

Implementing a new antibiotic allergy protocol in clinical practice: well-trusted but not used

P. Hanssen^{1*}, C. Nieuwhof², S. van Mens³, A. van de Plas⁴ and K. Horstman⁵

¹Faculty of Health, Medicine and Life Sciences, Maastricht University, Maastricht, The Netherlands; ²Department of Allergology and Clinical Immunology, Internal Medicine, Maastricht University Medical Center, Maastricht, The Netherlands; ³Department of Medical Microbiology, Maastricht University Medical Center, Maastricht, The Netherlands; ⁴Department of Clinical Pharmacy and Toxicology, Maastricht University Medical Center, Maastricht, The Netherlands; ⁵Department of Health, Ethics, and Society, Care and Public Health Research Institute CAPHRI, Maastricht University, Maastricht, The Netherlands

*Corresponding author. E-mail: priscillahanssen95@gmail.com

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Background: Suboptimal antibiotic prescriptions in patients with an antibiotic allergy label lead to increased incidence of adverse events and antimicrobial resistance (AMR). An antibiotic allergy protocol was developed in a Dutch academic hospital guiding optimal and safe antibiotic use in potentially penicillin-allergic patients. Informed by previous studies of implementation processes in clinical care, we studied the implementation of this protocol.

Methods: Medical professionals in the Departments of Surgery, Internal Medicine, and Pulmonary Care were interviewed. Additionally, focus groups were conducted in Internal Medicine and Pulmonary Care to validate the outcomes of the interviews.

Results: Dissemination of the protocol via the regular online hospital-wide guidance system did not have a significant impact on the knowledge about or use of the protocol. If healthcare professionals found the protocol, they thought it was valuable and expressed trust in the expertise embodied in it. However, its use in practice was rather minimal. Interviewees doubted the accuracy of the patient's histories about their previous adverse drug reactions, and/or the information in their medical records and concluded that adherence to the expert guideline was needlessly risky. They felt the acute allergic reaction risk for a patient outweighed the risk of suboptimal therapy or future AMR.

Conclusions: For successful implementation and dissemination of the protocol, the accessibility of the protocol, the information about the actual risks of following the protocol and the registration of allergic history should be improved. However, whether this actually results in improvement also depends on changes in the hospital culture and organization.

Introduction

In 2015, the WHO launched a Global Action Plan for Antimicrobial Resistance, and one of the objectives was 'to optimize the use of antimicrobial medicines in human and animal health'.¹ This objective entails stimulation of rapid diagnostics and more precise clinical protocols. Moreover, improved management of individuals with suspected antibiotic allergies is one of the areas where changes were recommended.

In patients with a penicillin allergy, other β -lactam antibiotics still are needlessly avoided. Several studies have shown that 5%–10% of hospitalized patients carry an antibiotic allergy label.^{2–4}

Suboptimal antibiotic utilization leads to increased incidence of adverse events and antibiotic resistance.^{5–7} A study has shown an increased incidence of MRSA and *Clostridioides difficile* in patients with a penicillin allergy label, mediated by the increased prescription of alternatives to β -lactam antibiotics.⁸ Recent literature shows that the prescription of these non- β -lactam antibiotics is often not necessary.⁵ Clinical resistance to the use of cephalosporins in patients with penicillin allergy is still present. There indeed is an increased risk (approximately 2% to 5% of the patients with a true penicillin allergy will react to cephalosporins), but the most likely risk is a benign cutaneous reaction. Clinically severe adverse reactions to cephalosporins are not seen in most

patients with an unconfirmed penicillin allergy (e.g. the risk of anaphylaxis is less than 1%). It is questioned whether the risk of a penicillin allergy outweighs the disadvantages of prescribing suboptimal antibiotic therapy.⁹

