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An Evaluation of Mumps Antibody Titers Among Pharmacy Students Before and After a University Mumps Outbreak

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**An Evaluation of Mumps Antibody Titers Among Pharmacy Students Before and After
a University Mumps Outbreak**

A Thesis

Presented to the College of Pharmacy and Health Sciences

and

The Honors Program

of

Butler University

In Partial Fulfillment

of the Requirements for Graduation Honors

Kiley Ann Shelley

May 3, 2017

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Table of Contents

Abstract	5
Background	6
Mumps Virus.....	6
MMR (Measles-Mumps-Rubella) Vaccine.....	6
Outbreaks and Studies in Recent Years.....	7
Butler University Outbreak.....	9
Need for Study	10
CDC Recommendations	10
Existing Studies	11
Current Study	11
Thesis Statement	12
Objectives	12
Methods	13
Study Design Part 1	13
Study Design Part 2	14
Inclusion Criteria Part 1	14
Inclusion Criteria Part 2	15
Proposed Statistical Analysis	15
Results	16
Discussion	17
References	23

ABSTRACT

Mumps outbreaks continue to transpire across the United States despite the available MMR (Measles-Mumps-Rubella) vaccine and seemingly high vaccination rates. There is limited evidence surrounding the management, impact, and prevention of mumps outbreaks. In particular, there are currently no formal recommendations from the CDC (Centers for Disease Control and Prevention) regarding the administration of additional doses of the MMR vaccine during a mumps outbreak. Furthermore, there are unanswered questions of possible waning of vaccine-induced mumps immunity and the impact of a third dose of the MMR vaccine to assist in mumps outbreak control. Existing studies suggest that administration of the MMR vaccine during a mumps outbreak may decrease the attack rate and number of mumps cases. This study will characterize mumps antibody titer levels of pharmacy students obtained before and after a university mumps outbreak. The current study will also assess for evidence of possible waning of vaccine-induced mumps immunity in pharmacy student subjects.

BACKGROUND

Mumps Virus

Mumps is a contagious disease caused by a Paramyxovirus, which is a member of the Rubulavirus family. The virus replicates in the upper respiratory tract and is transmitted through direct contact with saliva or respiratory secretions. The virus can also be transmitted via fomites. Common modes of transmission include sneezing, coughing, talking, touch contamination, or sharing cups and eating utensils. Once infected with the mumps virus, patients may exhibit the common clinical manifestation of parotitis, which presents as an inflamed jaw and cheeks.¹

A person infected with the mumps virus may also experience other vague symptoms such as fever, headache, muscle ache, loss of appetite, and tiredness. These symptoms usually appear 16-18 days after exposure to infection but the time may range anywhere from 12-25 days. The mumps virus will generally spread before the salivary glands begin to swell, and the spreading can continue for up to 5 days after the swelling starts.²

Measles-Mumps-Rubella (MMR) Vaccine

Mumps is a disease that has been highly preventable via the MMR vaccine that was approved for use in the United States in 1967. Since 1989 the CDC (Centers for Disease Control and Prevention) has recommended that children receive the first MMR vaccine dose when they are 12-15 months old, and a second dose when they are 4-6 years old. The median efficacy of the MMR vaccine is estimated at 78% (ranging from 49-92%) after the first dose, and 88% (ranging from 66-95%) after the second dose.³

Outbreaks and Studies in Recent Years

The number of mumps cases reported in the United States every year varies from several hundred to several thousand. As depicted in **Figure 1**, the number of mumps cases reported has varied significantly in recent years. According to the CDC, a mumps outbreak is defined as three or more cases of the mumps linked by time and place.⁴ Despite seemingly high vaccination coverage, mumps outbreaks continue to transpire across the United States, particularly on college campuses. The outbreaks have occurred in all parts of the country in highly vaccinated populations, as described in **Figure 2**. Several studies were completed during these mumps outbreaks, as described in **Figure 3**.



