 43% higher than the number of patients in the study at the end because some of those patients did not return their final questionnaire and therefore were considered to be part of the drop-out group.

5.4.1 Method of coding and analyses
The questionnaire consisted of 29 items, divided into 4 domains.

- Genesis of asthma 1 domain, 9 items;
- Reasons for an asthma attack, 1 domain, 8 items;
- Chronic bronchitis, 1 domain, 6 items;
- Emphysema, 1 domain, 6 items.

The questions are coded as follows: 2 = spontaneous correct, 1 = after questioning correct, 0 = don’t know and -1 = after questioning incorrect. The 5 red herring items (see 3) are coded reversibly: -2 = spontaneous incorrect, -1 = after questioning incorrect answer, 0 = don’t know and 1 = after questioning correct answer.

The possible range for the total score per patient therefore was minus 33 to plus 54. The data were analysed on the level of changes in mean scores per domain by different statistical methods, using SPSS for Windows.

5.4.2 Results knowledge TOM study
A high percentage (>80) of the patients knew from the beginning of the study that asthma means shortness of breath, wheezing, coughing, constriction of the bronchi, and that it has an allergic origin. They also knew that house-dust, pets and skin particles, smoke, and exercise may provoke an asthma-attack. More than 80% knew that chronic bronchitis also meant shortness of breath and involves a lot of mucus production. The knowledge about emphysema was much more limited. The development of knowledge on questions where less than 80% of the patients knew the correct answer has been performed per domain with table 5-9 as result.

5.4.3 Discussion and conclusion, the knowledge
From the results of the zero assessment it is clear that patients in general are quite well informed about asthma and etiological factors. They knew less about related topics like chronic bronchitis and emphysema.

Although there is no indication that the knowledge on asthma and precipitating factors has improved, it is clear that after 6 months and at the end of the projects more patients knew about chronic bronchitis and emphysema. The last aspect is important, because under-treated asthma may result in emphysema at a higher age.

The erratic knowledge changes in the two asthma domains indicate that it is not very useful to assess knowledge on well-known topics with this type of questionnaire. Furthermore, during the analysis of similar data from the OMA project, it became clear that
the type of questionnaire for assessing knowledge has to be developed further (see section 4-2 of this dissertation).

Table 5-9 Knowledge change in different domains TOM study

<table>
<thead>
<tr>
<th>Domain</th>
<th>Compared assessment with intake</th>
<th>% Patients with increased scores</th>
<th>% Patients with decreased scores</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma genesis and effects</td>
<td>6 months</td>
<td>29</td>
<td>51</td>
</tr>
<tr>
<td></td>
<td>24 months</td>
<td>42</td>
<td>39</td>
</tr>
<tr>
<td>Asthma attack, generating factors</td>
<td>6 months</td>
<td>46</td>
<td>36</td>
</tr>
<tr>
<td></td>
<td>24 months</td>
<td>39</td>
<td>48</td>
</tr>
<tr>
<td>Chronic bronchitis</td>
<td>6 months</td>
<td>44</td>
<td>34</td>
</tr>
<tr>
<td></td>
<td>24 months</td>
<td>48</td>
<td>37</td>
</tr>
<tr>
<td>Emphysema</td>
<td>6 months</td>
<td>53</td>
<td>34</td>
</tr>
<tr>
<td></td>
<td>24 months</td>
<td>56</td>
<td>25</td>
</tr>
</tbody>
</table>

5.5 Drug use behaviour, Dispensed Drugs and Compliance

As already discussed in Chapter 3 of this dissertation, the drug use by asthma patients usually is not optimal. Especially the lack of compliance with regard to inhaled corticosteroids may result in decreased asthma control. Additionally, when self-management has been put in place, patients hesitate to increase their use of corticosteroids as a response to decreased peak flows. The major interest during the TOM study in relation to medicines was on the effect of pharmaceutical care on asthma related medication. An improved use of preventive medication (inhaled corticosteroids of cromoglycates) leads to a decreased use of reliever-medication (betamimetics and anticholinergic drugs) and a decreased incidence of the use of rescue medication (courses of oral corticosteroids and antibiotics).

