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Stephanie F. James

*Regis University*, [sjames001@regis.edu](mailto:sjames001@regis.edu)

LaToya J. Braun

*Regis University*, [lbrown001@regis.edu](mailto:lbrown001@regis.edu)

Christine Feltman

*Regis University*, [cfeltman@regis.edu](mailto:cfeltman@regis.edu)

Robert Haight

*Regis University*, [rhaight@regis.edu](mailto:rhaight@regis.edu)

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## Development of an Integrated Immunology and Vaccines Pharmacy Elective

Stephanie F. James, PhD, MBA; Latoya Braun, PhD; Christine Feltman, PharmD; Robert Haight, PhD, MPA  
Regis University School of Pharmacy

### ABSTRACT

*Objective:* To describe an elective course on immunology and vaccines for pharmacy students that extends beyond basic immunization training.

*Design:* A three credit-hour Immunology and Vaccines elective was developed and taught by an immunologist, policy research expert, and pharmacist. The learning objectives of the course included: understanding how the immune system works with vaccines to provide protection against infectious diseases, the history and policies involved in immunization practice, and how to counsel the vaccine hesitant individual. Classes were conducted using a variety of formats; group projects, lectures, films, literature reviews and guest speakers. An end-of-course evaluation was used to gauge student opinion on course value. Students were evaluated by four exams and a final group presentation.

*Conclusions:* Students indicated that this course was valuable to their future pharmacy careers and provided insight into why people choose not to vaccinate and how they could use the course insight to properly educate such individuals.

**Keywords:** Immunology, Vaccines

### INTRODUCTION

The United States is experiencing a resurgence in vaccine-preventable diseases, in large part due to vaccine refusal and hesitancy.<sup>1</sup> The U.S. Department of Health and Human Services has made improving immunization rates a key objective in the Healthy People 2020 program. The American Pharmacists Association (APhA) offers an Immunizations Certificate training course that students and practicing pharmacists may complete through pharmacist.com. At the Regis University School of Pharmacy, this program is a part of a required two-credit course students complete during their first year, which requires students to pass a practical exam that assesses their immunization skills.

All states now allow pharmacists to administer immunizations,<sup>2</sup> although differences exist between states in the types of immunizations pharmacists may deliver, patient age limitations, and the use of standing order immunization protocol versus a prescription.<sup>3</sup> Despite such variation, it is imperative that all pharmacists are well educated regarding immunizations with information on: the human immune responses to infectious agents that are vaccine preventable; how vaccinations are formulated, developed and properly stored; vaccine laws and policy; patient counseling; and potential adverse effects. This additional education beyond the eight hour APhA certificate program would provide student pharmacists with the increased knowledge to strengthen their ability to counter the anti-vaccination movements.

At the Regis University School of Pharmacy, professors from the Departments of Pharmacy Practice and Pharmaceutical Sciences developed a combined Immunology and Vaccines (PHRM 795) elective to further extend the required coursework in immunology by providing more detailed education concerning the formulation, development and storage of vaccines beyond the APhA curriculum including the counseling the vaccine hesitant patient. The elective would also include current public health policy and court cases related to immunization mandates, reasons for vaccine exemptions, and a history of vaccinology. Students would also create and provide presentations in the community about the importance of vaccines.

### DESCRIPTION OF INNOVATIONS

The Immunology and Vaccines elective is a 3 credit, 16 week (one semester) course that integrates several faculty with expertise in immunology, drug formulation, policy analysis, and pharmacy practice. The APhA course, which includes 12 hours of self-study modules with assessment exams, 8 hours of live seminars with a final exam and a hands on assessment of immunization technique, is provided to the students the first semester of their P1 year. The elective course is offered for the P3 cohort of students to gain a deeper understanding after they have strengthened their pharmacology skills. This course is an innovative approach integrating immunology, vaccines and their development, patient counseling and policy. Herein, we discuss the development and design of this course, course outcomes, and how they support the 2013 Center for the Advancement of Pharmacy Education (CAPE) outcomes.<sup>4</sup>