Figure 1. Number of mumps cases in the United States from 2010 to 2016¹

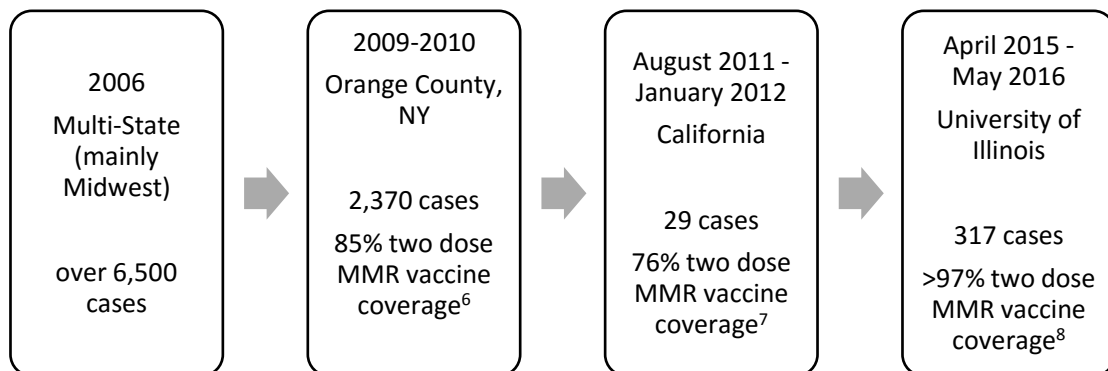


Figure 2. Recent outbreaks in the United States described with year, location, number of cases, and percent of cases that had the recommended two doses of the MMR vaccine⁵

During the course of the 2006 mumps outbreaks that spread across college campuses, the affected states worked with the American College Health Association (ACHA) and the CDC to recommend procedures to control the outbreaks. Recommendations included that students be required to have documentation of two MMR vaccine doses, and infected students be isolated for 5-9 days after onset of symptoms.⁹ A third MMR vaccine dose was not recommended.

A study conducted at a Kansas university during the 2006 mumps outbreak concluded that two MMR vaccine doses protect the majority of people from developing mumps.¹⁰ Two-dose protection was evidenced by a low attack rate in the roommates of students who had developed mumps. However, the study also concluded that two MMR vaccine doses are not effective enough to prevent an outbreak from occurring.

The University of Illinois recommended a third MMR dose during a mumps outbreak in 2015 due to the sustained transmission and high two dose MMR vaccine coverage at the school.⁸ Over a three-week period 8,200 MMR vaccine doses were administered at 5 immunization clinics. Although mumps cases declined in the following months, transmission of the mumps virus continued until May 2016. Thus, further evaluation is needed to determine if administering the MMR vaccine has an impact on the number of mumps cases during an outbreak.

When and Where Study Was Conducted	Study Method and Conclusion
2006 – A university in Kansas	Evaluated 2 dose MMR protection; 2 dose MMR protects majority of people from developing mumps but does not prevent outbreaks ¹⁰
2009 – Orange County, NY Study 1	Administered 3 rd MMR dose to families; attack rate 0% in those that received MMR, 5.2% in those who did not, not statistically significant ⁶
2009 – Orange County, NY Study 2	Administered 3 rd MMR dose to students grades 6-12; attack rate 0.06% in those that received MMR, 0.48% in those that did not, not statistically significant ¹¹
2010 – Guam	Administered 3 rd MMR dose to students age 9-14 years old; attack rate 0.9 per 1000 in those that received MMR, 2.4 per 1000 in those that did not, not statistically significant ¹²
2015 – University of Illinois	Administered 3 rd MMR dose to students and staff; mumps cases declined but transmission continued, further evaluation needed ⁸

Figure 3. Studies conducted during mumps outbreaks, the study method, and the conclusions drawn from the study

Butler University Outbreak

In February 2016 Butler University reported a mumps outbreak. The Marion County Public Health Department issued guidelines to manage the mumps outbreak. These guidelines were recommendations for all individuals on campus – students, staff, and faculty – to receive a dose of the MMR vaccine, specifically: 1) those born before 1957 were strongly advised but not required to get a third MMR dose 2) those who were unvaccinated or unable to provide documentation of vaccination were required to receive a first MMR dose and the second MMR dose 28 days later 3) those who had documentation of one MMR dose were required to receive a second MMR dose 4) those that had documentation of the recommended two MMR vaccine doses were not directly addressed. Butler held immunization clinics in February, where over

3,600 MMR doses were administered. The mumps outbreak was declared over in May 2016, with a total of 24 mumps cases reported.