It was also expected that the knowledge about asthma medication as a whole increased, possibly leading to a better use of medicines. Therefore patients were asked the colour of preventive and relieving drugs (which is standardised in The Netherlands) and the sequence in which they would take this medication. Data on inhaler technique have not been analysed.

5.5.1 Method

Intervention (n = 70) and reference patients (n = 230, internal and external reference group combined) were asked in different sections of the final questionnaire, which was sent back to the research centre directly, if they were ever non-compliant, deliberately or non-intentionally (reported behaviour). A sample of such a questionnaire can be found as an appendix 6 to this dissertation.

In the field of knowledge about their medication patients were also asked in which sequence they would take the blue (reliever) and the brown (preventer) drug. Intervention patients were asked what the different colours of drugs stood for: blue for relievers, brown for...
preventers and green for longer-term relief (long acting β-stimulants like salmeterol and formoterol).

All available prescription data on drugs involved in asthma treatment from intervention and reference-patients were entered into a database using their ATC code. Table 5-10 lists the drugs included, with their ATC code, based upon the commonly used drugs in airway diseases in The Netherlands, and identified in the population. Salmeterol and formoterol were not included because their role in asthma-treatment during the study was unclear and not yet described in any treatment standard. Theophylline and derivatives are hardly used in asthma treatment in The Netherlands anymore and therefore were not included. Ipratropium is occasionally used as reliever medication.

Table 5-10  ATC-codes of drugs included in TOM analysis

<table>
<thead>
<tr>
<th>Corticosteroids (oral)*</th>
<th>Beta-mimetics**</th>
</tr>
</thead>
<tbody>
<tr>
<td>H02AB06</td>
<td>R03AC02 Salbutamol</td>
</tr>
<tr>
<td>H02AB07</td>
<td>R03AC03 Terbutaline</td>
</tr>
<tr>
<td>Antibiotics*</td>
<td>Corticosteroids inhaled***</td>
</tr>
<tr>
<td>J01AA02</td>
<td>R03BA01 Beclometasone</td>
</tr>
<tr>
<td>J01CA04</td>
<td>R03BA02 Budesonide</td>
</tr>
<tr>
<td>J01CE05</td>
<td>R03BA05 Fluticasone</td>
</tr>
<tr>
<td>J01CR02</td>
<td>Anti-asthmatics, other***</td>
</tr>
<tr>
<td>J01DA08</td>
<td>R03BC01 Nedocromil</td>
</tr>
<tr>
<td>J01EE01</td>
<td>R03BC03 Cromoglicic acid</td>
</tr>
<tr>
<td>J01FA06</td>
<td>Anticholinergics**</td>
</tr>
<tr>
<td></td>
<td>R03BB01 Ipratropium bromide</td>
</tr>
</tbody>
</table>

* Rescue medication    ** Relievers       *** Preventers

The participating pharmacists provided data usually from 6 months before the study until the end of the study (24 months after intake), unless the patient had dropped out. The dispensing frequency and the number of prescribed daily dosages (pdds) dispensed were analysed in periods of 6 months and then compared to the period before the intervention. The five available periods were: period 0 (6 months before intake), period 1 (6 months after start intervention), period 2 (6-12 months after start intervention), period 3 (12-18 months after start intervention) and period 4 (18-24 months after start intervention). For the reference patients the starting date was the date of distributing the zero assessment questionnaires.

If, from the data provided by the pharmacy, it was not clear that the whole 6 months period was covered, the period was set to missing. The data were processed using Microsoft Excel conversion, Dbase V for windows programs, and then analysed using SPSS version 7.5.
Reliever medication
To study the use of reliever medication, the number of days dispensed were analysed for the 5 periods of 6 months mentioned above, based upon the number of units obtained at refills and the pdd. The numbers of days dispensed were calculated as follows:

\[
\text{Daysdispensed} (\%) = \frac{\text{Noofunits} \times \text{strength}}{\text{PDD}} \times 100
\]

Preventive medication
For the preventive medication (inhaled corticosteroids and cromoglycates) compliance was analysed. The percentage of compliance was calculated per period of 6 month, based upon the number of units dispensed (tablets, capsules, inhalations) and PDD as follows:

\[
\text{Compliance} = \frac{\text{noofunits} \times \text{strength}}{\text{PDD} \times 180}
\]

Rescue medication
The number of prescriptions for rescue medication (courses of antibiotics and oral corticosteroids (\(\leq 20\) days)) were compared per period of 6 months.

