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Evaluating the implementation fidelity of New Medicines Service for asthma patients in community pharmacies in Belgium


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Abstract

Background

In October 2013, a New Medicines Service (NMS) was introduced in community pharmacies in Belgium to support asthma patients who are novice users of inhaler devices with corticosteroids. The protocol-based intervention used the Asthma Control Test (ACT) and the Medication Adherence Report Scale (MARS) to assess asthma control and medication adherence. The NMS is the first initiative that puts advanced pharmaceutical care into practice in Belgium. The present study evaluated the degree to which the NMS programme is delivered as intended, drawing on the concept of implementation fidelity (IF).

Methods

The main dimensions of IF and potential moderating and facilitating factors for the implementation of NMS in community pharmacies were evaluated using telephone interviews with pharmacists (n=497), semi-structured interviews with patients eligible for NMS (n=30), focus groups among general practitioners (n=72) and lung specialists (n=5), and a work system analysis in community pharmacies (n=19).

Results

The uptake of NMS in Belgian community pharmacies remains low. In addition to practical barriers, pharmacists found it difficult to identify new asthmatic patients when they were not informed about the diagnosis. A lack of commitment from physicians, patients and pharmacists was noted in the early start-up phase of the programme. Many pharmacists did not see how NMS differed from the existing pharmaceutical care. Physicians considered this service as part of their own tasks, and discouraged ACT for asthma follow-up in the community pharmacy.

Conclusion

The introduction of the NMS programme was not sufficiently embedded in the Belgian health care organisation, causing a low uptake and resistance to its implementation by pharmacists, patients and other health care professionals. To increase the uptake of this type of service and its possible extension to other patient groups, more collaboration among the different health care professionals during design and implementation is necessary, as well as systematic data collection to monitor the quality of the service, better training of pharmacists, and more information for patients and physicians.

Keywords

Pharmaceutical care; New Medicines Service; Belgium; protocol-based care; implementation fidelity

Acknowledgments

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Conflict of interest
None.
Introduction

Asthma is a chronic airway condition that affects around 300 million people worldwide. It causes a substantial health burden, ranking as the 15th leading cause of disability according to the Global Burden of Disease 2013 study. Inadequate control of asthma symptoms is a serious problem, despite the availability of effective medication and dissemination of global asthma management guidelines. Correct inhaler technique and proper medication adherence are critical determinants of the success of asthma management. However, several studies have shown that inhalation technique errors are common and that adherence to chronic asthma medication is generally poor.

Community pharmacists can play an important role in improving asthma management, by providing education on appropriate use of asthma medication. There is evidence that community pharmacy based interventions can substantially improve inhalation technique, medication adherence and asthma control.

In October 2013, a new community pharmacy asthma service was introduced in Belgium. The service is a form of New Medicines Service (NMS), which was recently introduced in the UK, with the aim to improve adherence to newly prescribed medication. The Belgian NMS is a protocol-based intervention for asthma patients who are novice users of inhaled corticosteroids (ICS), meaning first use in the past 12 months. The aim of this NMS is to optimise the inhalation technique and to improve therapeutic adherence. The protocol for this NMS contains the Asthma Control Test (ACT) and the Medication Adherence Report Scale (MARS) as tools to assess asthma control and medication adherence.

After informed consent from the patient, two counselling moments are planned per individual patient. Pharmacists receive a fixed fee of 20 euros for every NMS session (maximum two per patient per year, i.e. one assessment and one follow-up). The protocol states that the pharmacist should select the eligible patients first, in casu: newly prescribed ICS, patient with asthma and use of emergency medication. The first counselling moment (assessment) should take place at a moment separate from dispensing the medication (one to seven days later than the first dispensing) and the second counselling moment (follow-up) two to six weeks after the assessment (Figure 1). The implementation of NMS was facilitated by providing a protocol and an online software-tool to guide the pharmacists through that protocol. This is the first time Belgian community pharmacists receive a fee for a pharmaceutical care service that is provided separately from medication dispensing.