The mumps outbreak at Butler University generated unanswered questions: What was the impact of administering the MMR vaccine during the mumps outbreak? Was there evidence of waning mumps immunity in the students and/or Butler community? Could the presence of waning mumps immunity increase the likelihood of a mumps outbreak and/or developing the mumps infection?

NEED FOR STUDY

CDC Recommendations

The current MMR vaccination schedule recommended by the CDC and ACIP (Advisory Committee on Immunization Practices) is to receive two doses at the ages of 12-15 months and 4-6 years old. The package insert for the MMR vaccine states that neutralizing antibodies to the mumps virus are still detectable in most individuals 11-13 years after receiving the first MMR vaccine dose.¹³ Although there is limited evidence that the neutralizing antibodies from the MMR vaccine last longer than that time period, the CDC has not released any further recommendations amid the mumps outbreaks across the United States.

Presently, there are no formal recommendations from the CDC regarding administration of a third MMR vaccine dose during mumps outbreaks. The CDC does, however, provide guidance for populations in which administration of a third MMR vaccine dose may be considered: 1) outbreaks in people with high two-dose vaccination coverage (>90% of the population) 2) intense exposure settings likely to facilitate transmission 3) evidence of

sustained transmission for longer than two weeks 4) high attack rates (>5 cases per 1,000 people).⁴ Butler University's outbreak meets the CDC's criteria, as the population is highly vaccinated, the college campus is an intense exposure setting, and there was evidence of sustained transmission of the mumps virus for longer than two weeks. Nonetheless, additional data on the impact and safety of the third MMR vaccine dose is needed to develop more concrete guidelines for future outbreaks.

Existing Studies

While some studies have shown a decline in attack rates after administration of a third MMR vaccine dose, the possibility that the declines were unrelated to the intervention could not be excluded.^{11,12,14} Additionally, despite the decrease in mumps incidence demonstrated by studies, the data is insufficient to recommend for or against the use of a third MMR vaccine dose to assist in controlling mumps outbreaks.⁷ Furthermore, it is evident from continued mumps outbreaks that the MMR vaccine does not fully protect vaccinated individuals from developing mumps infections, but studies have shown that it can decrease the number of mumps cases and lessen complications from the mumps virus.¹⁵ It is clear that more studies are needed to better understand the impact of the MMR vaccine and possible waning immunity.

Current Study

The current study will provide insight into the characteristics of mumps serologic titers observed in 2nd, 3rd, and 4th professional year pharmacy students with or without receipt of a third MMR vaccine dose following a university outbreak. The study will also evaluate pre-outbreak mumps serological titers in 3rd and 4th professional year pharmacy students to assess the impact of time on vaccine-induced mumps antibody titers. In addition, the current study will be continued and will assess post-outbreak mumps titers obtained from the 3rd and 4th year

students, which may allow for the assessment of any quantitative changes that occurred in mumps antibody titers with consideration of time and/or receipt of a third MMR vaccine dose. If waning immunity is demonstrated among the study subjects, the data will provide evidence to support the need to potentially adjust the health information required for matriculating students before campus move-in. Overall, the study will add to the body of evidence surrounding the management, impact, and prevention of mumps outbreaks.

THESIS STATEMENT

Mumps outbreaks continue to transpire across the United States. As mentioned earlier, the CDC does not have formal recommendations regarding the administration of the MMR vaccine during mumps outbreaks due to lack of sufficient data. However, existing studies suggest that administration of the MMR vaccine during a mumps outbreak may decrease the number of mumps cases.

What is the impact of the administration of a third MMR vaccine dose on the mumps antibody titers among 2nd, 3rd, and 4th year Butler University pharmacy students? Do 3rd and 4th year Butler University pharmacy students demonstrate evidence of waning vaccine-induced mumps immunity?

OBJECTIVES

The primary objectives of this study are to: 1) characterize mumps antibody titers before and after a mumps outbreak 2) determine the quantitative impact of a third dose of the

MMR vaccine on mumps antibody titers 3) assess for evidence of waning vaccine-induced mumps immunity.

METHODS

The current study has been approved by the Butler University IRB (Institutional Review Board). This study consists of two parts. The first part of the study is a retrospective, observational review of electronic health records to assess immunization and mumps titer data for 2nd, 3rd, and 4th year pharmacy students. The second part of the study is a prospective, longitudinal cohort study collecting data on current post-outbreak mumps antibody levels in 3rd and 4th year students.

