Original Publication

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Rash in Breast-Feeding Mother: Standardized Patient Case for Clerkship Students

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Abstract

Introduction: Adverse drug reactions are a leading cause of morbidity and mortality. The full impact of these reactions is often not recognized by health care providers, which can lead to a cascade of additional medications prescribed to treat adverse effects caused by the inciting medication. **Methods:** In this exercise, clerkship students are presented with a standardized patient portraying a medical problem. The students must identify the underlying cause of the problem, drawing on their knowledge of pharmacology, clinical therapeutics, special populations, and pharmacogenetics, to uncover and correct the deeper medical concerns, and compose a SOAP note. Thirty-five minutes were allotted for each student for this case. **Results:** To date, this scenario has been used with all 23 third-year medical students at our regional campus. We found that most students tended to prematurely close the case after identifying the one obvious primary problem, leaving other issues unresolved. **Discussion:** Utilizing this case with third-year medical students highlighted the need for continued reinforcement and application of pharmacologic principles throughout the clinical years of training. Furthermore, given that recent medical graduates often feel unprepared to prescribe safely and effectively, this case may also have utility as a teaching and discussion tool among medical residents. Additionally, it can be used in interprofessional educational activities with learners from pharmacy or nursing programs who will be involved in dispensing or administering medications to patients.

Keywords

Medication Errors, Newborn, Breast Feeding, Adverse Drug Reaction, Rash, Pharmacology, Medication Safety, Personalized Medicine, Special Populations, Pharmacogenetics

Educational Objectives

By the end of this standardized patient case, students will be able to:

1. Recognize a medication-related allergy.
2. Propose/communicate an appropriate alternative.
3. Organize prior pharmacology knowledge with clinical concepts to identify medication-related concerns in a breast-feeding mother.
4. Identify pharmacogenetic concerns.
5. Develop a plan to address/communicate personalized medicine needs.

Introduction

Medication errors are described by the National Coordinating Council for Medication Error Reporting and Prevention as “any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in control of the health care professional, patient, or consumer.”¹ This term applies to multiple steps in the medication selection, prescribing, communication, education, monitoring, and medication-use process. When medication errors are prevented, the incidence of adverse drug reactions (ADRs) decreases and outcomes improve. Yet even in the absence of overt medication errors, ADRs continue to be a serious health issue. ADRs have been defined as noxious and unintended responses to a drug and are estimated to be the reason that 4.3 million Americans seek medical care

Citation: Karpa K, Stollar K. Rash in breast-feeding mother: standardized patient case for clerkship students. *MedEdPORTAL*. 2016;12:10453. https://doi.org/10.15766/mep_2374-8265.10453

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All appendices are peer reviewed as integral parts of the Original Publication.

annually.² In actuality, the true incidence of ADRs is probably underrecognized, and these situations are often misdiagnosed.³

When attempting to determine the primary reason for medical errors or adverse drug events, eyes turn to the medical team to evaluate proper and safe prescribing. In the United States, medical school curricula incorporate pharmacology education primarily during the first 2 years of medical school, but there is no standardized exam that focuses specifically on medical student prescribing skills. When medical students leave the classroom and begin residency, prescribing is the task they are expected to perform most often; however, data show that prescribing medication safely is the task that they feel least confident completing.⁴

On the other hand, in the United Kingdom, medical students are formally assessed to ensure they are adequately prepared to begin prescribing. Designed by the British Pharmacological Society and the Medical Schools Council, the Prescribing Safety Assessment is a UK-wide skills assessment that ensures key safety prescribing competencies of fourth-year medical students are met. The exam has eight sections covering prescribing, prescription review, planning management, providing information, calculation skills, ADRs, drug monitoring, and data interpretation.⁵

Similarly, based upon nearly 2 decades as a pharmacology educator, one of us, Kelly Karpa, believes that more opportunities for students to practice thinking about and applying pharmacology-related material following the basic science years of training (but before beginning residency) are warranted.

This simulation is one of four scenarios piloted to assess medication-related skills and clinical reasoning among all third-year medical students at our regional medical school campus. However, any health professions students (especially medical, physician's assistants, nursing, or pharmacy) with prior pharmacology knowledge would be appropriate candidates to complete this case. It is a low-stakes, formative assessment designed to evaluate a student's ability to identify adverse drug events and develop an appropriate plan.

