

## Manuscript Details

<b>Manuscript number</b>	JPHC_2018_171
<b>Title</b>	An Intervention to Increase HPV Vaccine Initiation Rates in Adolescent Males
<b>Article type</b>	Research paper

### Abstract

**Abstract Introduction:** In 2016, the Centers for Disease Control and Prevention reported the average Human Papillomavirus, (HPV) vaccine initiation rate among males was 50% versus 63% for females. The objective of this project was to increase HPV vaccine initiation rates among males aged 11-21. **Methods:** Quasi-experimental design investigated pre-and post-HPV vaccine initiation rates at a pediatric practice that serves a diverse population. The intervention included an electronic medical record (EMR) prompt, an educational presentation, and monthly email updates to providers. De-identified HPV vaccine initiation rate data were collected, pre-and post-intervention and matched with providers. **Results:** A paired two-sample t-test evaluated differences in pre-post vaccine initiation rates. HPV vaccine initiation rates increased overall by 6.5% during the twelve-week project period. The EMR prompt was favored by 75% of participating pediatric providers. **Discussion:** Small gains can be made over a short period of time to improve HPV vaccine initiation rates among adolescent males. **Keywords:** HPV Vaccine and Males, Intervention and HPV Vaccine, Provider Barriers and HPV Vaccine Rates.

<b>Keywords</b>	Keywords: HPV Vaccine and Males, Intervention and HPV Vaccine, Provider Barriers and HPV Vaccine Rates.
<b>Taxonomy</b>	Health Promotion and Health Maintenance, Adolescent Health
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Mary K. Swartz PhD, RN, CPNP, FAAN  
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Dear Dr. Swartz:

I would like to submit a manuscript to Journal of Pediatric Health Care. The manuscript describes a quality improvement intervention for pediatric providers to increase Human Papillomavirus, HPV vaccine initiation rates in adolescent males.

I have more than 14 years-experience as a Family Nurse Practitioner in a diverse pediatric primary care practice and aware of the vital role providers play in the recommendation and application of preventive health immunizations. In 2016, the Centers for Disease Control and Prevention reported the average initiation rate for HPV vaccination among males was 50% versus 63% in females with lower completion rates among males from diverse backgrounds.

This project sought to increase HPV vaccine initiation rates among males aged 11-21. A multi-prong intervention was implemented at a pediatric practice in Massachusetts that serves a diverse population. De-identified HPV vaccine initiation rate data were collected, pre-and post-intervention and matched with providers. A paired two-sample t-test evaluated differences in pre-post vaccine initiation rates. HPV vaccine initiation rates increased overall by 6.5% during the twelve-week project period.

Please email me at [lisa\\_marchandciriello@uml.edu](mailto:lisa_marchandciriello@uml.edu) or call (978) 994-3861 if you have any questions.

Sincerely,

**Lisa A. Marchand-Ciriello**

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## An Intervention to Increase HPV Vaccine Initiation Rates in Adolescent Males

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Keywords: HPV Vaccine, Males, Intervention, Provider Barriers, HPV Vaccine Rates

An Intervention to Increase HPV Vaccine Initiation Rates in Adolescent Males

### Abstract

**Introduction:** In 2016, the Centers for Disease Control and Prevention reported the average Human Papillomavirus, (HPV) vaccine initiation rate among males was 50% versus 63% for females. The objective of this project was to increase HPV vaccine initiation rates among males aged 11-21.

**Methods:** Quasi-experimental design investigated pre-and post-HPV vaccine initiation rates at a pediatric practice that serves a diverse population using a multi-prong intervention. The intervention included an electronic medical record (EMR) prompt, an educational presentation, and monthly email updates to providers. De-identified HPV vaccine initiation rate data were collected, pre-and post-intervention and matched with providers.

**Results:** A paired two-sample t-test evaluated differences in pre-post vaccine initiation rates. HPV vaccine initiation rates increased overall by 6.5% during the twelve-week project period. The EMR prompt was favored by 75% of participating pediatric providers.

**Discussion:** Small gains can be made over a short period of time to improve HPV vaccine initiation rates among adolescent males.