Study Design – Part 1: Data was collected by reviewing demographics, immunization records, and mumps titer information in electronic health records of 2nd, 3rd, and 4th year students, as listed in **Figure 4**. Per pharmacy program protocol, all students had titers obtained in their 2nd year of pharmacy school before starting experiential rotations. All collected data was coded and de-identified prior to being recorded on data sheets and entered into an excel spreadsheet for data analysis.

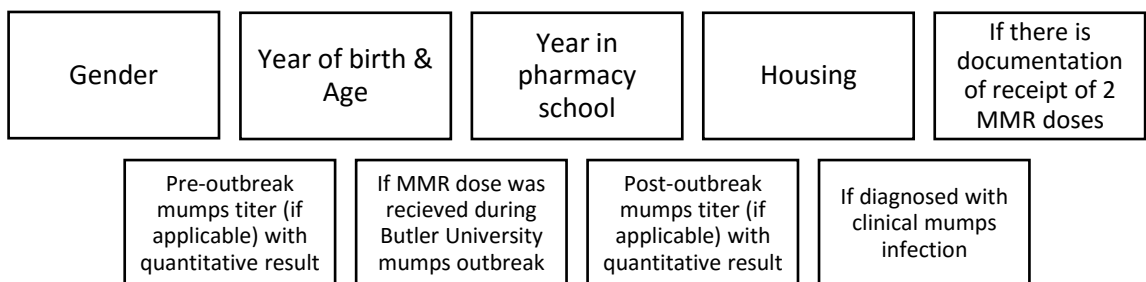


Figure 4. Data collected from the eligible student electronic health records at Butler University Health Services.

The 2nd year pharmacy students did not have a pre-outbreak titer obtained because the outbreak occurred prior to their 2nd year of pharmacy school. The 2nd year students may have received a third MMR vaccine dose during the Butler University mumps outbreak. In Fall 2016, the 2nd year students had a mumps antibody titer obtained as a pharmacy program protocol. The 2nd year student post-outbreak mumps titer data will be assessed to characterize and quantify mumps antibody titers in those that did receive a dose of the MMR vaccine during the outbreak vs. those that did not.

The 3rd and 4th year pharmacy students had pre-outbreak mumps antibody titers obtained per pharmacy program protocol in Fall 2015 or Fall 2014, respectively. This data will be assessed for evidence of waning vaccine-induced immunity to the mumps virus. The waning of immunity is demonstrated by a negative mumps antibody titer result, 1.0 or less. The 3rd and 4th year students may have received a third MMR vaccine dose during the Butler University mumps outbreak.

Study Design – Part 2: The 3rd and 4th year pharmacy students have been recruited and underwent informed consent. After consenting, the 3rd and 4th students were asked to go to the Butler University Student Health Services clinic to undergo a standard venipuncture, which is a collection of about 3.5 mL of blood. The blood samples obtained were sent to Mid America Clinical Laboratory, where the specimens undergo testing for mumps virus antibodies (IgG). The results of the assay were reported to Butler University Student Health Services in a confidential manner and entered into the electronic health record for data collection. This data will be assessed for quantitative changes in titer over a 1 or 2 year time period, and also for quantitative changes following receipt of a third MMR vaccine dose, if applicable.

Inclusion Criteria – Part 1: Butler University professional phase pharmacy students in their 2nd, 3rd, or 4th year of the program, who have had their mumps antibody titers obtained per

pharmacy program protocol during the 2nd professional year of school. The potential study subjects were identified via Butler University College of Pharmacy and Health Sciences records according to class standing lists for the 2nd, 3rd, and 4th year pharmacy students at the time of initiation of the study.

Inclusion Criteria – Part 2: Butler University professional phase pharmacy students in their 3rd or 4th year of the program, who were consented and had post-outbreak titers obtained at the Butler University Student Health Services. The potential study subjects were identified via Butler University College of Pharmacy and Health Sciences records according to class standing lists for the 3rd and 4th year pharmacy students at the time of initiation of the study.