These insights were the basis for the development of a new antibiotic allergy protocol. The protocol contains information about how to define allergic symptoms (criteria for immediate versus non-immediate reaction), and indication of a possible, probable or proven allergy, based upon signs and symptoms together with an estimation of severity. When one symptom of IgE-mediated reaction was present, a reaction is classified as possible. The reaction is classified as probable when multiple symptoms are present. Doctor observed or after testing is classified as a proven reaction. Severity is classified as mild (immediate type only urticarial reaction, non-immediate type mild exanthema, erythema, possible fixed drug reaction) or severe (every allergic complaint apart from mild). Based on the final estimation of allergic symptoms an (alternative) treatment option is proposed. The protocol includes a chart showing possible cross-reactivity within β -lactam antibiotics and a flow chart to facilitate treatment choices in suspected β -lactam allergy. The protocol does not include information about taking an allergy history. It does contain guidelines for documenting the allergy in the patient's electronic history. The protocol was developed as part of a set of improvements, aiming at ameliorating the correct identification of allergic patients in the electronic hospital files, and improving medication guidance by linking the allergy information to the electronic prescription system. The protocol was developed through literature review and consensus meetings in 2018, using input from plenary discussions with medical professionals from the departments of Pharmacy, Internal Medicine, and Medical Microbiology. In May 2019, the protocol was formally implemented in the Dutch hospital where it was developed. The protocol was made available for all staff using the hospital-wide guidelines system (the Online Document and Information Navigation system, ODIN), it was announced by a general e-mail to all medical professionals and by targeted e-mails with instructions to the hierarchical relevant leaders of the different medical specialties.

After this, we decided to study the implementation process. In this article, we present the results of a qualitative study of the implementation of the new antibiotic allergy protocol (AB-allergy protocol) in a Dutch hospital.

Methods

Methodology, setting and selection of participants

We chose to study the implementation of the AB-allergy protocol in three medical wards where physicians often prescribed antibiotics for patients with an allergy registration: the Departments of Internal Medicine, Pulmonary Care, and Surgery. In total, we conducted 13 semi-structured interviews with different medical professionals who were engaged in prescription decisions. Besides that, we presented the outcomes of the interviews to groups of medical professionals of the Departments of Internal Medicine and Pulmonary Care to further explore the findings and to check if the individual interviews were interpreted correctly. These focus group interviews were recorded and analysed.

The professionals were invited to participate in the study by e-mail or by phone call, sometimes through snowballing. The interviews took place in the hospital and the duration varied from 30 to 60 min, depending on the

availability of participants. The interviews were conducted approximately 1 month after the formal implementation of the protocol. In the Department of Internal Medicine, three specialists, two doctors in training and one nurse specialist were individually interviewed. The focus group conducted in this department was attended by approximately 30 medical professionals (specialists, doctors in training, and medical interns) of which 16 actively contributed to the discussion. In the Department of Pulmonary Care, three specialists and two doctors in training participated in an individual interview. The focus group in this department was attended by five medical professionals (specialists and doctors in training), whom all contributed. In the Department of Surgery, two specialists were interviewed individually. No focus group was conducted in this department: the low response rate was due to the surgeons' limited availability. All interviews and focus groups were audio-recorded and additional notes were taken.

For the individual interviews, an interview guide was developed. The main themes were familiarity with the protocol, the current dissemination of the protocol, the relevance of the protocol, a case description of a patient with an antibiotic allergy and application of the protocol for this case, trust in the protocol, professional autonomy and the protocol, leadership and hospital management of protocols. Data were analysed using the qualitative data analysis supporting software ATLAS.ti.8.4. and were discussed with the team of researchers in three rounds. In the focus groups, the first author presented six statements, representing the main findings of the interviews, and discussed these statements with the medical professionals. Based on this discussion, some findings were fine-tuned. If necessary, additional information concerning the protocol was shared during the focus meetings.

Ethics

The current study was conducted in keeping with the Faculty's standards for non-WMO research. The registration number is FHML/GH_2019.089. Participants were only included in the research when they had signed an informed consent form.

Results

Too many e-mails/protocols

When asking about the new AB-allergy protocol, few participants recalled that they had received an e-mail about it. The excessive number of e-mails that the medical professionals receive was mentioned as an explanation for this neglect.

'I receive many e-mails about new protocols, this creates a barrier [...] It's too much.'

(Specialist 1, internal medicine)

Furthermore, the electronic document ODIN system, which contains all protocols of the hospital, also hindered the effective dissemination. Participants mentioned that they had searched for the protocol, to prepare themselves for the interview, but some participants had trouble finding the protocol.

'There are many protocols, which is fine, but the annoying thing is to find them. Because ODIN and its search engine is a disaster.'