**Keywords:** HPV Vaccine, Males, Intervention, Provider Barriers, HPV Vaccine Rates.

### An Intervention to Increase HPV Vaccine Initiation Rates in Adolescent Males

Human Papillomavirus (HPV) is a viral infection that is the most common sexually transmitted infection (STI) in the United States (U.S.). HPV is spread from one person to another through anal, vaginal, or oral sex, or through close skin-to-skin mucosal contact during sexual activity (Centers for Disease Control and Prevention [CDC], 2016). For males, HPV has been identified as the cause of 63% of penile cancers, 91% of anal cancers, 72% of oropharyngeal cancers, and 100% of genital warts (Scherr, Augusto, Ali, Malo, & Vadaparampil, 2016). Currently there is no diagnostic test to screen males for HPV. The HPV vaccine was approved for administration to males by most private and Medicaid funded insurances in 2011. The Food and Drug Administration (FDA) approved the 9-valent HPV vaccine in December of 2014 to protect against HPV types 6, 11, 16, and 18 found in the 4-valent HPV vaccine and five additional strains: 31, 33, 45, 52, and 58. Strains 16, 18, 31, 33, 45, 52, and 58 accounts for 74% of all HPV related cancers in males (CDC, 2015). The Healthy People 2020 goal for completion of the HPV vaccine series is 80% for males and females ages 13 to 15 (United States Department of Health and Human Services, 2015).

### **Background**

The Advisory Committee on Immunization Practices (ACIP) in 2011 added the recommendation for males ages 9-21 to receive the HPV three vaccine series to reduce the incidence of HPV infections and cancers associated with the virus in males. In 2015, the ACIP evaluated the endorsement for administration of the HPV vaccine as a Category A recommendation and routine vaccination recommended at ages 11-12 in both sexes that may be administered until twenty-six years of age (Petrosky, et al., 2015). Despite a safe vaccine profile

and proven longitudinal immunogenicity against strains of HPV known to cause oropharyngeal, penile, and anal cancers in men, vaccine rates remain low. Nationally, the national average of provider recommendations for the HPV vaccine in males as only 30 to 50% (Allison et al., 2013). In 2016 the CDC reported the average vaccine rate for one HPV vaccine for females was 63% versus 50% for males with lower completion rates among males from diverse socioeconomic backgrounds.

Researchers have identified a need for culturally sensitive educational materials for parents to aid in their decision to vaccinate, as vaccination rates are lower among those who identify as a racial or ethnic minority group. Latino parents have reported HPV vaccine rates as low as 20.7% among their male offspring. In addition, 38% of these parents reported the number one barrier to their children receiving the HPV vaccine was that they were not aware of it (Kepka, Ding, Bodson, Warner, & Mooney, 2015). Researchers who have reviewed available literature have documented that parents of adolescents are interested in culturally sensitive educational materials regarding the HPV vaccine (Lechuga, Swain, & Weinhardt, 2012; Fishman, Taylor, & Frank, 2016). Parents have identified their child's health care provider as the main source of guidance for recommendations of this vaccine, although less than 30% of providers nationally are routinely recommending this vaccine to males (Burdette, Webb, Hill, & Jokinen-Gordon, 2016). Researches who analyzed results from the National Immunization Survey documented positive parental attitudes toward HPV vaccination: only 23% of parents of females and 37% of parents of males were unlikely to vaccinate their children against HPV (Kram, Schmidt, Saghezchi, & Russell, 2015).

Improvement in the uptake of the HPV vaccine has been noted through the use of reminder calls, postcards, and text messaging, although the most effective studies have included



combined interventions of reminders and educational materials or provider recommendations (Cassidy, Braxter, Charron-Prochownik, & Schlenk, 2014; Fiks et al., 2013; Staras et al., 2015). Multiple researchers have evaluated HPV vaccine uptake as a result of implementation of educational or provider interventions (Alexander et al., 2015; Burdette, Webb, Hill, & Jokinen-Gordon, 2016; Fishman et al., 2016; Lechuga et al., 2012; Scherr et al., 2016). Modifications in the electronic medical record (EMR) have notified providers that patients were overdue for an immunization. These modifications may increase HPV vaccination rates and series completion if used effectively (Bundy et al., 2013; Fiks et al., 2013; Perkins, Zisblatt, Legler, Trucks, Hanchate & Gorin, 2015).