Proposed Statistical Analysis: Data will be analyzed using Excel. A Chi-Square test will be used to compare categorical variables for 2nd year student data split into Groups 1 and 2. Group 1 will be 2nd year students who received a third MMR dose and demonstrated positive post-outbreak mumps titers. Group 2 will be 2nd year students who did not receive a third MMR dose and demonstrated positive post-outbreak mumps titers.

Data from 3rd and 4th year students will be split into Groups 3 and 4. Group 3 will consist of 3rd and 4th year students who had positive pre-outbreak mumps titers. Group 4 will consist of 3rd and 4th year students who had negative pre-outbreak mumps titers. The Paired T-Test will compare the mean pre and post-outbreak mumps titers of Groups 3 and 4, assessing for a statistical difference.

RESULTS

The 2nd year pharmacy class had a total of 112 students at the time of initiation of this study. The class demographics include 70% (n = 78) female with an average age of 22 years old (± 1.29). Overall, all students had documentation of receiving the two-dose MMR vaccination series and no students were diagnosed with the mumps. During the mumps outbreak at Butler University, 70% (n = 78) of the students received a dose of the MMR vaccine. Of the 2nd year students that received a dose of the MMR vaccine during the mumps outbreak, 98.7% (n = 76) had positive mumps antibody titers obtained per protocol after the outbreak. Of the students who did not receive a dose of the MMR vaccine during the outbreak, 75.8% (n = 25) demonstrated positive mumps antibody titers obtained per protocol after the outbreak.

The results of the pharmacy school protocol mumps antibody titers indicated that 11 of the 112 students (9.8%) had negative titers. All 11 students received a dose of the MMR vaccine after the negative titer resulted. Of these 11 students, 2 students had titers obtained a year earlier in Fall 2015 and received a third MMR dose in January 2016 just prior to the mumps outbreak. Of the remaining 9 students with negative mumps antibody titers, 8 did not receive a third MMR dose during the Butler University mumps outbreak. However, 1 of the 9 remaining students had received a third MMR dose during the mumps outbreak. Thus, that student had a negative mumps antibody titer approximately 8 months after receiving a dose of the MMR vaccine. This student received a fourth MMR dose after the negative titer result was obtained.

When quantitatively interpreting the mumps antibody titers, a value greater than 1.0 is considered a positive titer. The average quantitative result of the mumps antibody titer in the 2nd year students was 2.88 (± 1.39). When the quantitative titer result was broken down into

those who did vs. did not receive a third MMR dose during the outbreak, the levels were 3.14 vs. 2.38, respectively.

At the time of thesis preparation, data collection and analysis remains ongoing for the 3rd and 4th year students. Overall, all students had documentation of receiving the two-dose MMR vaccination series prior to the outbreak and no students were diagnosed with the mumps. Thus far, data for 97 of 4th year students has been recorded. Of these 97 students, 15.5% (n = 15) had negative titer results when their titers were obtained per pharmacy program protocol prior to the mumps outbreak. These 15 students demonstrate evidence of waning mumps immunity. All 15 students did receive a third MMR dose after the negative titer result was obtained. The average quantitative level of the mumps titers in the 4th year students was 2.62 (\pm 1.34). During the Butler University mumps outbreak 58% (n = 56) of students received a dose of the MMR vaccine. As data collection continues for the 3rd and 4th year students, more results will be available regarding pre and post-outbreak titers.

DISCUSSION

As of March 25, 2017 there have been 1,965 mumps cases reported in 2017.⁵ Outbreaks continue to occur across the United States, specifically on college campuses. There is currently a lack of data to explain why these outbreaks continue to occur among populations with high two-dose MMR vaccination coverage. Moreover, there are no formal recommendations from the CDC on how to address the mumps outbreaks that continue to occur.

During the outbreak at Butler University, two immunization clinics took place and over 3,600 MMR vaccines were administered to the Butler students, staff, faculty, and community. In

May 2016, about 3 months after the first reported cases of the mumps at Butler, the outbreak was declared over with a total of 24 reported cases of the mumps.