The NMS is an example of Cognitive Pharmaceutical Services (CPS). CPS can be defined as “professional services provided by pharmacists, who use their skills and knowledge to take an active role in contributing to patient health, through effective interaction with both patients and other health professionals”. In the UK, NMS is classified as an Advanced Service in community pharmacy: “The underlying purpose of a New Medicine Service is to promote the health and well-being of patients prescribed with new medicines for long term conditions.” Essentially, this kind of service takes the community pharmacists beyond the provision of standard pharmaceutical care. Moreover, it is a significant driver of a practice change in community pharmacy, as the remuneration of community pharmacies is increasingly moving from product supply to patient-centred service supply.

As the NMS is a new intervention, which, if successful, could be generalized to services related to other medication, it is necessary to evaluate it. A crucial element in this evaluation is the way the intervention was implemented. Indeed, the success of an intervention programme not only depends on its innovative nature or the strategy or methodology that it entails, but also on the quality with which it is implemented. In this paper, we focus on the process of implementing the NMS programme in Belgium. For that purpose, we draw on the notion of implementation fidelity (IF), or
the degree to which an intervention is delivered as intended. Investigating the IF can help to clarify why an intervention succeeded or failed, and can prevent the type III error, i.e., the attribution of the absence of significant effects to the shortcomings of the intervention itself, when in fact it resulted from poor implementation.18

The aim of the current study was to evaluate this new community pharmacy asthma service, and more specifically its implementation.

Implementation fidelity

To study the IF of the NMS programme we drew on the conceptual model proposed by Carroll et al. (Figure 2).11 This model describes the main dimensions of implementation fidelity and highlights potential factors that moderate the implementation of a programme, thereby affecting its effects. The principal concept in this model is the adherence to the program, which refers to the degree to which the active parts of the intervention have been delivered by the providers (i.e., the pharmacists) to the participants (i.e., the patients) with the planned frequency, duration and intensity. Adherence is operationally defined by four components: (a) the content of the intervention (was the full content delivered to the participants?); (b) its frequency and (c) duration (was the intervention delivered with the frequency and duration prescribed by the developers?); and (d) coverage (have all pharmacists/patients who should have participated in the intervention actually done so?). The combination of the frequency, duration and coverage of the intervention are referred to as the intervention dose. The level of IF can be moderated by four interrelated variables: (a) Intervention complexity refers to the nature and comprehensiveness of the intervention, whereby an intervention is more complex if several providers are involved, if it comprises several sessions, and if there are several groups of participants; (b) Facilitation strategies such as a manual, training and feedback help to optimize and standardize the fidelity of the implementation; (c) The quality of delivery refers to the dedication of the individuals who are responsible for delivering the intervention; (d) Participant responsiveness refers to the participants’ enthusiasm for and perceived relevance of the intervention. Hasson18 suggests two additional moderators, notably: (e) Recruitment, which refers to the procedures that were used to attract potential participants in the intervention, the reasons for non-participation, and the presence or absence of specific participant subgroups; and (f) Context, which refers to the culture and the organizational structure in which the intervention takes place (e.g. positive working climate, norms to change, shared decisions, communication).

When applying this model to the introduction of the NMS, we extended it by adding two facilitating factors for implementation of new services in the community pharmacy that were described by Roberts et al., namely remuneration and external support/assistance.15

Methods and data

Data collection methods
To evaluate the IF of the NMS programme, a variety of research methods was used in a complementary manner.
Firstly, a work system analysis was used to evaluate the integration of the NMS in community pharmacy practice. For this purpose, the NMS programme was analysed according to the SEIPS model, using the stepwise procedure proposed by Karsh. Concretely, observations and interviews in a purposive sample of community pharmacies were performed.

Secondly, the uptake of the NMS programme by Belgian pharmacists was evaluated through a claims data analysis (registration of NMS) and individual telephone interviews with pharmacists. For the latter, a semi-structured interview questionnaire was used, including questions regarding reasons for (not) providing the service, applied tools etc.

Thirdly, individual semi-structured interviews were held with patients to ask how they experienced the NMS (regarding desirability, context, perceived effectiveness etc.).