### COURSE DESIGN

The Immunology and Vaccines elective met once a week for 3 hours and was divided into four units (See Appendix 1 for objectives): immunology and disease, vaccine development

**Corresponding Author:** Stephanie F. James, PhD  
3333 Regis Blvd, H-28, Denver, CO 80221-1099  
(303)964-6168; [Sjames001@regis.edu](mailto:Sjames001@regis.edu)

and formulation, vaccine hesitancy and counseling, and a final unit that discussed other types of vaccines, including those for animals and potential cancer vaccines. The units were each taught by experts in their field (e.g. an immunologist taught the units pertaining to immunology, a formulation scientist taught the formulation and development units, and a pharmacist and public policy expert taught the hesitancy and counseling sections). After each unit, students were given an exam. At the end of the term, students also worked in groups of four to design a presentation regarding vaccines for a specific age group (e.g. parents of children under 12, adolescents, adults and senior citizens).

A desired outcome of the course was to provide students with a deeper knowledge of how vaccines work with the normal immune system to confer protection and to give student pharmacists the information they need to provide the immunizations (also as part of CAPE Domain 1)<sup>4</sup> Vaccine preventable diseases, such as measles, pertussis, and polio, are not common in the United States, and hence are not covered in detail in our traditional required pharmacy coursework. This course provides students with the opportunity to gain additional knowledge of how the innate and adaptive immune systems function collaboratively to respond to such infectious pathogens that are vaccine preventable. Particular objectives are to differentiate between cell mediated and humoral immunity and how the T and B cells function together to generate a memory response. Specific diseases that are vaccine preventable are used to illustrate these objectives. In addition, students learn the pathogenesis and symptoms of selected vaccine preventable diseases, which are especially important for community pharmacists who may encounter patients with symptoms of a vaccine preventable disease and refer them to the appropriate resources.

This elective also differentiated from the APhA curriculum by including objectives as to how vaccines are developed (e.g. attenuated, recombinant, and inactive) and the biotechnological engineering used for each type of vaccine. Because many current vaccine controversies are in regards to vaccine ingredients, the history of current vaccine manufacturing processes was also discussed, including safety and purity analyses, appropriate storage conditions and their effect on vaccine stability, and the functions of vaccine excipients and adjuvants.

After the students were provided with a thorough background in immunology and vaccine development in the first half of the course, they are challenged to use this knowledge by practicing providing patient-centered care and advising patients regarding the importance of vaccines (CAPE Domain 2)<sup>4</sup> For some assignments, students were given patient scenarios and were expected to work in groups to determine the best way to approach a vaccine-hesitant patient or parents. As part of this

unit, students are introduced to an individual who did not vaccinate herself or her child due to religious preference. Students were able to hear the reasons why vaccine hesitant and vaccine objector individuals choose not to vaccinate and were able to ask open questions as to how they would like to be approached and counseled regarding immunizations. This allows the student pharmacists to understand the various aspects of parents' and patients' perspectives on vaccinations and learn how to be more sensitive in the methods with which they approach their patients in regards to patient counseling (CAPE Domain 4)<sup>4</sup> Additionally, as part of the course, students created a presentation for a specific audience of their choosing (seniors citizens, adolescents, or young children) and presented to groups outside the university. This course also encouraged students to learn about the different groups involved in immunization practice and policy and to study ways in which pharmacists can be advocates for immunizations by working with other agencies (e.g. health departments, non-profits, and schools.) Students watched a documentary ("The Vaccine War" PBS Frontline, 2015), in addition to the 2016 film "Vaxxed" and were asked to critically evaluate the arguments each film presented for accuracy.

In the last unit, students were introduced to topics pertaining to immunizations not covered in the APhA curriculum. These included vaccine preventable diseases that are common in animal populations and can spill over into humans. The importance of keeping domestic animals immunized to prevent threats to humans (such as rabies) was discussed. Students also read primary literature articles and reviews detailing the progress of vaccines in clinical trials to prevent certain cancers.