Steven A. Rubin, chief of the Laboratory of Method Development at the FDA's Center for Biologics Evaluation and Research is studying immune responses to the MMR vaccine and its prevention of the mumps. Outbreaks are still occurring across the United States, specifically at college campuses. Rubin states that their "research indicates that by college age, levels of anti-mumps virus antibodies had declined substantially."¹⁶ When studying college-age participants who received a third MMR vaccine dose, Rubin and his team observed an increase in antibodies in the first month after vaccination. However, within one year of the third MMR vaccine dose the antibody levels dropped back down to nearly pre-third MMR dose levels. It was concluded that a third MMR vaccine dose is unlikely to provide long-term protection, and the researchers have now turned their efforts towards ways to improve the MMR vaccine.¹⁶

This study has aimed to characterize pharmacy student mumps antibody titer levels before and after a university outbreak. Thus far, the findings of this study support the theory that there is possible vaccine-induced waning immunity to the mumps virus by the time people are college-age. This waning immunity is defined by a mumps antibody titer level of 1.0 or less. Waning immunity was demonstrated by the 15.5% of the 4th year students that had negative pre-outbreak mumps antibody titer results. Prior to obtaining titers, all students had documentation of receiving the recommended two MMR vaccine doses. Thus, lack of vaccination cannot explain the negative titer results. This data will be presented to the leaders of the Butler University Health Services to consider possible adjustment to the policy for incoming students regarding required immunization and/or titer documentation.

The current study is obtaining post-outbreak mumps titer results for 3rd and 4th year pharmacy students. Once all data has been collected, results will be able to compare quantitative changes in mumps antibody titer over a 1 or 2 year time period. The results may also be able to compare quantitative changes in titers in those who did vs. those who did not get a dose of the MMR vaccine during the mumps outbreak. The results of this study will add to the body of evidence of the studies mentioned above, regarding sustained increased mumps antibody titer levels following receipt of a third MMR vaccine dose.

Two studies involving a third MMR vaccine dose were completed in Orange County, NY during the 2009 mumps outbreak. The first study offered a third MMR vaccine dose to members of a household within five days of a member of the household experiencing onset of mumps symptoms.⁶ The recommendation of a third MMR dose was proposed even though the ACIP does not advocate administration of a third MMR vaccine dose during mumps outbreaks as post exposure prophylaxis. Of the 239 eligible people, 28 (11.7%) received a third MMR vaccine dose. The attack rate was 0% for those who received the third MMR vaccine dose, versus a 5.2% attack rate for those who had two MMR vaccine doses but did not receive a third dose. The difference in the attack rates of these two groups was not statistically significant ($p = 0.57$).⁶ Although the data statistically did not demonstrate a difference in attack rates between the two groups, the lower attack rate could be considered clinically significant. Thus, the study supports the idea that more evidence is needed related to the management, impact, and prevention of mumps outbreaks.

The second study completed in Orange County, NY offered third MMR vaccine doses to students in grades 6-12, in which many of the mumps cases occurred.¹¹ The participating schools had to provide evidence of ongoing transmission of the mumps virus two weeks prior to the intervention, along with documented high two-dose MMR vaccine coverage. Of the 2,178

eligible students, 1,755 (80.6%) received a third MMR vaccine dose. The attack rate among those who received the third MMR vaccine dose was eightfold lower (0.06% vs. 0.48%) than those who did not, but this was not statistically significant (95% CI 0.01-1.32, $p = 0.097$).¹¹ The study concluded that the third MMR vaccine dose may limit the size and duration of an outbreak, but the findings from the study do not support the use of a third MMR vaccine dose in national vaccination programs.

A study completed in Guam during a mumps outbreak in 2010 administered 1,068 third doses of the MMR vaccine to eligible students ages 9-14 at seven different schools.¹² It was found that those who received a third MMR vaccine dose had an attack rate of 0.9 per 1000, compared to an attack rate of 2.4 per 1000 in those who had 2 or less MMR vaccine doses. This was a 60% lower attack rate, but was not statistically significant ($p = 0.67$).¹² Nonetheless, the study did conclude that the administration of a third MMR vaccine dose may be effective for controlling mumps outbreaks. This study, as well as the others mentioned above, supports the idea that more evidence is needed related to the management, impact, and prevention of mumps outbreaks.

A study published in 2014 assessed the magnitude and duration of aggregate mumps virus neutralizing antibody responses after administration of a third MMR vaccine dose. The breakdown of study subjects' mumps virus neutralizing antibody levels over time is illustrated in **Figure 5**. The study found that those who had high seropositive titers continued to possess high seropositive titers.¹⁴ This study is significant because it indicates that a third MMR vaccine dose could increase mumps virus neutralizing titers, which could help control outbreaks. However, only 52.5% of the participants sustained high mumps virus titers one year after receiving the third MMR vaccine dose. For this reason, more evidence of mumps neutralizing titers is needed to determine the role that a third MMR vaccine dose can play in controlling mumps outbreaks.