Since 2011, there have been a minimal number of studies conducted that examined reliability and validity of educational interventions for patients and their families along with provider recommendations to increase the initiation and series completion of the HPV vaccine in males. Systematic reviews written by Fu, Bonhomme, Cooper, Joseph, and Zimet, (2014), Niccolai and Hansen (2015), Smulian, Mitchell & Stokley (2016), and Walling et al., (2016) evaluated interventions to improve HPV vaccine acceptance as a study outcome. Both Smulian et al. (2016) and Walling et al. (2016) reported a limited generalizability of results, a need for further research focusing on provider-based interventions, and a more diverse socioeconomic population to include more males.

The combination of evidence based educational interventions include the use of electronic medical alerts, and strong consistent provider recommendations as the most reliable and cost-effective measures to increase the uptake of the HPV vaccine in males. Researchers have reported text messaging, call, and mail reminders as a sole intervention displayed mixed results (Chao et al., 2015; Szilagyi et al., 2013). A multi-prong educational intervention to

providers that includes electronic medical and email reminders that improves adherence to the ACIP HPV vaccine guidelines for the male population may increase the rate and completion of this immunization in order to reduce transmission of the virus that leads to HPV related cancers.

### **Purpose**

The purpose of this quality improvement project was to improve HPV vaccine initiation rates by 5% in males ages 11-21 during the project period. Specific objectives were: 1. To evaluate the impact of an educational intervention on HPV vaccine rates in males aged 11-21, and 2. To identify which of the three interventions in hierarchical order, were most beneficial to providers.

### **Theoretical Framework**

Roger's Diffusion of Innovation Theory (Kaminski, 2011) consists of four key elements: innovation (intervention), communication (transfer of knowledge), time (time to diffuse or accept), and a social system (organization). These elements flow through a five- stage process, which includes knowledge, persuasion, decision, implementation, and confirmation. This theory framed the researcher's approach to the quality improvement project in the following steps. First, pediatric providers were introduced to the intervention during a presentation on techniques to improve HPV vaccine initiation rates in males aged 11-21. Details of the approach to be used for improving vaccine rates were discussed at that time with the anticipation that vaccine rates might improve. The analysis of the data would then lead to confirmation or rejection of the innovation. This approach has been described as a useful method for instituting change in practice (Kaminski, 2011).

## **Methods**

This quality improvement (QI) project used a quasi-experimental design to investigate rates of HPV vaccine initiation before and after a provider-focused intervention. Vaccination initiation rate data were collected at two time points, pre-and-post intervention. The QI project consisted of an educational slide show presentation to pediatric providers that informed them of an overview of the project, past HPV vaccine rates, common barriers to vaccination and interventions and to improve HPV vaccine initiation rates.

### **Sample and Setting**

The sample was comprised of 13 pediatric providers employed at three pediatric practices that serve a diverse ethnic socio-economic population in northeastern Massachusetts. The provider mix consisted of eight board-certified pediatricians and six certified nurse practitioners who were employed from May of 2016 through September of 2017 and who consented to participate in the project. Provider data included, sex, years of experience, and provider type (Table 1). The cohort of interest for the QI project consisted of convenience sample of males aged 11-21 who presented for care between June and September 2017 and who had not initiated the HPV vaccine series (Table 2). Exclusion criteria included males who have whose age lied outside the age range for the study, and males who did not present for care during the project time frame.

### **Procedure**

The QI project was considered received exempt status from the Institutional Review Board (IRB) at the University of Massachusetts Lowell. Informed consent from the pediatric

providers was obtained. Prior to the implementation of the project, de-identified HPV immunization rates for males ages 11-21 were collected for the time period of June through August of 2016. This cohort from the previous year served as the baseline comparison group. Next, providers attended an educational program that outlined the project and all provider interventions. During the educational program providers were given evidence-based culturally sensitive recommendations using the “You are the Key” and “Tips and Time Savers for Talking with Parents about HPV” (CDC, 2016). This was provided to assist in communication with vaccine hesitant parents. The aims of the presentation were to address the health care disparities of vaccination rates and focus on techniques to improve the HPV vaccine rates among males aged 11-21. Providers were asked to take the time necessary to succinctly discuss with parents/patients their recommendation for the HPV vaccine during the office visit.