Although students were expected to complete a proper physical exam on the standardized patient (SP), this was not formally evaluated because we only had the ability to record the audio from the encounter, not the video.

After taking the patient's history, students were expected to develop an appropriate plan. To accomplish this successfully demanded that students move beyond the obvious and consider two additional aspects from the patient's history requiring clinical reasoning: that the patient represented a special population and that there were pharmacogenetic implications in this scenario.

Special population groups are defined as individuals with unique sets of needs. There are a multitude of ways that special populations may be categorized. These specialized groups fall outside the description of an average patient and often present a challenge to medical personnel due to a heightened need for individualized treatment plans. The SP in this assessment forces students to consider special needs of breast-feeding women.

In addition, this case also necessitates synthesis of information and clinical reasoning to consider pharmacogenetic implications and the need for personalized medicine. According to the Food and Drug Administration, personalized medicine is an "innovative approach to disease prevention and treatment that takes into account differences in people's genes, environments and lifestyles."⁶ The field of personalized medicine recognizes that each patient is diverse and unique; as a result, medications affect individuals differently. Variants of genes involved with both drug activation and metabolism are known to lead to adverse events when appropriate precautions, including avoiding some medications entirely or adjusting dosages of others, are not undertaken.

In the literature, an existing case by Rajasekaran, Hall, and Alfonso highlights the significance of proper prescription writing to decrease adverse effects.⁷ However, that case presents a simplified situation in which learners must simply write a prescription without application of clinical reasoning skills. Other cases in which clinical reasoning skills must be applied to solve complex medication-related situations, including

scenarios in which medication reconciliation/optimization is necessary, have been reported by Dr. Karpa and colleagues.⁸⁻¹⁰ Similarly, the SP case described herein challenges learners to consider a multitude of factors related to medication safety. While there are some existing simulation cases that address considerations for pregnant women, none appear to contain considerations for breast-feeding women in regard to prescribed medications. Moreover, simulation cases involving pharmacogenomics are sparse to nonexistent. Pharmacogenomics and personalized medicine are concepts that are quickly gaining traction in the real world as more medications require dosage adjustments or even complete avoidance among certain populations. Therefore, medical students should be exposed to the concept of pharmacogenomics before experiential rotations and should have opportunities to apply their knowledge to scenarios reminiscent of authentic patient care.

As a whole, this SP case addresses medication safety from a variety of perspectives. An argument can be made that the initial drug choice represented a medication error (it is not the most appropriate choice for the patient), thus leading to an ADR. Furthermore, the case forces students to evaluate medication appropriateness in a holistic way that takes into account not only the woman but also her child who is being breast-fed. As such, the case necessitates that students look beyond the obvious and challenges them to avoid premature closure when developing a plan to address all of the medication concerns. As a pharmacist, Dr. Karpa observes, identifies, and corrects medication-related problems on a regular basis. This case is based upon three different women who have experienced every single aspect represented within this scenario. Furthermore, Dr. Karpa works with medical students on a regular basis and is acutely aware of gaps between knowledge and application. Thus, her personal experiences have informed development of this resource.

Methods

The case was developed by Dr. Karpa, who is a pharmacist and pharmacologist. When developing this case, consideration was given to creating a scenario that would encompass several different aspects of medication safety. Aspects include identifying a patient problem as being medication-related, identifying an appropriate medication alternative, avoiding premature closure, and considering pharmacogenetic implications. This case was designed as an internal assessment of pharmacologic knowledge and application of third-year medical students.

Per instructions, Appendix A describes logistical information. Appendix B includes materials for the SP, including the case template. Appendix C describes recruitment materials. Appendix D references behavioral measures and describes the blueprint and timekeeper materials.

Student instructions for part 1 and part 2 of the case are included (Appendix E). The instructions for part 1 provide students with a general overview of the patient they are about to encounter, including vital signs for the SP. Students are asked to gather necessary information from the SP, assess and diagnose the SP's problem, and then effectively communicate a plan to the SP before leaving the room. Students are given 15 minutes to accomplish this.

The instructions for part 2 inform students they will be writing a note using the SOAP (subjective, objective, assessment, plan) format. They are asked to list positive and negative findings from the history and physical used in developing their differential diagnosis. They are also asked to describe the most plausible diagnosis and their plan for the SP. Again, students have 15 minutes to write their note and submit it electronically.