Finally, the opinions and attitudes of general practitioners (GPs) and lung specialists regarding the NMS programme were explored via focus group discussions and individual interviews using a semi-structured questionnaire addressing the feasibility of the service in inter-professional collaboration. The methodology and full results of these focus groups and interviews are detailed elsewhere.

Participants
Between January and March 2015, observations and interviews were done in a purposive sample of 19 pharmacies in Flanders, providing the data for the work system analysis. Full details and results of this analysis are available elsewhere.

The analysis of the claims data for the illustration of the uptake of NMS was done by the Association of Pharmacists in Belgium and includes all registered NMS interventions between October 2013 and September 2015. For the telephone interviews with Belgian pharmacists, a total number of 497 pharmacies were randomly selected based on location and were contacted by telephone between April and December 2014 (seven months after the service became available), resulting in 380 pharmacists who completed the full questionnaire (246 Dutch-speaking and 134 French-speaking pharmacists).

For the patient interviews, 30 patients (21 Flemish-speaking and 9 French-speaking) were recruited between July 2014 and March 2015, using three different tracks: (1) Three patients were recruited by the pharmacists after the telephone interviews, which included a question to select eligible patients to participate in the study; (2) Eighteen patients were selected from the health insurance database (registered NMS in Pharmanet) and, following their informed consent, contacted for an interview; (3) nine eligible patients (based on NMS criteria) were selected during consultation with the specialist physician. Regular procedures were applied during this consultation, after which informed consent was explained and asked for. Patients who consented were contacted by the researcher to participate in an interview.

Between March and May 2015, eight focus groups involving a total of 72 GPs were organized during the meetings of local quality circles, and five interviews were held with lung specialists. Physicians were selected randomly and contacted by email and telephone to check for willingness and availability to participate.
Ethical approvals
For the telephone interviews with pharmacists and interviews with patients, ethical approval was obtained from the University Hospital in Antwerp (B300201422979).

Results

Adherence
To assess the adherence to the NMS, the number of NMS interventions performed by all Belgian pharmacies was estimated using the reimbursement claims. As shown in Figure 3, there was a seasonal fluctuation in the number of dispensed NMS in the period between October 2013 and September 2015. The moving 12-month average shows a slow increase from 18.3 thousand to 21.8 thousand of services provided. However, these numbers are probably an underestimation, as not all pharmacists claimed reimbursement for the NMS they performed.

As inferred from the telephone interviews, one in four pharmacists (25.8%) out of 380 had delivered one or two NMS with the same patient, with on average five counselling interventions per pharmacy. Of those who had performed an NMS, a relatively large group had performed only one (27.8%; n=27). According to the work system analysis, from the pharmacists who had performed an NMS 37% indicated that they had performed at least one follow-up NMS.

The duration of a NMS service depended on the kind of tools used. The work system analysis indicated that pharmacists who used an online tool spent on average 16 minutes on one counselling intervention, and those who used their own tool (own developed digital questionnaire), approximately 15 minutes. In contrast, when no tool was used at all, pharmacists only spent 6 minutes on average on the service.

Moderators
Participant responsiveness (pharmacists and patients)
As indicated by the results from the telephone interviews (Table 1), pharmacists primarily experienced practical barriers to implement the NMS programme (22.4%). Having no time or lack of staff were commonly expressed reasons for not engaging in NMS. One of the most important barriers to performing NMS was the requirement to obtain a signature (informed consent) from the patient to start up individual counselling and to open an electronic record for follow-up. Pharmacists would find the NMS more feasible if the signature of the patient was not mandatory.

Another reason for the low responsiveness of pharmacists to engage in the NMS programme was the lack of knowledge about the protocol and the rationale for the NMS intervention: 10.1% of the pharmacists that were interviewed found the patient profile unclear as a selection criterion for the intervention, or indicated a lack of experience with NMS (see Table 1). This is corroborated by the view of the GPs and lung specialists, who indicated during the interviews and focus groups that they considered the pharmacist insufficiently trained to perform asthma assessment of patients and to use the ACT.

