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Taking an HPV Vaccine Research-Tested Intervention to Scale in a Clinical Setting

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Introduction

Research tested interventions are seldom ready for wide spread use [1]. Successful intervention design demands a user-centered and iterative approach [2] that often requires additional development to ready programs to be taken to scale. Here we describe the process of adapting a National Cancer Institute (NCI) research tested intervention program (RTIP) for HPV vaccination, “Women’s Stories”, [3] for implementation in Planned Parenthood (PP) community clinics. PP was chosen because their clinic model offers a scalable infrastructure that is available in every state and they serve underserved populations who are most in need of access to preventive services. In contrast to the “build it and they will come model” commonly used in public health [4], we argue for starting with the end user and integrating the intervention into their existing system. In this manner, if evidence supports taking the intervention to scale, dissemination is built into the original design. This approach stems from a combination of product development and community-based participatory research practices [5,6]. We first offer a description of the original NCI-designated RTIP, provide a description of the adaptation phases, and conclude with a summary of challenges encountered and lessons learned.

Women's Stories: The HPV Project Intervention

The original intervention encouraged HPV vaccination among young adult college women ages 18-26 using video-based vaccine decision stories or narratives. The intervention was developed based on a Narrative Engagement Theory (NET) [7], which emphasizes eliciting health content from and with the target audience. A video was developed portraying five prototypical vaccine decision stories. The stories include: a susceptibility story, a self-efficacy re-enactment, a story that speaks to the safety of the HPV vaccine, a cue-to-act dorm room discussion re-enactment, and a physician narrative disclosing a personal mother-daughter conversation. The intervention was tested in a randomized controlled trial at one university where it nearly doubled vaccination and was subsequently designated by NCI as a RTIP [3,8].

After the successful initial college study resulting in the RTIP, the developers sought to adapt the intervention to reach underserved women who had lower rates of HPV vaccination and higher rates of late-stage cancer [9-11]. This led to a partnership with PP that started with Planned Parenthood of Southeastern Pennsylvania (PPSP), which serves a diverse clientele through twelve clinics [12]. Initial collaboration began with one PPSP clinic who serve predominantly African-American women many of whom are Muslim. Moreover, the PPSP community clinic serves young adult women who may or may not be attending college. Thus, initial efforts were focused on adapting the intervention content to resonate with these young adult women.

Informant interviews were conducted with the intended target audience to identify relevant vaccine decision narratives that would be perceived as authentic with local community members

who attend the PPSP clinic.

Adapting the Intervention to a Community Clinic Context

The adaptation process consisted of five phases. The first two phases focused on adapting intervention content, whereas the latter three phases involved adapting the intervention to the clinic setting.

Phase I: Informant Interviews

Procedure & Data Analysis: Informant interviews (N=26) were conducted in person with PPSP clients ages 18-26 at PPSP onsite counseling offices to elicit vaccine decision narratives and identify motivations that led to vaccinating. Both vaccinated and unvaccinated women were recruited from PPSP clinic waiting rooms asking women if they would participate in an interview prior to their clinic visit to talk about their vaccine decision. Women received \$20 as compensation for their time. Only women were recruited given that PPSP predominantly serves women and not men. An experienced African-American interviewer recruited women on site at the clinic and conducted the interviews aimed at eliciting decision stories to understand motivations and barriers to HPV vaccination among young adult women. Women were also asked for feedback about how best to design a health kiosk that would be placed in the waiting room to educate women about HPV vaccination (pictures were shown of a health kiosk to prompt discussion). Interviews were audio-recorded and transcribed verbatim with identifying names removed and pseudonyms replacing names. Data were analyzed initially using cultural grounding methods [13,14] identifying emergent codes derived directly from the data.

Subsequently, the research team coded the data at a second, more abstract level for emergent prototypical decision stories using prior established methods [15]. The research team additionally used a constant comparison method [16] to discuss and compare prototypical decision stories. Details of the phase I interviews are provided in a separate manuscript [17].

