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# **Assessment of the Validity of Patient-Stated Allergies: De-Labeling and Education**

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## **Introduction**

The initial direction of the project was to implement a research based protocol to identify and de-labeling patients with a patient-stated penicillin allergy who were not truly allergic. After the protocol was researched and developed, the project was abruptly halted due to the lack of data to support the justifiable need in this population, lack of sufficient communication among all the stakeholders, questions regarding the financial cost of implementing, and strong concerns regarding the educational needs of nursing staff and interviewing patients, assessing for allergies, and documenting results. Thus, after developing the initial project protocol, the project team was redirected to provide allergy assessment education to the nursing staff so that they may provide reliable and accurate documentation of risks for allergies. Phase I of this project describes the initial project development that took place in the initial plan. Phase II of this project describes the resulting nurse education process that was ultimately implemented and evaluated.

## **Introduction of the Problem: Phase I**

Penicillin allergies are the most commonly reported drug allergy among patients (Nasr, et al., 2014). It is estimated that eight percent of the population carries a self-reported history of a penicillin allergy (Macy, 2015). Of which, according to Blumenthal, et al. (2014), only 1% of patients are found to be allergic. These mislabeled patients continue to receive broad-spectrum antibiotic treatment, increasing the risk of adverse outcomes, when 1<sup>st</sup> line antibiotics, such as beta lactams, could have been administered. This practice also results in increased healthcare costs and increased antibiotic resistance. Penicillin de-labeling protocols are becoming prominent components to Antibiotic Stewardship Programs (Bourke, Pavlos, James & Phillips, 2015). Through specialized education in the area of IgE mediated reactions specifically, health care providers without a specialization in allergies, are able to evaluate patient-stated allergies to determine if a reaction might be due to an immune response, pharmacological adverse effect, or other non-related factors.

## **Introduction of the Problem: Phase II**

Through focused group meetings of stakeholders, hospital physicians identified lack of thorough documentation of assessments of patient allergies by nursing staff as an issue leading to increased use of broad-spectrum antibiotics. If physicians had more information about the reaction, clinical judgment could be used as to whether or not a medication could be trialed despite patient-stated allergy. Therefore, the project was refocused away from de-labeling protocol development to the development of an evidenced-based educational module for staff nurses within the hospital on how to properly assess and document patient-stated allergies.

## **Literature Review**

The steps to the successful de-labeling include an in-depth patient interview and allergen skin-testing, which includes a skin prick test and an intradermal skin test followed by an oral challenge for those who qualify. Accurate and thorough interviews are imperative to help determine eligibility for skin testing. Nasr, et al. (2014) outlined questions to be included in a patient allergy assessment. They include asking when reactions occurred, what medication was

taken, why medication was taken, how the patient reacted, how soon after taking the medication the reaction occurred, what other medications were taken at the time, and what happened after the medication was stopped. Skin testing has a high sensitivity in the detection of penicillin allergies and has been well validated through numerous studies (Mawhirt, Fonacier, Calixte, Davis-Lorton & Aquino, 2017).

Several learning theories have been developed to describe how humans learn. Andragogy is a learner-focused mode of teaching introduced by Malcolm Knowles. His theory assumes that adult learners have more life experiences and tend to focus more on the reason for new learning than content (Curran, 2014). Since the target group of the education was adult nurses, the theory of andragogy helped guide the development of the educational intervention. Curran (2014) noted the key principles of andragogy, which include: Learners need to know why they need to learn something; the teacher is a facilitator and learning is collaborative; experience is relevant to learning; learners become ready to learn when curriculum is meaningful; learning is active and generally interactive; and, learners are self-directed and motivated by both intrinsic and extrinsic motivators.

Autonomy and self-direction are key concepts in adult education seen repeated across current literature (Curran, 2014). The ability of nurse educators to combine theory and practice into an educational intervention that reaches a variety of learners is critical in the dissemination of knowledge and practice changes. Educational interventions should be supported with a variety of strategies to ensure application and continued change in practice (Haggman-Laitila, Mattila & Melender, 2016).

This information was used to guide the development of the education for the staff nurses. Education was presented to staff in an informal interactive presentation, followed by a question and answer session. Keeping in mind that adult learners need to know why they need to learn something, background information was presented. The importance of the education and how their actions directly impact patient care outcomes was also included. Lastly, staff nurses were provided a “tip sheet” outlining the highlights of the presentation.