#### CRITICAL ANALYSIS

The Immunology and Vaccines course elective was conducted in the fall semester of the academic year 2015 and again in 2016. Each section enrolled twelve third-year pharmacy students. Course evaluations were completed both years at a response rate of 100% and 88.24%, respectively. Course evaluations indicated that students viewed the course as valuable to their education and were interested in the topics covered.

Students stated that the most valuable aspects of the course were the foundational knowledge delivered via lecture, followed by discussion sessions. This learning style was utilized especially during the immunology and vaccine formulation units. Students provided comments on course evaluations, such as "...liked lectures and then small group discussions afterward" and "...also enjoyed the great classroom discussions we had." Having discussions between the students and faculty, after foundational knowledge was delivered via lecture, seems to have had a positive impact on the student's ability to synthesize the information and gain a greater understanding of the content from each class. This was

also reflected in high exam scores (minimum 89.26%, maximum 100%, average 94.78%).

Students found the information presented on identifying reasons for vaccine hesitancy and describing counseling points to be very helpful. Our curricula extrapolated on the instruction students receive during the APhA course in that we also provided documentary films featuring vaccine hesitant parents and a religious objector. In course evaluations, students commented frequently on how much they appreciated hearing from actual vaccine hesitant individuals. One student stated that “more than the actual hesitancy lesson, watching the Vaxxed documentary and listening to the guest speaker has given me insight into anti-vaxxers.” A second student stated that they now know “how to talk to patients about getting vaccinated.”

A final assignment was for students to create a presentation about the importance of vaccines to a specific population of people. These populations included parents of young children, adolescents, and adults. The objective of this assignment was for students to utilize their foundational knowledge and patient counseling skills to improve their communication skills with patients of different perspectives and ages. Students gave their presentations to classmates and, if there was an opportunity, community groups such as senior living facilities or parent-teacher organizations. Positive statements were observed in course evaluations, such as “I also really like the idea of working with our communities through this class and trying to help get the vaccination rates up higher and educating people about vaccines”.

The course evaluations also indicated that the students found interest and importance in the course. One student stated that “This course was very intellectually stimulating and interesting.” Another student stated, “The lectures were the most valuable to my learning”. A third student stated, “This is a great elective class, I learned so much... and stress levels were minimal for this class.” The interest and importance found in this course indicates that students were engaged in their learning and see the importance in immunology and vaccinations to their future careers as pharmacists.

Student pharmacists gaining an understanding of the different perspectives of patients and techniques for improved communication will give them much needed skills to counsel patients and hopefully improve vaccination rates in the United States. Based upon the high exam scores and student comments on evaluations, our objectives of increasing student understanding of: 1) how the immune system responds to immunizations, 2) vaccine development and formulation, 3) patient hesitancy and counseling, and 4) animal and cancer vaccines were met.

## NEXT STEPS

Because many different healthcare providers can administer immunizations, there may be some controversy as to the most appropriate place for patients to be counseled on and receive immunizations. However, for improved patient care, the entire healthcare team needs to be working in unison. Knowing that immunizations are an important aspect of public health,<sup>5</sup> having all healthcare providers promoting the importance of being up-to-date on all vaccinations and providing needed vaccinations can only help with improving public health nationwide. Our goal is to create a more inter-professional commitment to immunizations as conflict between healthcare providers on who should administer and get credit for providing immunizations is only detrimental to public health and the well-being of our patients.

To foster this spirit of mutual respect and cooperation, subsequent offerings of the Immunology and Vaccines course will be provided to both pharmacy and nursing students at Regis University utilizing a team-based learning (TBL) format. Teams will be comprised of both pharmacy and nursing students that must work together to solve case studies and applications in vaccine immunology, formulation and development, and patient counseling. The inter-professional nature of a course including multiple healthcare providers will increase the understanding of the different perspectives between pharmacists and nurses.

## CONCLUSION

Pharmacists are in a unique position to counsel and provide patients with immunizations. This pharmacy elective course provided practice-relevant skill development beyond basic immunization training.

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**Appendix 1.** Example course calendar and objectives of an Immunology and Vaccines elective course.