“I don’t know whether the pharmacists’ education provides in-depth information about this pathology. I have some pharmacists as patient in my practice, and I
notice that they know more than common patients, but certainly not everything. No blame attached.” (interview with lung specialist)

On the other hand, for patients the main barrier to engaging in the NMS was attitudinal. The interviews with the patients indicated that they are mostly unaware of the initiative and that they experience it as slightly uncomfortable.

“It is a strange experience [to meet with the pharmacist separate from medicine delivery]. Because, what can they do? But yes, you know, in the end, they deliver the drugs, so they could keep an eye on that!” (semi-structured interview with patient, 1)

**Comprehensiveness of the programme description**

To apply an NMS counselling intervention, a number of criteria must be fulfilled. A first criterion for NMS is the diagnosis of asthma. Although this may seem evident, this criterion represented an important barrier for many pharmacists and physicians to engage in NMS. On the one hand, physicians indicated during the interviews and focus groups that they found it difficult to clearly state the starting point of asthma in their diagnosis. The pharmacists, on the other hand, found it difficult to identify new asthma patients when they were not informed about the diagnosis (see Table 1). The latter was confirmed by the telephone interviews, the work system analysis and interviews with pharmacists.

“it is not so easy to make the diagnosis of asthma. Suppose we [GPs] know, how can the pharmacist know then? What bothers me most is that the pharmacist can also be way off target. He might think it is an asthma patient, while it is not.” (focus group with GPs)

A second criterion is the first dispensing of an inhaled corticosteroids. This was complicated by two issues. On the one hand, there is the low number of patients who have been newly diagnosed with asthma fulfilling all the criteria and, therefore pharmacists found it hard to efficiently recruit patients. On the other hand, patients reported they felt no need for assistance since they had used similar devices before, and failed to see the added value of the service.

“He [the pharmacist] responded that there is something new where we have to extra inform patients. Yes, but in my case, there is not much added value, because I am already well informed about the procedure since 10 years now.” (semi-structured interview with eligible patient, 15)

As revealed by the focus groups discussions, some GPs found it inappropriate that pharmacists can initiate a NMS service without a physician’s approval, and suggested that the NMS service should be prescribed and that feedback from the pharmacist should be added to the patient’s file (if applicable). Although the current NMS protocol allows the NMS to be prescribed by a GP or specialist, the protocol included no structured feedback towards GP and/or lung specialist after the NMS.

**Strategies to facilitate implementation**
The implementation of NMS was facilitated by a step-by-step protocol and a web-based software tool to guide the pharmacists through that protocol. Most of the pharmacists who participated in the telephone interviews and who had performed NMS had used this web tool (66.0%) and found it useful. From the work system analysis, it appeared that pharmacists who used the web-tool spent more time on a NMS and addressed more topics from the protocol than pharmacists who did not use the tool.

As revealed by the interviews, pharmacists considered the remuneration for NMS as an important step in the evolution of pharmaceutical care and as a motivation for pharmacists to perform NMS. In contrast, the focus groups with the GPs indicated that they found it unnecessary or even inappropriate to give a fee to pharmacists to provide this kind of service, in proportion to existing services in general practice.

> “But pharmacists receive 40 euros for two consultations. We receive 30 euros for a pile of administrative work. That is not in proportion! I think what we do for the Global Medical patient Record (GMR) is much more extensive than what the pharmacist does for this NMS.” (focus group with GPs)

**Quality of delivery**

The results of the work system analysis showed that the use of the software tool enhances the implementation of the NMS service in practice. More pharmacists using the tool provided the service at a private designated space and during a separate appointment (as suggested in the protocol). During the service delivery, most time is spent on medicine-related aspects (demonstrating inhaler device, correct use of rescue medication, drug-drug interactions), than on patient-related aspects (expectations and knowledge of patients). In contrast, only half of the pharmacists whose work system was analysed (n=10) took the ACT from the patient, the other half did not consider the ACT to be an added value for the service. The informed consent was signed and handed over to the patient in less than half of the cases (n=8). Most pharmacists made a registration of the NMS (for remuneration) (n=13) and handed over the summary of the service they had provided to the patient without signature (n=13). Most pharmacists involved in the work system analysis (n=17) had attended a specific training on NMS before performing the service.