Findings: Eight vaccine decision stories were identified as prototypical among African-American young adult women attending PPSP: (a) HPV (un)awareness, (b) wanting to stay healthy, (c) practitioners not mentioning HPV, (d) keeping female reproductive parts healthy, (e) including men in vaccine messages, (f) experiencing an abnormal Pap smear, and (g) cancer stories [18]. An example decision story among a vaccinated woman illustrated the importance of cues women take from their clinicians: “I’ve been talking to my primary care provider since I’ve become sexually active. She told me different ways to prevent...just different things from happening. She gave me information about the HPV vaccine. She said it was good to get. You never know who has it. It’s good to be aware. She told me about it preventing cancer. She told me a little bit not a lot.” Most unvaccinated women had not received HPV vaccine recommendations from their clinicians.

Interviews also elicited additional feedback about familiarity with and use of health kiosks in waiting rooms, and receptivity to receiving vaccine reminder messages on Smartphones. Women were more familiar with food kiosks used in gas stations or coffee shops and less familiar with health kiosks, but expressed a willingness and interest in using health kiosks in the waiting room.

Clinic Staff Interviews: Two staff were interviewed to share their understanding of how the HPV

burden is perceived among their patients and how HPV vaccine communication is handled at their clinic. They noted one of the biggest problems is a lack of education among PP clientele. Patients are unaware of HPV and lack an understanding of the severity of HPV if it advances. Interest in the vaccine commonly occurs after being exposed to HPV. Staff acknowledged that the biggest problem was the lack of opportunity to educate patients prior to exposure to infection, including men who come in for routine screening. Obtaining insurance coverage was noted as another major obstacle. The vaccine is too expensive for patients to pay out of pocket and obtaining insurance coverage, which often must be sought during or immediately after a clinic visit (on the spot), can be insurmountable. For example, sometimes patients are seen during clinic times when insurance offices are closed (Saturdays, or weekday evening hours). Other times, patients are simply unwilling to wait for the time it takes to receive insurance approval. Further, while the Affordable Care Act (ACA) covers HPV vaccination for women aged 18 to 26 and men aged 18-21, insurance stipulates that vaccination is covered only when delivered by the primary care provider in many cases. PPSP is often not the primary care provider and consequently, patients experience insurance barriers. This in turn contributes to PPSP practitioners not routinely mentioning or recommending HPV vaccination.

Phase II: Translating Decision Narratives into Prevention Messages

Developing the Intervention Videos: Prototypical vaccine decision narratives were translated into four scripts creating composite narratives using previously established procedures [19]. The research team discussed the identified prototypical scripts (from Phase I data analysis) that would lend themselves to the intervention with consideration of practical elements; for example,

that stories needed to be told and delivered within short one minute video stories delivered on a health kiosk in a waiting room, the use of multiple stories from which women could choose, and the inclusion of men in at least one story. Also, a balance was needed between ensuring engaging stories that were authentic and kept women's attention while keeping fidelity with medical accuracy. Given the low awareness of HPV, it was collaboratively decided that one of the four decision scripts needed to be tailored to an audience with little or no HPV knowledge. Thus one decision story was developed for "beginners" who had either never heard of HPV or knew little about it. The decision story was delivered as a monologue in which a young woman retells a story about her cousin who was unaware of HPV and the vaccine. The monologue retells how the cousin initially declined vaccination because she did not know what HPV was, how the cousin learned about cancer risks associated with HPV from her sister, and that she re-considered and eventually vaccinated against HPV.

[INSERT FIGURE 1 ABOUT HERE: screenshot image of close-up face shot of woman (monologue) & screen description]

The remaining three scripts convey: (1) learning about the real risk and potential consequences of HPV through a conversation between two female friends (kitchen conversation); (2) learning about HPV and cancer risk for men through a conversation between a male and female friend (park bench conversation); and (3) learning about doctors' strong support for vaccination through a physician strongly endorsing HPV vaccination to a young women during a well-visit when she shares she is considering becoming sexually active. Each narrative ends with reinforcement messages that exemplify the themes: Be Protected, Ask your doctor about the HPV shot, Talk to

your friends about getting vaccinated for HPV.