## **Project Methods**

The initial goal of this project was to develop an evidence-based protocol for a 154-bed independent community hospital in rural southern Illinois, to safely and successfully identify and de-label patients who did not have true penicillin allergies (Phase I). After reviewing available data on safely de-labeling patients, and speaking with the Director of Pharmacy, a protocol was developed that was tailored to fit the needs of the community hospital. It was then presented to the Antibiotic Stewardship team at the community hospital, which was comprised of an Emergency Department Physician, Surgical Physician, Inpatient Medical Physician, Director of Information Technology Services, Director of Pharmacy, Director of Nursing, Director of Infection Control, and Nursing Managers. The Antibiotic Stewardship team met on a monthly basis to discuss status of interventions being implemented and plans to move forward.

After a meeting with all stakeholders prior to implementation, the direction of this project was abruptly changed. The de-labeling protocol that was developed for the community hospital was printed in packet form, handed out to members of the team, and highlights of the protocol were discussed. The Director of Pharmacy presented data that were collected on use of broad-spectrum antibiotics in the hospital, as well as rates of patient-stated penicillin allergies. During this meeting it was determined by the physician team members that the data presented by the pharmacist did not support the need for implementation of such a protocol. The data indicated

that the use of broad-spectrum antibiotics was not as frequent as the pharmacist had predicted. There were also new disease-specific treatment order sets that were developed as part of the Antibiotic Stewardship Program within the hospital, which did not utilize beta-lactam antibiotics, thus physicians did not see the need for a penicillin allergy de-labeling protocol.

Physicians expressed concerns that the nursing staff was not skilled in interviewing patients and documenting information about patient-stated allergic reactions. This statement was validated by a chart audit performed by information technology (IT). Data were pulled over a one-month period: 147 patients had a patient stated allergy to penicillin and only 55 of those patients had a documented reaction charted. Those that had a reaction charted, had only a single word reaction (rash, itchy, nausea, diarrhea) with no additional information about the reaction. Physicians argued that providers would be able to better assess whether or not a patient-stated allergy was a true allergy, or if benefit outweighed risk, if a more thorough allergy history was taken by nurses and documented in the patient's electronic medical record (EMR). This also required a change to be made to the EMR to require nurses to document an allergy with a reaction and allow a free text box for additional information obtained from the patient about the reaction to be documented. The new goal of the project was to develop an evidenced-based educational module for staff nurses within the hospital on how to properly assess and document patient-stated allergies (Phase II). The educational module focused on preparing the nursing staff to become full participants in the process of assessing patients' allergies.

The educational intervention was developed from recent literature and adapted to engage adult learners for all staff nurses in the hospital. The educational intervention was initially delivered via PowerPoint presentation and a "tip sheet" at a scheduled skills day for ICU nurses. The PowerPoint presentation was modified after receiving staff input following the initial presentation. A recorded voice-over PowerPoint presentation and a PDF version of the "tip sheet" were provided to the nursing education department for future dissemination to nursing staff. Outcomes that were measured included: overall understanding of proposed changes to patient allergy documentation, knowledge of importance of thorough documentation for improved patient care, appropriateness of the educational format, and overall clarity of the education provided. These were measured through completion of evaluation surveys by staff nurses in attendance, following the pilot educational presentation.

## **Evaluation**

There were many barriers that prevented implementation of the project in its original form (Phase I). The pharmacist did not collect background data to justify that this project should be implemented. Prior to the development of the de-labeling protocol, supporting data could have been requested and reviewed, which would have revealed that the protocol may not have been necessary and could have helped to identify the root of the problem earlier. Buy-in from the necessary stakeholders was also not obtained prior to protocol development. The physicians did not know what the protocol entailed until it was presented to them during the meeting. If the physicians were included in the initial planning stages of the project, they might have been able to offer insight into the root of the problem, which in this case, was provided after the research was gathered and protocol was developed. Attempts could have been made to obtain stakeholder buy-in prior to development of the de-labeling protocol. Lastly, meetings of stakeholders were only conducted at monthly intervals, which slowed processes down with regard to decision-making and planning. These monthly meetings were the only times the team communicated, shared ideas, and planned for interventions. If meetings were scheduled more frequently, or if

more thorough communication had occurred on the front-end about the de-labeling and skin testing protocol, perhaps a lot of time could have been saved. The SIUE student team made many attempts to contact the Chief Nursing Officer to help move the project forward. These attempts resulted in being directed back to the Director of Pharmacy and Nursing Coordinator who were leading the Antibiotic Stewardship Program.