Following the intervention, the nurse practitioner leading the project worked with the information technology department to develop and implement a care alert within EMR of males ages 11-21. This care alert notified providers during an office visit that the patient was due for an HPV vaccine. Parents of males ages 11-17 or males 18-21 also received culturally competent, bilingual, HPV educational information from the CDC containing frequently asked questions about HPV at the vaccine check in to all appointments. Monthly HPV initiation vaccine rates for June, July and August 2017 were obtained from the EMR and emailed to providers. This provided an update for individual provider progress. Overall HPV vaccine rates for the practice were also included to demonstrate progress toward meeting the 80% vaccination rate goal set by the CDC.

## Data Analysis

Descriptive statistics were gathered and analyzed to evaluate the characteristics of the providers and the cohort of interest. A two-sample t-test evaluated the difference in pre- and post-intervention male HPV vaccine initiation rates. Providers ranked the quality improvement interventions in hierarchical order according to the level of worth in improving HPV vaccine initiation rates.

## Results

Thirteen pediatric providers, which represented 100% of the eligible providers at the practice, participated in the *Educational Intervention to Increase HPV Vaccine Initiation Rates in Adolescent Males*. See table 1 for the characteristics of the provider sample. The cohort of interest consisted of 520 eligible males aged 11-21 who had not received the HPV #1 vaccine. These adolescents represented urban and suburban communities in northeastern Massachusetts. The mean age of the males in this cohort was 13.13 years in 2016 and 13.04 in 2017. Private insurance, (Aetna, Blue Cross Blue Shield, Harvard Pilgrim, Tufts, Unicare, and United Health Care) and state funded insurance providers (Medicaid, Neighborhood Health Plan, Network, Boston Medical Center, and New Hampshire Medicaid), represented the main sources of payment for care. The characteristics of the cohort are seen in Table 2.

Following the educational intervention, the EMR intervention and weekly e-mails, HPV vaccination rates in males 11-21 increased by 6.5% surpassing the targeted increased rate of 5%. June through August of 2016 served as the baseline comparison. During this time, the HPV vaccine initiation rate for the providers in this study was 38.5%. Post-intervention, the HPV vaccine initiation rate for June through August of 2017 (following year) was 45%; this rate

continues to fall short of the Healthy People 2020 goal of an 80% vaccination rate. See Table 3 for the number of HPV vaccines administered during the project time periods of 2016 and 2017.

A two-sample t-Test compared the mean number of initial HPV vaccines given pre-and post the educational intervention. Although there was improvement in vaccine initiation, there was no significant difference in HPV vaccine initiation rates pre-and post-intervention, ( $t\text{-stat} = -1.33$ ,  $p = .09$ ). A comparison of the HPV vaccine initiation rates per provider demonstrated overall positive results pre-to post-intervention with vaccine initiation rate gains ranging from 4% to 34% that yielded overall HPV vaccine initiation rates per provider from 17% to 87%. A secondary objective for the quality improvement project included evaluation the effectiveness of the educational intervention, the EMR prompt, and the email reminders. Figure 1 describes the perceived effectiveness of each intervention.

### **Discussion**

This QI project was designed to increase HPV vaccine initiation rates among males aged 11-21 in line with ACIP guidelines to meet Healthy People 2020 goal of an eighty percent vaccination rate. An educational intervention was implemented for pediatric providers using evidence-based interventions to reduce barriers to HPV vaccination. Despite the small sample size of pediatric providers ( $n=13$ ), this increase of successful recommendations of the HPV vaccine post-intervention is an important step in health promotion and disease prevention for adolescent males in two key areas. The reduction of barriers associated with HPV vaccination with a diverse sociodemographic population suggests that bringing issues to the attention of experienced providers can improve practice. Although the impact of the educational intervention on HPV vaccine initiation rates among the cohort of interest was not statistically significant ( $t\text{-stat} = -1.33$ ,  $p = .09$ ), the findings are clinically important.

The EMR prompt within the health records of the cohort of interest was widely accepted and reported by the providers as the most effective part of the intervention to increase initial HPV vaccine rates. This prompt was positioned in the charts as an alert that appeared upon opening of the health record. It remained present at the top of the screen until that record was closed, reminding the provider to view the vaccine record. The presence of this alert within the chart may have increased provider viewing of the vaccine record within the chart.