[INSERT FIGURE 2 ABOUT HERE: graphic intervention screenshot of 4 stories]

Piloting Scripts: The four scripts were pilot tested with 12 female PPSP clients ages 18-26.

Women were recruited from the waiting room, screened for eligibility, read scripts, completed a survey that assessed their level of engagement, and answered interviewer questions about what they did and did not like, and provided suggestions for improvement. Women completed a 9-item measure of engagement with items drawn from the Narrative Engagement Scale [20] and from the Audience Engagement Scale [21]. Responses used a 5-point Likert scale ranging from strongly disagree to strongly agree. The survey captured the extent to which women found the scripts interesting and believable, and to what extent scripts led to personal reflection and critical thinking about vaccination. The interviewer also asked women to indicate what they did and didn't like about each script with suggestions for improvement.

Findings: Findings are summarized in Table 1 and based on them further edits were made to scripts to reflect findings from the target audience.

Phase III: Health Kiosk Interface Design

Procedure: The next step was to design an interactive, engaging interface. The research and technology development teams worked collaboratively to create a prototype. Input not only from the research team, but from Phase I informant interviews was integrated into the interface design.

Women in phase I had been shown a picture of a prototype health kiosk and were asked to comment how the kiosk could be designed to engage women in the waiting room.

Findings and Product Revision: Women wanted the kiosk to be visually informative with clear signage about what the kiosk was about. Women also said that bright colors should be used to attract attention and that the kiosk screen and menu should be interactive. Finally, given that many women were less knowledgeable about female reproductive anatomy, they wanted a female reproductive graphic to explain where the cervix is and how HPV can affect the cervix. The research team consequently designed the kiosk interface to include an interactive female anatomy graphic that allowed users to learn more about how HPV affects the cervix by interfacing with the graphic and having information cartoon bubbles shoot out from the graphic.

[INSERT FIGURE 3 ABOUT HERE: kiosk interface of female anatomy with talk bubble]

Touchscreen fact bubbles (like cartoon bubbles) were generated from the anatomy when touching the kiosk screen. A user-friendly interface allowed women to navigate freely between the videos and the health information based on user-centered design research showing that user satisfaction is higher with this kind of design [22]. User interfaces (kiosk screens) that allow users to navigate freely (as opposed to being directed to information) through the menu and self-select what information and the order in which users choose to view and read information results in higher user satisfaction [23].

A key challenge was signage to bring users to the kiosk. A balance was needed to avoid the

potential stigma of using an STD-related kiosk while at the same clearly conveying to users the kiosk's purpose. A group decision involving the entire study team was made to have the signage focus on women's health (signage was placed above the kiosk screen) avoiding potential stigma to use the kiosk (due to possible embarrassment if labeled as HPV) and to avoid causing any potential psychological damage.

[INSERT FIGURE 4 ABOUT HERE: picture of health kiosk]

Phase IV: Usability Study

Procedure: A usability study was conducted (N=16) at the clinic by an independent researcher. Forty-one women were approached with sixteen women meeting criteria and volunteering. In a private office they used the kiosk navigating its interface and the female anatomy graphic followed by watching all four videos. Feedback was obtained about content, ease of use, and audio. Participants also completed a survey measuring usability metrics (see Table 2).

Findings: The kiosk was easily implemented, experienced no technical problems, and was evaluated positively by women using it. It was anticipated that women would use the kiosk in the clinic waiting room and benefit from the experience.

Phase V: Waiting Room Observational Study

Procedure: A waiting room observational study was conducted over two days to evaluate actual

kiosk use. The kiosk was placed in the waiting room, and a research team member observed kiosk use and general behavior over two days.