Only those patients of whom drug data were available during more or less the whole study-period have been evaluated, being 62 intervention and 191 reference patients. If data in certain periods were incomplete, this period was marked as ‘missing’ in the analysis. The data were processed using Microsoft Excel and Dbase V for windows, and then analysed using SPSS version 7.5.

5.5.2 Results

Reported behaviour
At the time of the last questionnaire 66% of the reference patients and 84% of the intervention patients said that they sometimes did not take their medicines according to the instructions on the label, but took more or less than indicated. There was no clear correlation between this finding and responses dealing with self-management (see also the section 5-6).

Knowledge about medication
At the start of the project 70% indicated that they took their sympaticomimetic drug before their inhaled corticosteroid. At the end 92% of the intervention patients would follow that sequence whereas the percentage in the reference group did not change.

The percentage of intervention patients, who correctly named the action of the blue medication (short acting beta-mimetic agents), increased from 77 to 95%. For the brown medication (inhaled corticosteroids) the percentage went up from 68 to 92% and for the
green medication (long acting beta-mimetic agents, which were relatively new at the time of the project) from 11 to 24%. No data on this aspect were available from the reference group.

Drug use, inhaled reliever medication

Data on the use of reliever medication was available for 62 intervention (88.6%) and 191 reference patients (90.1%). Table 5-11 reflects the mean number of reliever dosages dispensed, over the period recorded. Between intervention and reference patients there was no significant difference at all periods. However, the decrease in dispensed reliever medication was significant for the intervention patients (Student t-test for paired samples) between the period 0 and 1 (p=0.01) and between the period 0 and 3 (p<0.01). An ANOVA-procedure showed no significant differences throughout.

<table>
<thead>
<tr>
<th>Table 5-11</th>
<th>Mean no of days of dispensed reliever medication, TOM patients with valid data in period</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reliever medication</strong></td>
<td><strong>Period 0</strong></td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
<td>151 (n=50)</td>
</tr>
<tr>
<td><strong>Reference</strong></td>
<td>142 (n=180)</td>
</tr>
</tbody>
</table>

Drug use, inhaled preventive medication

Data on the use of preventive drugs were available for 53 intervention (90%) and 189 reference patients (90%). Table 5-12 reflects the mean overall compliance (%) of the calculated daily dose per 6 months period. In the period after the intake the difference between intervention and reference patients was significant at a 0.1 confidence level (Student t-test) in favor of the compliance of the reference group. In neither group changes between the different periods were significant at a 99% confidence level (Student t-test for paired samples).

An ANOVA-procedure also did not indicate significant differences.

<table>
<thead>
<tr>
<th>Table 5-12</th>
<th>Compliance (%) of calculated daily dose with preventive medication, TOM patients with valid data in period</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preventive medication</strong></td>
<td><strong>Period 0</strong></td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
<td>69.6%</td>
</tr>
<tr>
<td><strong>Reference</strong></td>
<td>70%</td>
</tr>
</tbody>
</table>

Drug use, rescue medication

According to the drug data, 567 short courses of antibiotics or oral corticosteroids (<=20 days) were given to 42 different intervention patients (60%) and to 129 reference patients (61.4%) over the total period. Table 5-13 shows the mean number of courses per patient.
The difference in the mean number of courses between intervention and reference group in period 1 (0-6 months after intake, \( p<0.06 \), asymptotic Student t test) and in period 2 (6-12 months after intake, \( p<0.09 \), asymptotic Student t test) was significant. Although the decrease of the mean number of courses in the intervention group is clear (Student t test for paired samples), this decrease is only significant at a 0.4 level between the period 0 and 1. The changes in the reference group were not significant. An ANOVA-procedure showed no significant differences.