(Doctor in training 2, internal medicine)

The combination of an overload of e-mails and protocols and the poor search engine creates an effective barrier for doctors to become familiar with the protocol.

'There are already more than 5000 protocols in that thing, in ODIN. Try to get the one protocol you need. Even to find a simple protocol like prophylaxis for thrombosis, you get 40 hits that are not of any use. [...] The only thing I want with protocols is that when I type in 'antibiotic allergy' that this protocol will pop up. And that I will not get 50 others of which I think: that is not the one, and this is also not the one. . . Because then we will lose interest and will call the infectious disease specialist anyway.'

(Specialist 1, surgery)

Participants stated that they would rather use the so-called 'SWAB guidelines' for choosing the antibiotics for allergic patients. These (currently outdated) national guidelines for antibiotic treatment provide an overview of the advised antibiotics that can be given for a specific infection, including advice for alternative antibiotics in case the patient is allergic. Besides the fact that the SWAB guidelines are well known, and all participants know where to find SWAB. SWAB is also considered very convenient to use.

'SWAB is very easy and quick to use. For example, if I look for pneumonia, CAP, select the causative agent, I click on it and I get the first, second, and third choice. So, it just works very efficiently.'

(Specialist 8, pulmonary illnesses)

'If you can choose between going through one protocol or going through two protocols, you will choose to go through one protocol. And if this (SWAB) provides you with an alternative for a patient with a severe reaction, then that is the first step. If you cannot figure this out, then you will consult the AB-allergy protocol.'

(Specialist 3, internal medicine)

Additionally, some participants mentioned that they use protocols specifically (e.g. dealing with neutropenic fever) that are made for their department.

Trust in the protocol, distrust in patient stories

The individual interviews and focus groups revealed that the participants have considerable trust in the protocol itself. The participants based this trust on the idea that a protocol resulted from a structured and strict procedure. The protocol also gained credibility by the fact that the authors of the protocol are experts in the field of antibiotics and allergies.

Participant: *'For the sake of convenience, I will assume that the people who have written a protocol like this have more knowledge about it than I do. [...]'*

First author: *'So, there is trust in the protocol?'*

Participant: *'Yes, in the procedure and often in the people who are involved.'*

(Specialist 2, pulmonary illnesses)

The protocol provides a guideline on the safe prescription of antibiotics, based on the allergy history. Participants reported that they distrust the information provided by the patients, as patients often

do not recall their exact symptoms. Moreover, patients often confuse symptoms of an antibiotic allergy with side effects.

'It is not the case that I do not trust the protocol, but sometimes I do not trust the patient.'

(Specialist 5, internal medicine)

'The registration is often based on a patient's story who does not know the exact circumstances. So, then you have a registration of which you question what the meaning of that registration is.'

(Specialist 15, internal medicine)

Participants were skeptical about the allergy registration in the patient file, as it was felt that the label was based upon unreliable patient stories. Moreover, the formal allergy registration is often vague, wrong or even lacking. Additionally, the control mechanisms in the registration system, previously installed to improve the safety of real allergic patients, creates a barrier to follow the protocol.

'I worked with [name author of the protocol] so I think I perform a proper anamnesis. But when you choose to disobey the registration, you will get six phone calls from people who ask if you are sure because it is recorded that the patient has an allergy. Then I think 'never mind'. I will just do it the regular way, so it saves me all the phone calls.'

(Specialist 18, internal medicine)

The present is more important than the future

Some participants mentioned that they do not want to adhere to the protocol in perceived risky situations and choose the 'safe alternative'.

'I noticed in the flow chart that you can give the antibiotic when a patient has relatively mild allergy symptoms, but I think that I am still being cautious and often choose a safer alternative. [...] I am supportive of adhering to protocols as well as possible. However, it is difficult that you did not see the allergic reaction on the patient yourself, so you have to work with the information that the patient provides you.'