SP training and instruction materials (Appendix F) for the case are included. The training material should be provided to the SPs 2 weeks in advance so that they can review the material prior to formalized training with a faculty member. Included within this document is an SP checklist for student assessment, which can be used by the SP to indicate what the students have asked about, what the students have recommended, and what skills the students have performed. The SP checklist also details the pharmacologic concepts that individual items address. The SP is asked to complete the checklist immediately after each student exits the room (the SP completes the checklist while students write their SOAP notes).

After SOAP note completion, students reenter the SP room for 3 additional minutes. These 3 minutes are dedicated time for the SP to provide feedback to the student. During feedback interaction, the SP is asked to share information with the student regarding generalized strengths and weaknesses of the interaction, rather than the specifics of the checklist. For example, the SP is instructed to first ask, “How do you think that went?” Subsequently, the SP provides her general thoughts to the students about the encounter, such as the following:

- “You were very confident about X, but you should also think about Y.”
- “You were so focused on me that you failed to consider the implications for my baby even when repeatedly asked.”
- “You seemed really unsure of yourself” or “You seemed really confident about X, but you should probably go look that up.”

The SP is instructed to follow up with the question, “What would you do differently next time?”

Additional materials include a faculty SOAP rubric (Appendix G) that contains specific guidance for grading the students’ SOAP notes, a sample newspaper ad (Appendix H) and flyer (Appendix I) that were used to advertise/recruit SPs, and a sample student schedule blueprint (Appendix J) outlining how students flowed through this (and three additional) stations. This scenario is represented in the blueprint as Case 1 and SOAP 1, although Cases 1, 2, and 3 were on the same time schedule.

Additionally, a sample of the verbal instructions offered during the morning session by the timekeeper is provided to keep students on schedule (Appendix K).

Logistics

The SP cases were conducted in a simulation center over 2 days with all 23 third-year medical students at our regional campus. The rooms to which students were assigned did not have video capability, but the audio was recorded for each student-SP encounter. One timekeeper was assigned to ensure that encounters were kept on time. With 15 minutes dedicated to part 1 of the case (SP-student encounter), 1 minute allotted for walking to the computer for SOAP note writing, 15 additional minutes to write the SOAP note, 3 minutes for the SP to provide feedback, and 1 minute to rotate to the next station (we had four different medication-related cases happening at the same time), 35 minutes total were allotted for each student for this case. Appendix J identifies the minute-by-minute actions of the student.

Preparation and SP Training

Two individuals were trained as SPs for this case. One was trained as the primary SP; the other was trained as a backup in case the primary had a conflict or illness on event dates. The primary was the only SP used for all 23 students who participated in the scenario. This SP had recently given birth and was lactating. Her body habitus (enlarged breasts, stretched/distended belly/skin, fundus height above the brim) greatly enhanced the authenticity of the role that she was portraying, but this is not a necessity. In fact, the backup SP we had recruited for the role was a young woman in her early 20s who had never had children. If a perinatal SP had not been available, we would simply have added a description of a postpregnancy body habitus to the case information that students received and coached the SP about postpartum women potentially being emotional, usually tired, and very worried about their baby.

Two weeks in advance of training, SPs were sent the case and checklist for review. During training, a faculty member read the case aloud with the SPs, communicated the rationale behind specific case components, and answered questions that the SPs raised. In addition, the SPs and the faculty member also engaged in role-playing. The SP who was not role-playing was able to observe and critique. During training, SPs completed the checklist, which was reviewed and discussed among the SP trainees and faculty member for accuracy. If there were any checklist items that did not appear clear, these were reviewed and corrected at the time of the role-play. Since the trainer was also the creator of the case, changes were made to the case when the SPs had appropriate ideas to incorporate. At this time, the SPs were also given instructions for providing feedback to students. Specifically, SPs were instructed to give feedback describing how they felt they had been treated as a patient during the encounter. During

training, ways that SPs felt they or family members had been treated by various health care professionals in past authentic health care encounters were discussed (e.g., “I feel like my doctor listens to me when. . . ,” “I felt disrespected when. . . ,” etc.) to provide context. SPs were encouraged to use the sandwich method (e.g., tell something that went well, then something that could be improved, followed by reinforcing what went well) when providing feedback to students.