Table 5-13 Mean number of courses of antibiotics and/or oral corticosteroids and number of patients with valid data per period in TOM study

<table>
<thead>
<tr>
<th>Courses of antibiotics or corticosteroids</th>
<th>Period 0</th>
<th>Period 1</th>
<th>Period 2</th>
<th>Period 3</th>
<th>Period 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention (( n_{total}=42 ))</td>
<td>0.65</td>
<td>0.47</td>
<td>0.46</td>
<td>0.61</td>
<td>0.49</td>
</tr>
<tr>
<td>(n=40)</td>
<td>(n=36)</td>
<td>(n=37)</td>
<td>(n=38)</td>
<td>(n=41)</td>
<td></td>
</tr>
<tr>
<td>Reference (( n_{total}=129 ))</td>
<td>0.70</td>
<td>0.77</td>
<td>0.74</td>
<td>0.73</td>
<td>0.79</td>
</tr>
<tr>
<td>(n=121)</td>
<td>(n=126)</td>
<td>(n=121)</td>
<td>(n=126)</td>
<td>(n=103)</td>
<td></td>
</tr>
</tbody>
</table>

Discussion and conclusion on the drug use

Optimal drug use in asthma patients is difficult to assess from pharmacy records. First there is a number of possible biases in the databases themselves, mostly dealing with erroneous data concerning the daily use. Secondly it is difficult to assess what the optimal drug use for an individual patient should be. This could be quite different for different patients and certainly can change almost daily for reliever medication. Thirdly, like in every drug use process, the patient’s adherence with taking the medication as prescribed can be questionable. Also, with inhaled medication, it is quite difficult to assess if the patient uses the right inhaler technique. And last, but certainly not least, the way Dutch pharmacy computer systems record the number of dispensed dosages and the daily use of medication of inhalers is not uniform. This gives rise to possible errors in the calculations of the dispensed daily dosages but has been corrected during the data-entry.

In this study, a large proportion of the patients admitted to not being fully compliant with the use of the medication, as it was indicated on the label. This is in line with findings of others in The Netherlands. However, it can be questioned if this in itself is problematic, because an increased use of preventive medication would improve asthma control and result in a decreased use of rescue and reliever medication. Moreover patients nowadays are encouraged to regulate their own asthma medication, often with the help of a peak flow meter. However, ‘non-compliant’ patients did not indicate that they used self-management more often than ‘compliant’ patients did.

The analysis of the relieving medication in the intervention group shows a decreased use, compared with the reference group, significant for two distinct periods. This is an important finding. One should keep in mind that reliever medication is often still prescribed with a fixed daily dose, instead of prn. use. That may upset the type of analysis where the PDD is an element of the calculations.
Evaluation of the compliance with the preventive medicines was calculated on the basis of the available data concerning refills and daily use according to the prescription. Although the relatively low compliance in the first 6 months period for the intervention group is remarkable it was not statistically significant. In general there seems to be little difference between the intervention and reference group regarding compliance with preventive medication throughout the study.

The number of short courses of antibiotics and oral corticosteroids, and the use of reliever medication in the intervention group decreased. This was a clear indication of a better asthma control in the intervention group.

5.6 OTHER EFFECTS OF THE PROVISION OF PHARMACEUTICAL CARE

Although the main emphasis, when evaluating pharmaceutical care, is on the quality of life, other factors are also important. Several different items have also been included into the study such as the familiarity with the pharmacist and the pharmacy staff, opinions on the image and professional aspects of the pharmacist, the pharmacy staff and the physician, and the understanding of patient information leaflets.

5.6.1 Method

Data were collected through questionnaires sent to intervention and reference patients directly by the research centre before intake, and after 6, 12 and 24 months. Because there were hardly any differences between the internal and external reference group if those groups were combined for these analyses. Opinions were collected using either a 4 or 5 point Likert scale. In the final questionnaires, after 24 months, the option ‘don’t know’ was omitted, to force respondents to formulate either a positive or negative response.

The image in the field of medicines of the pharmacist, GP and pharmacist assistants was measured by asking respondents to give an opinion on the expertise of those professionals with the options to reply ‘not at all expert’, ‘somewhat expert’, ‘reasonably expert’, ‘expert’ and ‘very expert’. The proportion of respondents finding any of the professionals expert or very expert is given.

Intervention and reference patients were given a number of statements at the end of the project to which they could respond with ‘strongly agree’, ‘agree’, ‘disagree’ or ‘strongly disagree’. Data were analysed, after merging positive and merging the negative responses using the Chi-square test in SPSS for Windows, version 7.5.