(Specialist 1, pulmonary illnesses)

The participants fear a perceived allergy-related risk for the patients (short-term), without considering the risk of suboptimal therapy (more complications) or the development of antibiotic resistance (long-term). However, most participants did mention antibiotic resistance as the reason why the new protocol has been created. So, they are indeed aware of antibiotic resistance, but in daily practice, they choose to handle the acute situation defensively, instead of preventing relevant future problems. This finding has been discussed in the focus groups. Professionals of the pulmonary illnesses department recognized that they choose the short-term over the long-term. They explained that it feels logical to them because when being confronted with a sick patient, you do not want to take any 'risks'. They also explained that they never are confronted with long-term effects on antimicrobial resistance, and therefore long-term effects are not taken into much consideration.

‘We have a sick patient in front of us, do you want to take the risk that this patient is going to get more complaints?’

(Doctor in training 2, pulmonary illnesses)

When being confronted with a hypothetical antibiotic-resistance case, this doctor responds as followed:

‘We will not observe that anymore. So, it will not affect our approach.’

(Doctor in training 2, pulmonary illnesses)

An interesting finding is that the participants consider later discussions about medical care as valuable moments when their antibiotic prescriptions can be revised. So, the doctor does not feel the full responsibility to examine the best antibiotic option in the acute situation, because it can be revised at a later stage.

Discussion

Several studies have shown that 5%–10% of hospitalized patients carry an antibiotic allergy label.^{2–4} A point prevalence measurement in the researched hospital at the surgical and medical wards showed that even 20% of patients carried an antibiotic allergy label. Here, we present our data of a pilot study of the implementation of a new antibiotic allergy protocol, demonstrating that, even in an academic hospital setting, it is not easy to improve prescribing of antimicrobials. Furthermore, literature shows that implementation of new guidelines or protocols in medical care is a complex process. Well-established patterns and routines are difficult to change.¹⁰ Obstacles and hurdles that are mentioned in literature about improving patient care are for instance no familiarity, no sense of urgency, doubts about feasibility or success, lack of time and resources to learn new routines, lack of leadership and management.¹¹

In our study, we found that familiarity with the protocol could be improved. Our study took place only shortly after formal dissemination of the protocol. Dissemination of new protocols via the regular route in the hospital—publication in the hospital database and e-mailing announcements about this—did not increase familiarity with the protocol, as staff were overloaded by e-mails. To overcome this, the authors of the protocol made a quiz with protocol-related questions. They asked doctors and nurses to participate. The participants received a pocket-sized flow chart, summarizing the main findings of the protocol. This quiz was also accessible via e-learning. Furthermore, SWAB guidelines are currently being updated, which will improve concordance of the medical information in several guidelines. This will probably improve adherence to the local AB-allergy protocol.

Interestingly, if people did find the protocol, they found it valuable and they trusted the expertise that is embodied in it. Still, use in practice was hampered for two reasons. First, physicians felt uncertain about the severity of possible allergic reactions in practice. This finding is confirmed by a study on the adherence to guidelines for antibiotic use for community-acquired pneumonia in Dutch hospitals, which shows that physicians were afraid to prescribe narrow-spectrum therapy due to perceived risks associated with this therapy.¹² As further training of medical professionals may help to overcome this hurdle, a free e-learning module was developed and made available for medical and pharmacological

professionals nationally. Also, a specially trained nurse practitioner dedicated to antimicrobial stewardship will dedicate time to teach about rational antibiotic use and possible allergic reactions.

Second, interviewees doubted the allergy information provided by patients and the documentation of allergies in electronic patient files. As patients do not learn to systematically report relevant symptoms, doctors doubt the quality of patient stories about allergic reactions. Moreover, allergy labels are rather inappropriately generated in general practices and local pharmacies. A recent article indicates that allergy labels do not always adequately represent actual allergic reactions.¹³ As hospital prescription systems are increasingly electronically synchronized with first-line pharmacies, incorrect allergy labels can easily pollute the hospital environment, making correct allergy labelling a complicated affair. Here, an intensive collaboration between hospitals and first-line professionals will be essential.

To conclude, our study gave important clues to improve the dissemination and awareness of the protocol. We tried to improve teaching about allergic reactions with live discussions and e-learning, but the biggest challenge still lies in changing the organizational culture of hospitals: how to communicate effectively in a situation of information overload, how to value prevention in a context of acute care, how to teach patients to adequately communicate their allergic experiences, and how to collaborate with other medical institutions about allergy registration.

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Transparency declarations

None to declare.

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