A single faculty member listened to all audio recordings of each scenario. Some discrepancies between the SP’s recall and the audio were noted. Specifically, sometimes the SP volunteered information relevant to the case without waiting for students to make a specific inquiry. Yet in these instances, the SP identified on the checklist that the student had completed the task. Thus, the audio was used as the definitive record as to whether the student (as opposed to the SP) had done the task or made the inquiry.

Results

To date, this scenario has been used with all 23 third-year medical students at our regional campus. [Table 1](#) lists data gathered from the SP-student interactions. [Table 2](#) includes data gathered from written student SOAP notes.

Table 1. Summary From Standardized Patient Checklist

Item Assessed	N (%)
Family/social history and history of present illness	109 (55%)
Medication history	62 (55%)
Nonmedication communications with patient	55 (34%)
Medication communications with patient	6 (9%)
Pharmacogenomics factor	4 (17%)

Table 2. Summary From Student SOAP Notes

Item Assessed	N (%)
Subjective	70.0 (63.6%)
Objective	21.0 (31.8%)
Assessment	37.0 (42.0%)
Plan	15.5 (17.6%)

Students were found to be most successful at completing patient histories. Students excelled at addressing the current prescription medications the patient was taking. However, no students asked the SP about over-the-counter medications used. Few students inquired about dietary/herbal medications.

Students often failed to consider the safety of medications during breast-feeding until the SP expressed tremendous concerns about it. Students also inadequately advised the SP when rash resolution should be expected. Medication-related communication scores tended to be low. Many students acknowledged the antibiotic would need to be changed, but few students made the best recommendations for a breast-feeding mother whose child could have pharmacogenetic considerations.

Overall, the SP felt that the students often neglected to address her concern about the health of her baby. She described how, during interactions with most students, she repeatedly expressed concern about her baby’s well-being. Yet she felt that the students’ attention was primarily focused on resolving her situation without considering the implications for her newborn.

Students succeeded at stating subjective elements of the case; however, students inconsistently provided objective details. In SOAP assessments, most students recognized the drug allergy. However, many students failed to provide an appropriate plan for this patient. Students rarely created a plan that included the safest alternative empiric antibiotic options for this breast-feeding mother despite student access to medication resources.

Discussion

This case allowed faculty members to identify strengths and weaknesses within the pharmacology curriculum. Over the years, at many medical schools, time for formalized pharmacology curricular content has trended downward in favor of problem-based learning focused on organ-based medical conditions. The siloed learning of medications may result in difficulties when students are challenged to apply pharmacologic principles across organ blocks, as can occur in authentic patients as well as in this SP encounter. For example, students would have encountered various aspects relevant to this case in many different curricular blocks, including anti-infectives, pharmacogenetics, renal medicine, endocrine and reproductive medicine, and clinical skills (e.g., physical exam, communication). This case challenges students to draw upon their knowledge and link the information in meaningful ways that not only provide a correct diagnosis but also result in appropriate care plans being developed. The case highlights the need for continued threading and reinforcement of pharmacologic principles throughout the entire medical school curriculum. It also encourages students to consider an entire patient history rather than ending encounters prematurely when the first (and most obvious) problem has been identified.

One limitation to this assessment is the lack of a formalized grade given to student participants. When students participated in this activity, they were enrolled in one of 10 different clerkships. Thus, there was not a single course/clerkship to which a grade could have been consistently applied. Although students were required to attend, there were no repercussions for the effort exercised toward this patient case. If a formalized grade had been assigned, results may have differed from our findings. At the time this case was conducted, there had been discussions about also giving it to first-year residents in family medicine. Given this possibility, we opted against sharing detailed answers or checklists with the students. However, students were able to receive additional information about their performance and have questions answered when contacting faculty directly. Nonetheless, the results of this assessment were used to inform the incorporation of several clinical pharmacology activities into a third-year course focused on integrating basic and clinical sciences.

Future plans include possibly converting the scenario to an interprofessional online gaming format in which different disciplines can interact, discuss, and address the issues raised by the case in an interprofessional manner. An online format would also allow for greater ease with interprofessional education logistics, including schedule planning (of students, faculty, simulation rooms, and SPs), and eliminate the need to train SPs.

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Disclosures

None to report.

Funding/Support

Josiah Macy Jr. Foundation; Woodward Endowment for Medical Sciences Education.

Ethical Approval

This publication contains data obtained from human subjects and received ethical approval.

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Received: February 6, 2016 | **Accepted:** August 18, 2016 | **Published:** September 16, 2016