5.6.2 Results

At the beginning of the study 48.4% of the intervention patients and 46.4% of the reference patients personally knew the pharmacist of the pharmacy where they usually got their medicines. At the end of the project the proportion for the intervention patients was 97% and for the reference patients went down to 35.4%.

Whether a (professional) relationship between GP and pharmacist existed was still not clear to 38% of the intervention patients (and 59% of the reference patients) at the end of the project.
The image of the pharmacist and other professionals

Table 5-14 outlines the results of the questions on the expertise of the pharmacist, GP and pharmacist assistants as a reflection of their image in the field of medicines.

<table>
<thead>
<tr>
<th>Table 5-14</th>
<th>% of TOM patients finding professionals expert or very expert in the field of medicines</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0-month</td>
</tr>
<tr>
<td><strong>Pharmacist</strong></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>40.0</td>
</tr>
<tr>
<td>Reference</td>
<td>41.5</td>
</tr>
<tr>
<td><strong>Pharmacist assistant</strong></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>29.6</td>
</tr>
<tr>
<td>Reference</td>
<td>45.0</td>
</tr>
<tr>
<td><strong>GP</strong></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>71.9</td>
</tr>
<tr>
<td>Reference</td>
<td>75.8</td>
</tr>
</tbody>
</table>

* Option ‘don’t know’ omitted

Opinions of intervention and reference patients at the end of the TOM project differed significantly on the statements mentioned in table 5-15. There were no differences between the internal and external reference patients. Only patients who indicated that they had spoken with the pharmacist during the previous year were included.

<table>
<thead>
<tr>
<th>Table 5-15</th>
<th>Proportion of intervention or reference TOM patients agreeing with quoted statements at end of the project</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statement</td>
<td>Intervention (n=70)</td>
</tr>
<tr>
<td>If I want to know something about medicines, the pharmacist is the first person I think of</td>
<td>74%</td>
</tr>
<tr>
<td>The pharmacist is badly accessible if I want to speak with him/her *</td>
<td>10%</td>
</tr>
<tr>
<td>I now access the pharmacist more easily with questions about medicines than 2 years ago</td>
<td>84%</td>
</tr>
<tr>
<td>The pharmacist knows nothing about my diseases *</td>
<td>11%</td>
</tr>
<tr>
<td>I find I can communicate well with my pharmacist</td>
<td>96%</td>
</tr>
<tr>
<td>I now access the pharmacist more easily with questions about diseases than 2 years ago</td>
<td>51%</td>
</tr>
<tr>
<td>I do not care if I speak with the pharmacist or the pharmacist assistant</td>
<td>47%</td>
</tr>
</tbody>
</table>

The response to other statements (see table 5-16) showed no significant differences.

<table>
<thead>
<tr>
<th>Table 5-16</th>
<th>Proportion of patients agreeing with quoted statements at end of the TOM project</th>
</tr>
</thead>
</table>
I find I can communicate well with my GP 93%
As for me, repeating prescriptions can be done directly through the pharmacy 79%
I think they have all information about my drug use in the pharmacy 96%
The GP carefully watches my medicine-use 65%
The pharmacist knows more about medicines than I used to think 58%
The GP is badly accessible when I want to speak to him/her 17%

More asthma-related results
At the start of the project, 25% of patients used a peak-flow meter for the assessment of the severity of their asthma, mostly when the GP told them. After 1 year 75%, and at the end of the project 81% of the intervention patients used the peak-flow meter and in the reference group 20-21% of the patients only.

The reasons for using the meter were very similar in the intervention and the reference group: 7% used the meter daily, 47% if they were short of breath, 25% by request of the pharmacist and/or GP, and the remaining 21% for other reasons.

In both groups 77% of those patients who used the peak-flow meter also adapted their medication according to the peak-flow readings.