**Context of the intervention (external support/assistance)**

The current evaluation study suggests that physicians and patients were generally not aware of the intervention and that pharmacists lack collaboration with physicians (see Table 1). However, the acceptance of the intervention was also a topic of debate in the focus groups. GPs did not see the added value of the NMS intervention and some found it inappropriate that pharmacists receive a fee for this kind of services.

While the added value of this NMS lies in the structured assessment of the asthma control (using the ACT), adherence to the treatment (using the MARS questionnaire) and counselling of the correct inhalation technique, pharmacists often did not perceive the service as something new. As revealed in the interviews, one out of five pharmacists (19.1%) considered NMS to be already part of the standard service they provide in everyday practice (see Table 1). In addition, GPs during the focus groups indicated that they did not perceive the ACT test as an appropriate tool to be used by
pharmacists, as this could imply that the latter is making a clinical act. Some GPs experienced this kind of service as a threat to their expertise.

“It bothers me that they want to take something away from the GPs. Not only asthma, but they will also take hypertension, they will take cholesterol, ... that is my remark. We have studied for nine years. Pharmacist take five years and now they are completely invading our domain.” (focus groups with GPs)

In terms of the immediate organisational context of the NMS intervention, the physical space that is required in the pharmacy for an intervention to take place remains an important barrier for pharmacists to engage in NMS. A NMS requires a designated space where the pharmacist can guarantee privacy for the patient. Although the presence of a private space in the Belgian pharmacy is mandatory since 2009, lack of such a space remains a barrier.
Providing NMS services to newly diagnosed asthma patients is a new service in Belgium, and the first of its kind. To prevent making the type III error and attributing the absence of significant effects to the shortcomings of the intervention itself, it is important to evaluate whether the NMS was implemented successfully. The answer to that question, however, is not straightforward. While the uptake of NMS in Belgian community pharmacies remains low, the results from the implementation evaluation presented in this paper suggest that this is predominantly due to a number of weaknesses in the implementation of the NMS project. Specifically, there appears to be a lack of engagement from physicians and patients, but also from pharmacists in the early start-up phase of the service. However, this investigation has not only revealed the limitations of the programme, but also the possibilities of such an intervention in the Belgian context. As such, it points toward possibilities to improve the implementation and possibly the design of future counselling services in the community pharmacy, also others than only for asthmatic patients.

The main results from the study show that the intervention was not sufficiently embedded in the existing health care organization, meaning there was a lack of communication from the service commissioner towards patients, pharmacists and physicians. This resulted in a lack of engagement from the participants (pharmacists and patients) and other health care professionals (GPs and lung specialists), causing a low uptake and a large resistance to its implementation. Roberts et al. have shown that collaboration with physicians was the most important factor for successful implementation of interventions in the community pharmacy.15

While the current NMS is an attempt to install protocol-based care in community pharmacies, it lacks a clear vision of how its implementation fits in the current practice. The implementation of protocol-based care should be done more carefully, by assessing the needs, involving the participants and other health care providers in the development of the protocol, and taking the context of the practice into account.23

The uptake of this NMS in Belgian community pharmacies of 25.8% is slightly lower than a survey study in APB-pharmacies done in November 2013 which showed a participation of 33.2%.24 The current study showed an average of five interventions for individual patients per pharmacy, which can considered as a very low uptake compared to the uptake of other NMS in other countries. In 2012, the NMS for asthma patients in the UK recorded a drop-out in patients of 17% before the first consultation and 19% before the second consultation.12

It must be acknowledged that although this study allowed to partly describe how community pharmacists managed NMS in practice, it does not provide enough information to fully describe the quality of the services that were delivered, or to conclude whether the pharmacist did well in implementing NMS and if the patients benefited from it. Future initiatives should combine the evaluation of the implementation with quality control through systematic data collection. The example of the Netherlands shows how data can be collected to assess the quality of pharmaceutical services by collecting data from the pharmacists (quality indicators) and asking patients to assess the quality of the service (using Patient Reported Outcome Measures -PROMS)25,26. That way, permanent quality control becomes an inseparable part of pharmaceutical services.