Findings: Several problems were observed during this phase. First, the kiosk screen went into “sleep mode” and patients thought the kiosk was off. Second, routine, normative waiting room procedures included checking in at the front desk and then sitting down. Most patients sat quietly and used their cell phones or watched the TV while waiting. One woman briefly glanced at the kiosk but most women did not notice it. This was the case during both low and high volume times. Thus, no women utilized the kiosk on the first day.

To better understand this situation, eight women were approached and asked why they did not use the kiosk and what would motivate them to use it. Responses included “I didn’t notice it”, “I didn’t know what it was about”, and “It didn’t look like it was on” but said they would use it if staff prompted them. On day two of observation the receptionist prompted women to use the kiosk during check-in. Even with prompting, the kiosk was not used. While this was surprising given the prior day’s feedback, observations and interviews with staff revealed several considerations. Some women were already vaccinated, giving them little motivation to walk up to the kiosk. Also, the prompt by the receptionist came at the end of lengthy discussions about forms patients needed to complete. Finally, a PPSP research assistant spent an additional third day more directly prompting clients to use the kiosk. She explained that PPSP was testing the kiosk and looking for feedback. This approach was successful in getting clientele to use the kiosk.

Lessons Learned and Challenges in Adapting Prevention Interventions

Taking evidence-based intervention (prevention) programs to scale involves fast-tracking a series of steps that serve critically important goals for not only advancing science but for advancing the translation of science into clinical practice settings.

Lessons Learned from Adapting Women's Stories: The HPV Project

Whereas content adaption was a smooth process given our well-established methods [24] , the delivery platform and clinic setting posed several challenges. The most notable challenge was overcoming clients' normative waiting room behavior despite their positive feedback and assurances they would use the kiosk. This lesson underscores the importance of including observational studies when adapting an intervention to a new setting, as what people say they are interested in and willing to do does not necessarily translate into actual behavior in real-world settings.

Questions about appropriate platforms for delivering prevention interventions in the clinic setting is a reoccurring theme [25]. The pace at which digital technologies and intervention platforms change challenges effective and practical intervention development [26]. For successfully adapting a prevention intervention to a new setting, evaluating *all* implementation phases ensures the greatest likelihood of successful adoption. It also allows program developers to explain *which* aspects of adaptation prove to be obstacles, facilitators, or neither. Because of this study, our plans include integrating the intervention into established clinical practices; in particular,

integrating the intervention into check-in and exam room procedures to insure its use. We are also considering transforming the intervention into an independent e-learning module and an app that can be accessed on smartphones and tablets at the discretion of the individual.

Translational research is the study of how research findings are translated into programs, policy, and practice [27]. The “Women’s Stories” intervention is an excellent example of developing an evidence-based program to be used practically in the health care context. Within implementation science the nature and quality of how an intervention gets implemented is of great importance and two primary issues in implementation quality are fidelity and adaptation. Manualized interventions such as educational programs implemented by a health educator often suffer because the implementer does not teach the program as intended (i.e., lack of program fidelity), by leaving material out (“no video today!”), embellishing on material (insert fear message), or making adaptations to fit an intended audience [28]. The use of technology to deliver the “Women’s Stories” intervention overcomes these issues by delivering the program consistently each time without unnecessary revisions. Moreover, the need for adaptation to end users is not necessary because the end users were included in the design of the intervention.

Nevertheless, as the results of this study make evident, key questions regarding the sustainable uptake and adoption of this kind of intervention still remain. What are the most efficient means of getting the most patients exposed to the intervention in the clinical setting, while simultaneously considering the constraints of clinic resources such as time and money? If the target audience does not access the technology or use it correctly, fidelity is moot. A next step for “Women’s Stories” involves integrating the intervention into clinic check-in procedures, thus

ensuring exposure; but, what impact will this have on patient wait times? These and other questions are essential to answer as we continue in our translational efforts.

DRAFT

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