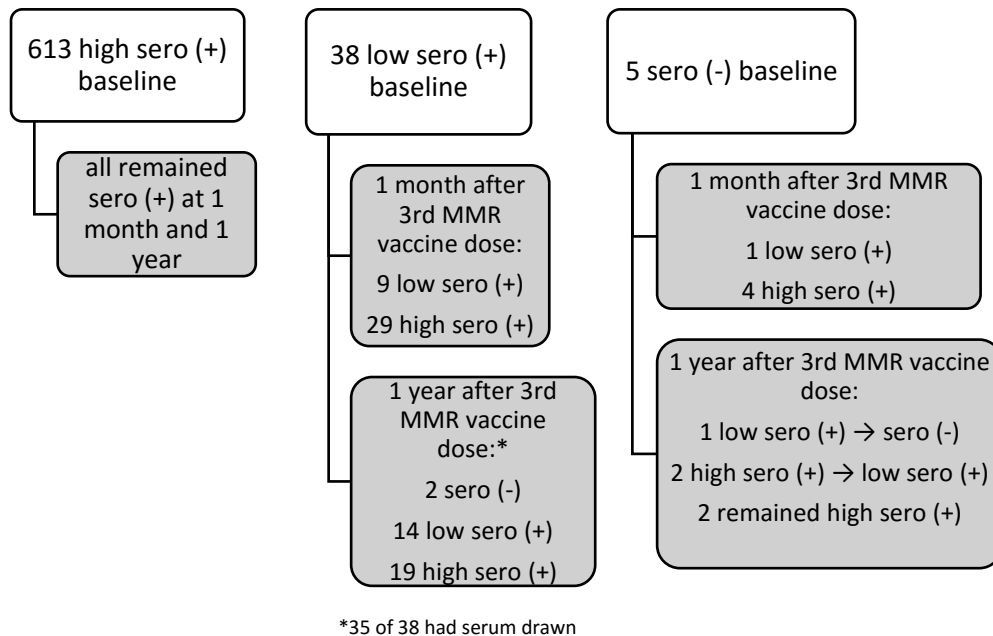


Figure 5. Classification of mumps virus neutralizing antibody responses of study participants after receiving a third MMR vaccine dose¹⁴

The current study is subject to limitations. The first part of the study is retrospective, and therefore the data relies solely on electronic health records and data collectors to provide accurate and sufficient documentation. In addition, the data for the first part of the study is coming from three classes of pharmacy students, adding up to less than 500 students. This is a small population and does not have a control group to compare to. Likewise, the second part of the study is completely voluntary and the number of participants may vary from 15 to 200 students. Furthermore, the data has been collected from one small, private institution. This may make any data and results difficult to generalize to a more diverse population.

Overall, the existing studies on mumps outbreaks, mumps antibody titers, and administration of the MMR vaccine during mumps outbreaks do show a decrease in mumps cases in those who receive the MMR vaccine during an outbreak. However, no studies thus far have shown a statistical difference in their results.

The outbreak at Butler University was managed similarly to other outbreaks that have been involved in published literature. The university had a high two-dose MMR vaccination coverage and administered the MMR vaccine at immunization clinics held during the mumps outbreak. Approximately 12 weeks after the clinics were held, the mumps outbreak was declared over.

The results of this study may add to the existing literature by providing additional data on evidence of waning immunity and the impact of administering the MMR vaccine during mumps outbreaks. The results of this study may also directly affect the Butler University campus and community if the leaders of the Butler University Health Services consider possible adjustment to the policy for incoming students regarding required immunization and/or titer documentation.

The current study will continue to collect data, including the remaining electronic health records and post-outbreak mumps antibody titers obtained for the 3rd and 4th year students. When all necessary data has been collected and recorded, statistical analysis will be completed. Results will be reported with applicable discussion and conclusions to accompany the data. When this study has been completed it is anticipated that its data, results, and conclusions will assist in developing the insufficient body of evidence surrounding the management, impact, and prevention of mumps outbreaks.

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