Introduction of evidence-based research to the pediatric providers in the form of a one-time presentation as an intervention to improve HPV vaccine initiation rates among the cohort of interest paralleled results documented in previous research (Bundy et al., 2013; Fiks et al., 2013; Perkins et al., 2015). Researchers have stated few providers report implementing evidence-based tools to increase HPV vaccine uptake (Scherr, et al., 2016; Alexander, et al., 2016). Evidence from public health researchers has shown repeated exposures to an intervention may be necessary to produce significant results (Das, et al., 2016). Repeated exposures to evidence-based research may be needed for providers to make practice-wide changes such as offering the vaccine as a bundle with the Tdap and Menactra vaccines at pre-teen physicals, focusing on the cancer prevention benefits of the vaccine, it's safety, and efficacy, and checking vaccine records at every office visit (Perkins, et al., 2015). Repeat exposures of interventions may also facilitate participant willingness and involvement in the educational intervention, hence yielding superior HPV vaccine results (Perkins, et al., 2015).

Researchers have reported that parents look to the provider for guidance and recommendations of this vaccine for their sons' although less than 30% of providers nationally are routinely recommending this vaccine to males (Burdette, et al., 2016). The CDC reported in 2016 that the national HPV vaccine initiation rate for males was 50% and the rate for

Massachusetts males was 63% in 2015 (CDC, 2016). Providers who care for adolescent and young adult males need to increase their recommendation of the HPV vaccine to reach the 80% vaccination rate goal to reduce the risk of HPV related cancers.

This group practice serves an ethnically diverse socio-economic population with an insurance mix of 50% private and 50% state funded insurances across urban and suburban settings. Greater than 500 males aged 11-21 presented for care during the intervention and baseline three-month time periods. The HPV vaccine initiation rate increased 6.5 % over the 12-week project period with provider HPV vaccine initiation rate increases of 4% to 34%. One hundred percent of eligible pediatric providers participated in this QI project that utilized vetted CDC educational materials. The effectiveness of each of the pediatric offices and the ability of providers to adapt to QI measures influenced the success of the project.

Based on the results from this QI project, small gains can be made over a short period of time to improve HPV vaccine initiation rates among adolescent males. These findings will offer the participating pediatric providers an analysis of their own clinical practice of HPV vaccine initiation among adolescent males that will hopefully facilitate expansion of vaccine administration. These pediatric providers may benefit from long term implementation of the EMR prompt within the electronic health records to alert providers at all office visits of vaccine that are due.

### **Limitations**

HPV vaccine initiation follow up data after the conclusion of the twelve-week QI project was not collected and therefore it is not known if the HPV series was completed. The use of a convenience sample for the eligible males, the length of the project time period, and the small sample size (n=13 providers) affected the statistical significance of the vaccine rate results.



Limitations within the quality improvement intervention also occurred. The effectiveness of the one-time, thirty-minute presentation may not be adequate to sustain improved practice. Lastly, the group practice as a whole does not have a vaccine policy in place requiring non-mandated vaccines and the diverse sociodemographics of this region in Massachusetts may require additional reassurances from their primary care pediatric provider prior to vaccine acceptance.

### **Conclusion**

Quality improvement measures are the future for providing economically responsible health care that focuses on health promotion and disease prevention. A low-cost educational intervention to pediatric providers that improved the HPV vaccine initiation rates among males aged 11-21 may be an example of providing this type of care. The EMR prompt is a low cost, environmentally friendly, and easy to implement intervention that was widely accepted by the provider sample participating in the QI project. This intervention placed within the EMR of the cohort of interest alerted the providers with repeated reminders to offer the HPV vaccine during an office visit. Researchers have identified modifications in the electronic health records that may increase HPV vaccination rates and series completion if used effectively (Bundy et al., 2013; Fiks et al., 2013; Perkins et al., 2015).