	<b>Objectives/Exams</b>	<b>Instructor</b>
<b>Unit 1: Immunological responses to vaccines and vaccine preventable diseases</b>		
Class overview Introduction to the Immune System	<ol style="list-style-type: none"> <li>1. Understand the requirements for successful completion of this elective.</li> <li>2. Describe the differences between the innate and adaptive immune systems.</li> </ol>	Immunologist
Cell mediated immunity to bacteria	<ol style="list-style-type: none"> <li>1. Describe how the innate and adaptive immune system respond to bacterial infections.</li> <li>2. Outline the antigen presentation process in response to bacterial infections.</li> </ol>	Immunologist
Cell mediated immunity to viruses	<ol style="list-style-type: none"> <li>1. Describe how the innate and adaptive immune system respond to viral infections.</li> <li>2. Outline the antigen presentation process in response to viral infections.</li> </ol>	Immunologist
Humoral immunology	<ol style="list-style-type: none"> <li>1. Describe the interactions of T and B cells that produce memory B cells.</li> <li>2. Describe the differences between T cell independent and dependent antigens.</li> </ol>	Immunologist
Active versus passive vaccines, subunit, viral and DNA vaccines	<ol style="list-style-type: none"> <li>1. Compare and contrast the different types of vaccines and list examples of each that are in the child, adolescent and adults immunization schedule.</li> </ol> <p><i>Exam 1</i></p>	Immunologist
<b>Unit 2: Vaccine formulation and development</b>		
Vaccine formulation and development	<ol style="list-style-type: none"> <li>1. Describe the relative timeline of advances in vaccine development.</li> <li>2. Provide examples of how public attitudes and/or adverse events supported vaccine advances.</li> <li>3. Describe the complexity of vaccine production, including provide examples of analyses that are conducted to ensure safety and purity.</li> </ol>	Formulation Scientist
Vaccine formulation and development/Vaccine delivery methods	<ol style="list-style-type: none"> <li>1. Describe the potential effects of variations in production protocols (e.g., storage of intermediates) have on vaccine stability.</li> <li>2. Identify safeguards pharmacists and other health care providers can take to ensure vaccines are stored properly.</li> <li>3. Describe of the dangers of freezing, as well as heat stress, to vaccine stability.</li> <li>4. Discuss vaccine excipients and adjuvants and evidence (or lack thereof) for their potential to cause adverse events in patient populations.</li> </ol> <p><i>Exam 2</i></p>	Formulation Scientist

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**Unit 3: Vaccines and public health**


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Vaccines and public health	<ol style="list-style-type: none"> <li>1. Define herd immunity.</li> <li>2. Describe the history of vaccinations relevant to public health, citing specific examples of how vaccines led to the eradication of a disease.</li> </ol>	Pharmacist
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Vaccine counseling/Vaccine hesitancy	<ol style="list-style-type: none"> <li>1. Hear presentations from an individuals that refuses vaccines due to religious preference and students will identify how that individual would like to be counseled to receive immunizations.</li> <li>2. Identify reasons why individuals refuse immunizations.</li> </ol>	Pharmacist
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*Exam 3*


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**Unit 4: Vaccine policy and challenges**


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FDA regulations, adverse effects, vaccine schedules	<ol style="list-style-type: none"> <li>1. Describe FDA regulations on immunizations, including the VAERS system.</li> <li>2. Review the current child, adolescent and adult immunization schedules.</li> <li>3. Describe why certain immunizations are given at certain ages.</li> <li>4. Describe potential adverse effects of immunizations, and what populations should not receive a particular immunization and the reasoning why.</li> </ol>	Policy Research Expert
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Animals and vaccines/Travel vaccines/Cancer vaccines	<ol style="list-style-type: none"> <li>1. List vaccines given to animals for diseases that may also occur in humans. Students will be able to discuss the importance of animal immunizations for human health.</li> <li>2. Identify resources to describe travel immunizations.</li> <li>3. Describe challenges and opportunities regarding the development of cancer vaccines.</li> </ol>	Policy Research Expert
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*Exam 4*