Table 5-17  Asthma control of users of peak-flow meters at end of the project

<table>
<thead>
<tr>
<th>Statement</th>
<th>Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>At least once a week problems with wheezing or tightness of the chest</td>
<td>Intervention (n=56)</td>
</tr>
<tr>
<td>Failed to attend school or work because of asthma during the last year</td>
<td>54%</td>
</tr>
<tr>
<td>Awakes during the night because of wheezing or tightness of the chest</td>
<td>42%</td>
</tr>
</tbody>
</table>

The increased use of the peak-flow meter in the intervention group and/or the overall provision of pharmaceutical care resulted in the tendency towards an improved control of the asthma at the end of the project (see table 5-17). The same tendency concerning asthma control can be seen when all patients in the intervention and reference group are compared at the end of the study. The improved asthma control did not show from the plain reported yearly frequencies of having tightness of the chest.

No influence of the pharmaceutical care provision could be seen on smoking behaviour. In both the intervention and reference group, approximately 30% of the participants smoked at the end of the study. However, in the intervention group 56% lived in a ‘cleaned environment’ while in the reference group the corresponding value was only 23%.
5.6.3 Discussion and conclusion

It is clear from the results that the professional image of the pharmacist improved because of the care provided. Intervention patients clearly agreed more than reference patients did with statements concerning the professional content of the interaction with the pharmacist, with one exception. During the project over 50% of all patients came to think that the pharmacist knows more about medicines than they used to think. This can be the result of the effect of completing the questionnaires over the years or of the ongoing public relations campaign of the Dutch professional pharmacist organisation KNMP and which started around 1995.

The proportion of patients using a peak flow meter, and who adjusted their medication accordingly, increased because of the care provided. The project resulted in better asthma control for those patients. No changes have occurred in patients’ smoking behaviour, however, this aspect did not receive special emphasis during the project.

5.7 Overall conclusion to this chapter about the TOM study

The general picture of the results of the TOM project is positive. More patients have started to use the peak-flow meter and became involved in self-management. In addition more patients were now using the reliever medication before their preventive medication. There was a better asthma control in the intervention group, which is clearly supported by the findings of the drug analysis. There is also an indication that the quality of life (according to the AQLQ) improved as a result of the provided care. The knowledge about fields related to asthma, e.g. chronic bronchitis and emphysema improved. There is no indication that a selection bias occurred as a result of the drop-outs from the study. Patients were satisfied with the provided care and found the regular consultations useful.

It is clear that the patients’ image of a pharmacist changed and they now have a more positive opinion of the capacities of pharmacists to help them with their drug use and coping with their disease.

Clear pharmacoeconomic data could not be obtained, due to the relative low number of intervention patients retained at the end of the study.

The overall picture resembles the results of the TOM asthma study in Finland, Germany and Denmark. Major peer-reviewed publications for both studies are still pending. Non peer-reviewed publications suggest however that in both cases there was a better process-control than in the Dutch study.

In Germany significant improvements were found in the field of the severity of the asthma (subjective and objective), compliance and knowledge, the asthma related quality of life and even in the general quality of life as measured by the SF-36. In Denmark the improvements in the field of asthma symptom status, days of sickness, quality of life (using the Nottingham Health Profile), knowledge and inhalation technique were significant. A publication on the cost-effectiveness of this TOM-asthma program will soon appear. The evaluation of the costs of the programme shows cost-effectiveness ratios between 0.18 and 0.56. The pay off time for the programme is 23 months (range 9-24 months in the sensitivity analysis). The authors conclude that community pharmacists can contribute to identify and solve drug-related problems in a cost-effective way with positive
impact on death from asthma and the clinical and psychosocial outcomes, although the program is time consuming and intensive for all participants.

Recently a report appeared from a similar Austrian study (co-ordinated by the Pharmcare Network) in which the outcomes were addressed more directly at a patient level than in the Dutch study. Patient stated that they noticed positive changes in their knowledge (71%), asthma related problems (50%), quality of life (47%), the use of their inhaling devices (57%) and the use of their peak-flow meters (53%). No significant negative changes were reported.

The Danish program and experiences from the other asthma studies in Europe have led to the development of a protocol and guidelines for pharmacy-based asthma services. This manual will be applied by pharmacy organisations all over Europe, guided by Europharm Forum.

The provision of (pharmaceutical) care during which there is an emphasis on the compliance with preventive medication, the proper use of peak-flow meters, inhaler technique and self management improves the patients’ asthma control, knowledge and satisfaction with care in all studies published to date, including the Dutch TOM-asthma study.

5.8 References to Chapter 5

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