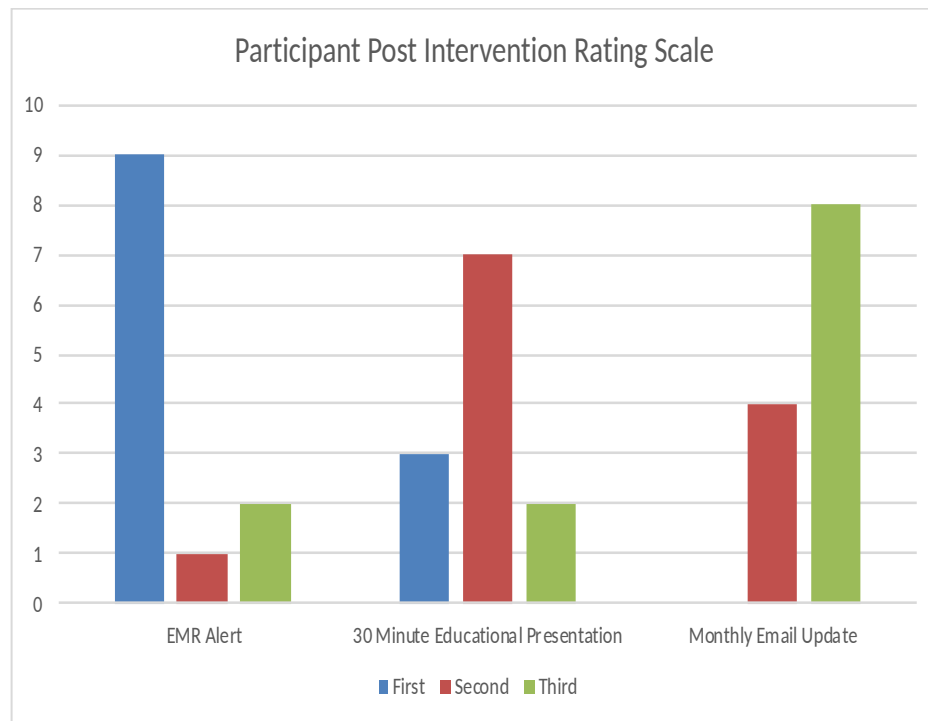
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## Appendix D



*Figure 1* Participant Post-Intervention Ranking Scale. Intervention effectiveness per provider using First-Most Effective, Second-Moderately Effective, and Third-Least Effective rankings.

## Appendix A

*Table 1*

*Provider Sample Years of Experience 2017 and Descriptive Statistics*

Provider Sample	Years of Experience
Mean	25.53
Standard Deviation	12.76
Range	46.00
Minimum	2.00
Maximum	48.00

*Appendix B*

*Table 2*

*Descriptive Statistics Cohort of Interest*

<i>Patient Age</i>	<i>2016</i>	<i>2017</i>
<i>Mean</i>	<i>13.13</i>	<i>13.04</i>
<i>Standard Deviation</i>	<i>2.78</i>	<i>2.56</i>
<i>Range</i>	<i>9</i>	<i>9</i>
<i>Minimum</i>	<i>11</i>	<i>11</i>
<i>Maximum</i>	<i>20</i>	<i>20</i>
<i>Population size N=</i>	<i>251</i>	<i>268</i>
<i>Insurance Provider Percent</i>		
<i>State</i>	<i>43%</i>	<i>50%</i>
<i>Private</i>	<i>57%</i>	<i>50%</i>

## Appendix C

Table 3

*Comparison of HPV #1 Vaccines Administered to Males June through August 2016 and 2017*

June through August	2016	2017
Number of HPV #1	97	121
Total Males	251	271
Percent Vaccinated	38.5%	45%



## Author Ethical Statement

We wish to confirm that there are no known conflicts of interest associated with this publication and there has been no financial support for this work that could have influenced its outcome.

We confirm that the manuscript has been read and approved by all named authors and that there are no other persons who satisfied the criteria for authorship but are not listed. We further confirm that the order of authors listed in the manuscript has been approved by all of us.

We confirm that we have given due consideration to the protection of intellectual property associated with this work and that there are no impediments to publication, including the timing of publication, with respect to intellectual property. In so doing we confirm that we have followed the regulations of our institutions concerning intellectual property.

We further confirm that any aspect of the work covered in this manuscript that has involved either experimental animals or human patients has been conducted with the ethical approval of all relevant bodies and that such approvals are acknowledged within the manuscript.

We understand that the Corresponding Author is the sole contact for the Editorial process (including Editorial Manager and direct communications with the office). She is responsible for communicating with the other authors about progress, submissions of revisions and final approval of proofs. We confirm that we have provided a current, correct email address which is accessible by the Corresponding Author and which has been configured to accept email from lisa\_marchandciriello@uml.edu.

Signed by all authors as follows:

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