



HPV vaccination uptake among those at greatest risk: Lessons learned from the field

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Presenter Disclosures


Colleen Crittenden Murray

The following personal relationships with commercial interests relevant to this presentation existed during the past 12 months:

Girls OnGuard was an Industry-sponsored grant with Merck, Inc.

Background

- Genital HPV is most common STD in the US
 - 14 million males and females newly infected annually
 - Over 80% of sexually active women are exposed to the virus within 3-4 years after first sex
- Approximately 75% of sexually active individuals will become infected in their lifetime



HPV Vaccine Uptake

- Rates are low, particularly among adolescents
- Only 53% of female adolescents 13-17 received one or more doses of the HPV vaccine and only 34.8% completed the 3 dose series (2006-2011 NIS)
- Racial and ethnic disparities exist in uptake
 - African Americans are less likely to initiate and complete vaccine series
 - African Americans are more likely to become infected, develop cervical cancer, and experience mortality from cervical cancer



What is Needed?

- To meet the needs of those at greatest risk, evidence-based interventions are needed
 - Novel
 - Innovative
 - Culturally-tailored
 - Theory-based
 - Multi-component
 - Cost-effective
 - Acceptable and adaptable
 - Effective in enhancing the adoption of health promoting behaviors



Purpose of Study

- To conduct a randomized controlled trial to test the efficacy of a theory-based, multi-component computer delivered media-based intervention, Girls OnGuard
- Main objectives:
 - Evaluate the efficacy of Girls OnGuard, relative to health promotion comparison condition, in enhancing uptake of Gardasil
 - Evaluate the efficacy of Girls OnGuard relative to the health promotion comparison condition, in enhancing compliance with receiving second and third doses



Theoretical Framework: Application of IMB Model

Enhancing Information


- Awareness of HPV infection among African American girls
- Correlates of HPV infection and benefits of HPV vaccination
- Factors influencing HPV vaccination acceptability

Increasing Motivation

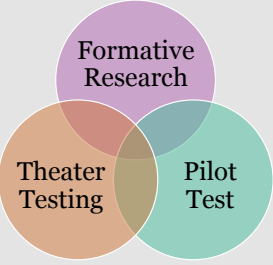
- Greater perceived susceptibility to acquiring HPV infection
- Higher perceived severity of HPV infection
- Perceived effectiveness of vaccine to prevent HPV infection
- Physician recommendation for HPV vaccination
- Familial acceptance of vaccination to prevent HPV infection
- Peer norms supportive of vaccination to prevent HPV infection

Introducing Behavioral Skills


- Modeling – observing same age, race, and gender adolescents obtaining vaccination
- Increasing confidence to obtain vaccination



Methods used to Develop Girls OnGuard




The diagram consists of three overlapping circles. The top circle is purple and labeled 'Formative Research'. The bottom-left circle is orange and labeled 'Theater Testing'. The bottom-right circle is teal and labeled 'Pilot Test'. The circles overlap in the center and at the intersections of two circles.




Intervention Development: Lessons Learned

- Formative data collected suggested:**
 - Lack of understanding about HPV and vaccination
 - Open-minded and interested in receiving additional information
 - Inconsistencies among providers in terms of vaccine recommendations
- Theater testing revealed:**
 - Dialogue edits and phrasing changes were needed to finalize content of media intervention
 - Information content was perceived to be useful, practical, and relevant
- Pilot testing indicated:**
 - Participant acceptability of completion time
 - Content was realistic and interesting
 - Computer-based media intervention was relevant to age group




Intervention Implementation

Recruitment and Screening	Procedure
<ul style="list-style-type: none"> 2010 – 2012, 5 health clinics in Atlanta Eligibility: <ul style="list-style-type: none"> Female Self-identify as African American 13-18 years of age at time of enrollment Unmarried Seeking reproductive of STD services Have not previously received HPV vaccine Provide written consent/assent and HIPAA when applicable 	<ul style="list-style-type: none"> ACASI (Audio-Computer Assisted Self-Interview) Survey Randomization Watch computer delivered intervention or comparison video All participants received standard-of-care counseling according to clinic protocol




Measures

- Quantitative data examined was collected using ACASI and medical chart abstraction 7-months post randomization
- ACASI measured:
 - Sociodemographics, sexual history, awareness of HPV and cervical cancer, perceptions about vaccines in general and the HPV vaccine, risk compensation, HPV vaccine acceptability, and normative beliefs
- Primary outcome:
 - Receipt of Gardasil vaccination
 - Completion of series
- Secondary outcome:
 - STI incidence during 7-months post randomization



Analysis (N=216)

- Descriptive statistics evaluated distribution of participants with regards to variables assessed in ACASI and primary/secondary study outcomes
- Bivariate analyses were conducted to test variables for possible inclusion in regression models
- Confounding factors were also assessed
- SPSS version 21 was used to perform all analyses



Primary Outcomes (N=204)

- **Primary (initial vaccination and completion of series):**
 - Only 12% of study participants (n=24) received at least 1 dose of the HPV vaccine
 - Equal number of adolescents in intervention and control groups
 - Of those who were vaccinated, more intervention participants were compliant with the series than controls
 - Intervention participants received more total doses of the vaccine (26 vs. 17 doses), $p=.12$



Secondary Outcomes (N=204)

- **Secondary (STD incidence):**
 - More intervention participants tested positive for STDs (50.9%, n=29/57 vs. 34%, n=18/53), $p=.075$
 - Collectively, there were more positive STD diagnoses in the intervention group (54 positives) vs. the control group (47 positives) 7-months post randomization, these diagnoses were not mutually exclusive
 - There were no differences between the total number of positive STDs among individual participants in the two study conditions ($M=.50$, $SD=.83$, range 0-4 positive STI diagnoses per individual, $p=.452$)



Summary

- This study is among the first to evaluate a brief, computer administered culturally- and gender- tailored intervention to enhance Gardasil uptake among a high-risk population
- Demonstrated feasibility of computer-administered media-based intervention in clinical setting
- Although not statistically significant, we observed greater uptake of Gardasil among adolescents in the intervention condition
- Overall vaccine uptake was low



Summary Continued

- Unique to this study, we eliminated financial barriers and created a targeted intervention
- So, why was uptake so poor??? Million dollar question!
- There may be other salient barriers to HPV vaccination for this population



Implementation and Evaluation: Lessons Learned

Implementation

- Clinic-based interventions are feasible but traditional clinic hours are not totally conducive to reaching adolescents
 - Transportation issues
 - Interference with school
- Longer intervention may have been needed
- Factorial design to disaggregate components on the intervention could have been helpful
- More visual emphasis may have been needed from provider's perspective to build trust and increase credibility



Implementation and Evaluation: Lessons Learned

Evaluation

- Need tracking system in place to better monitor/evaluate vaccine doses outside of those at partnering clinics
- Rethink randomization procedure in order to help assure study groups are equivalent
- The addition of a follow-up assessment would have been both useful and beneficial
 - To help clarify what the most influential factor was for more intervention participants receiving vaccination
 - To understand what happened during provider visit
 - To know how perceived susceptibility changed post-intervention



Conclusions

- Feasibility of intervention was evidenced by high participation rate, 91%
- Acceptable to patients and clinic providers and can be implemented without adversely impacting clinic flow
- Must figure out how to monitor patient-provider interactions as this may have a profound impact on perceived susceptibility and whether adolescents elect to be vaccinated
- Further research is needed that elaborates on the methods from this study and expands on the duration of the intervention to truly enhance vaccine uptake in this vulnerable subgroup



Thank You!

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