Since the ultimate realization was that nursing staff was not thoroughly documenting allergy history, the decision was made to first educate staff on the importance of allergy history documentation (Phase II). This education included physiology of allergies, types of allergic reactions, identification of true drug allergies, and anaphylaxis. Ways in which patient allergies and allergy assessment should be correctly documented in the newly updated EMR were also included. A “tip sheet” with some of the highlights from the presentation was provided to the staff following completion of education module.

Time constraints limited the opportunities available for implementation. The hospital implemented the update to the EMR quickly after identification of the problem and wanted to use the educational module to reinforce the importance of this practice change, and teach staff how to correctly document allergies in the new record. Barriers have been identified for continued use of the practice change, which include the time it takes for nurses to complete a thorough allergy history assessment and then accurately document the assessment. Steps to address the additional time necessary for completion of a thorough allergy history assessment was out of the scope of this project, but would be an area of consideration for the hospital with regard to nurse-patient ratios.

Implementation was completed as part of a planned skills day for the Intensive Care Unit staff in the form of a ten-minute presentation, five-minute question and answer session, and five minutes for survey completion to evaluate the education presented. Of the planned fifteen nurses to be present for the pilot educational presentation; eight nurses were in attendance. Although the group that received the pilot education presentation was much smaller than anticipated, the overall results were positive. The nursing staff that were present asked questions following the presentation, which then sparked more in-depth discussion of allergies.

Survey questions were developed to identify areas of improvement, assess overall understanding, and identify plans to change practice. Time allotted for presentation, discussion, and evaluation survey completion was a limiting factor when developing survey questions. Take-home surveys were considered which would have allowed more time for staff members to provide richer information, however this option presented additional barriers such as lost surveys and delayed feedback. Surveys that staff submitted after the education were reviewed and summarized to determine if there were any changes that needed to be made before the education was handed off to the hospital for continued use.

The results of the survey indicated that many of the nurses thought they had a good understanding of patient allergy documentation and its importance prior to the educational experience. However, following the educational presentation, they recognized the gap in their knowledge, and the importance of thorough allergy assessment and documentation. All staff indicated the education presented prepared them to be able to conduct a thorough allergy history assessment and will influence how they carry out allergy assessment in the future. The nursing staff in attendance agreed that the education format was appropriate, clear, and well understood.

### **Impact on Practice**

The education module was placed into a PowerPoint presentation with voice-over recording of the presentation at the request of the hospital. The PowerPoint presentation and the “tip sheet” were to be placed on the online learning system for all patient care staff in the hospital to complete. Nurses will benefit from the education through increased awareness of importance of thorough allergy assessment and documentation and how to complete an allergy assessment. This project will also provide a more complete picture of individual patients allergies to prescribers, allowing them to make more informed decisions on antibiotic prescribing.

### **Conclusions**

The lack of success of Phase I of this project was due to the neglect of basic steps in project development. These included a failure to establish actual need, failure to involve all stakeholders in the assessment of the problem, and failure to include stakeholders in the development of the plan. The financial costs of implementation were not considered and effective communication was lacking. The take-home message of the lack of success of the initial project was that projects involving many individuals require participation of all of the stakeholders from the beginning, and cannot be accomplished in isolation.

The overall goal of this project was to implement a practice change. The initial goal was to develop an evidence-based protocol that would safely and successfully identify and de-label patients who did not have a true penicillin allergy. This was not accomplished due to lack of communication among stakeholders, cost considerations, and lack of supporting data. A new root problem was identified and a new goal was developed. The new goal was to develop and implement an evidenced-based educational module for staff nurses within the hospital on how to properly assess and document patient-stated allergies. A revised allergy assessment section was also added to the EMR. The educational module was ultimately provided to the nursing education department of the hospital for continued use as part of required education for all staff responsible for patient care.

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