The advantages of permanent quality control are considerable. Through efficient data collection, the government can make assessments and prospections for future investments or make adjustments based on clear data. Pharmacists get a better overview of the efforts they have made and can report
any barriers they experience. Overall, quality control increases transparency in health care services, which in turn will increase the quality of the care that is provided. Although this kind of quality control can give the pharmacists an untrustworthy feeling and therefore feel being targeted, it is an essential step towards establishing the new role of pharmacists in the organisation of primary care today and in the future.

Quality improvement can also be done through education and training. Although some training on introducing NMS was provided by the pharmacist’s organizations, these occurred only after the initiation of the project in October 2013. In the UK, community pharmacists are obliged to follow a training programme and have to achieve national accreditation through a competency-based assessment before they are allowed to provide advanced pharmaceutical services. This was a strong driver for increasing the engagement of pharmacists in NMS in the UK 16,28.

Recruiting patients for evaluating pharmaceutical services by consulting the national insurance database (Pharmanet) is unique in Belgium. The advantage of this recruiting technique is clear: you obtain an objectively composed sample of respondents. However, we encountered several hurdles. First, there is a considerable delay between the data collection (when NMS is delivered) and the availability of the patient’s data for the research, which is minimum three to four months, due to administrative processes and privacy issues. These issues in the data flux need to be addressed in order to collect data and evaluate the quality of these new services in pharmaceutical care.

The expansion of pharmaceutical care practices and the decision to invest in pharmaceutical care should be seen in the larger context of the improvement of the organisation of primary care. The increasing pressure on general practitioners will force them to delegate tasks to other health care professionals. As such, patients will increasingly be managed within a network of care, where primary care evolves from GP-centred care towards patient-centred care. Therefore, primary health care professionals need to communicate and collaborate closely in order to take up the responsibility for the health of the individual patient 29. Furthermore, patients will increasingly be stimulated to perform self-care for minor ailments, in order to decrease the number of GP consultations 30. The role of the pharmacist today seems to be underused 31. It is clear that extending the tasks of community pharmacists in primary care requires an important mind shift from both health care professionals and patients 32.

Conclusion
In conclusion, the shift to more inter-professional collaboration in primary care in the near future is unavoidable and necessary. This should be implemented as part of a global strategy in which pharmacists also will play an important role. To increase the uptake of this type of service and its possible extension to other patient groups, more collaboration among the health care professionals during design and implementation is necessary, as well as systematic data collection to monitor the quality of the service, better training of pharmacists, and better information for patients and physicians.
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Tables and figures

Figure 1: Flow chart for the New Medicine Service for novice asthma patients using ICS (Inhaled Corticosteroids) in community pharmacies in Belgium
Figure 2: Conceptual framework for implementation fidelity (based on Hasson)
Figure 3: Reimbursement claims for NMS interventions by Belgian community pharmacies (Oct 2013-Sept 2015), divided by assessment (first interview) and follow-up (second interview).

Upper panel (a): monthly figures

Lower panel (b): the moving 12-month average
Table 1: Reasons to not engage in New Medicines Counselling (NMS) in pharmacists who have not yet performed NMS (N, %)

<table>
<thead>
<tr>
<th>Reason</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Practical issues (lack of time or room)</td>
<td>124</td>
<td>22.4</td>
</tr>
<tr>
<td>Patients’ refusal</td>
<td>109</td>
<td>19.7</td>
</tr>
<tr>
<td>NMS is already a standard task in community pharmacy</td>
<td>106</td>
<td>19.1</td>
</tr>
<tr>
<td>Patient profile as selection criterion is too narrow</td>
<td>89</td>
<td>16.1</td>
</tr>
<tr>
<td>Patient profile as selection criterion is unclear</td>
<td>19</td>
<td>3.4</td>
</tr>
<tr>
<td>Lack of collaboration with physicians</td>
<td>50</td>
<td>9.0</td>
</tr>
<tr>
<td>Lack of experience in NMS</td>
<td>37</td>
<td>6.7</td>
</tr>
<tr>
<td>Other (being retired, temporary position in pharmacy)</td>
<td>20</td>
<td>3.6</td>
</tr>
</tbody>
</table>