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Title of Project
A qualitative exploration of opinions regarding the provision of school-based human papillomavirus (HPV) education for middle adolescents (15-17years) in Northern Ireland

Lay summary of the project
There are 600,000 cases of HPV-associated cancers annually, the majority being cervical cancer and oropharyngeal cancer, where radiotherapy forms a major component of definitive treatment.

Despite the implementation of school-based HPV vaccination programmes, educational interventions are inconsistent and largely directed at parents of 11-13 year olds. As the average age of first sexual intercourse is 15-17 years old, a second educational intervention for middle adolescents could have a strong impact on HPV/cancer prevention.

This project will explore perceptions of current HPV education in secondary schools in Northern Ireland for adolescents aged between 15-17 years old. Through this project we will gather opinions from students, teachers, and nurses regarding the design and implementation of an appropriate intervention for this age range. This will involve conducting focus groups with students and teachers in secondary schools in Northern Ireland and nurses involved in the HPV vaccination programme.

Principle Aims:
This project aims to utilise feedback from a variety of stakeholders, current relevant literature and behavioural science theories and models, to design a HPV educational intervention, which is appropriate for middle adolescents in secondary schools in Northern Ireland. This will involve conducting focus groups with students and teachers in secondary schools in Northern Ireland and nurses involved in the HPV vaccination programme in secondary schools in Northern Ireland; the aim being to elicit their views on HPV vaccination and associated cancer education provision to middle adolescent students in secondary schools in Northern Ireland.

Review of the literature and identification of current gaps in knowledge
Human papillomavirus (HPV) infection is the most common sexually transmitted infection of the reproductive tract[1,2] with the highest incidence occurring among teenagers and young adults[3,4]. Prophylactic HPV vaccinations, having the potential to prevent up to 90% of cervical, vaginal, and anal cancers[5], have been available for females since 2006[6] with many countries also introducing vaccines for males in recent years[5]. Religion[7,8], gender[9], socioeconomic factors[10], and ethnicity[10,11,12] have all been found to influence vaccination uptake.

School-based education programmes have been very effective in producing significant positive changes in HPV knowledge and sexual behaviour intentions[9,13-15] though they typically involve 9-13 year old adolescents. As a consequence of this young age, educational HPV programmes have tended to focus on educating parents rather than students as parents are usually the primary decision-makers in the process for this age group[16-20]. However, parents and education providers are often uncomfortable discussing sexual practices of adolescents[21] and are often concerned that promoting

HPV vaccines may have the effect of encouraging sexual activity among adolescents although there is no evidence to support this notion[22,23]. Consequently, the majority of adolescents who receive the vaccination have low awareness and knowledge about the HPV virus, especially regarding cancer risks[24]. Lack of parental acceptance of HPV vaccinations has been identified as being one of the main barriers of higher vaccine uptake[25,26].
Numerous countries report the average age of first sexual intercourse to be between 15-17 years old including the UK, US, France and Sweden[20,27-31] and therefore providing information regarding HPV risk is most relevant at this age, where adolescents are fundamentally more involved in decisions about their health and sexual practices[9,32]. Many economically developed countries, while providing the HPV vaccination, do not have national school-based programmes embedded in their curricula and therefore little information is provided regarding HPV at any point in the national school curriculum[33-35]. Consequently, it is estimated that adolescents 15-19 years old, still acquire 50% of all new STIs[36,37] and are at the highest risk of contracting the virus[14,38].

A systematic review of the literature[39], identified 15 English-language studies globally which explored the impact of school-based interventions on students, including middle adolescents 15-17 years old. All fifteen studies reported a significant improvement in their outcome measures post-intervention, including changes in knowledge, attitude and perception with regard to HPV vaccination and associated cancer prevention. However, only three of the fifteen studies explored the actual effect of the intervention on HPV vaccination uptake[3,40,41]. While Grandahl et al.[3] found that HPV vaccination uptake rates increased to a higher degree in the intervention group, Davies et al.[40] did not find any difference between their intervention and control groups. Davies et al.[40] proposed that, due to the HPV vaccination coverage being so high in both groups (>85% uptake), this finding could be related to a possible ceiling effect. In contrast to this, Grandahl et al.'s[3] pre-intervention vaccination rate was only 52.5%, increasing to 59% after the intervention. The third smaller study by Yoost et al.[41], reported that HPV vaccine initiation/completion rose from 38% to 71.4% 6 months post-intervention. Consequently, combined findings from these three studies, demonstrate the potential to increase HPV vaccination uptake rates through school-based interventions for this age range, especially in geographical areas where the initial vaccination uptake is quite low.

A variety of interventions were used through the 15 studies, with Davies et al's.[40] and Gargano et al's.[18] studies resulting in the most diverse and engaging interventions. For example, Davies et al.'s[40] intervention included an interactive lesson, take-home magazine, DVD with guide, app and website educational resources with relaxation methods to help increase the student comfort with the topic. Grandahl et al.[3], Davies et al.[40] and Gottvall et al.[42], while covering the aforementioned topics, also included education around sexual behaviour, condom use and transmission routes of infection. Gottvall et al's[42] intervention even involved practical teaching about use of condoms. All fifteen studies designed only one standard intervention despite sometimes having a wide age range of participants e.g. Gargano et al.[18] designed the same intervention for all students ranging in age from 11 – 18 years of age. Adolescence is a time of constant transition where major developments related to sexuality takes place[43] resulting in unique information needs at different ages in the adolescent spectrum. It is, therefore, paramount, that interventions are specifically designed to address the needs and interests of middle adolescents who have priorities that are different to their younger counterparts. Additionally, it is essential that this population play a key role in informing the creation of any proposed future intervention for this group.
The content of the interventions largely focused on cervical cancer with little discussion around oropharyngeal cancer, which has now become one of the leading HPV associated cancers globally[44]. Many adolescents who have not had vaginal intercourse, have engaged in sexual activity in the form of oral sex[45-47] but are unaware that HPV can be transmitted via this route[48]. Only a small number of studies[3,40,41,42] really encouraged the use of open dialogue around the important issues relating to sexual behaviour and HPV risk. In the eligible studies, the education intervention was taught by a

variety of professionals including teachers, healthcare professionals and the research team [39]. However, a recent review by Pound et al.[49], found that students often described their sexual education lessons with teachers as being clinical, with teachers often embarrassed to discuss issues like oral sex, and students equally reluctant to open up about private matters to their teachers. For this reason, the concept of peer education is an interesting one, though this was only explored in one isolated study[50].

Currently, there is no evidence that HPV education is being provided by schools in the UK to middle adolescents who are most likely to adapt their future health and sexual practice behaviours as a result of this education. They are also at an age where self-consent to vaccination is an option in the UK. This review demonstrates that even a short educational intervention with few resources can have a significant impact on knowledge and attitudes to safe sex and HPV vaccination, and potentially increase HPV vaccination uptake. However, interventions need to be adapted to this specific age group and include mixed genders. They should be sensitively constructed with input from students, teachers and the community[15]. Intervention designs generally lacked the incorporation of behavioural science theories in their development which can result in a more robust and engaging practical approach to education delivery[18,40,42].

Methodology

Design

Qualitative data will be captured from focus groups to ascertain attitudes regarding the current education provided to year 12 students (15-17 years old) regarding HPV vaccination, HPV associated cancers and self-protection against HPV acquirement. Studies found that teenagers preferred focus groups to individual interviews as they provided a more relaxed, less intimating environment, having their peers around them to offer additional support[51,52].

Participants

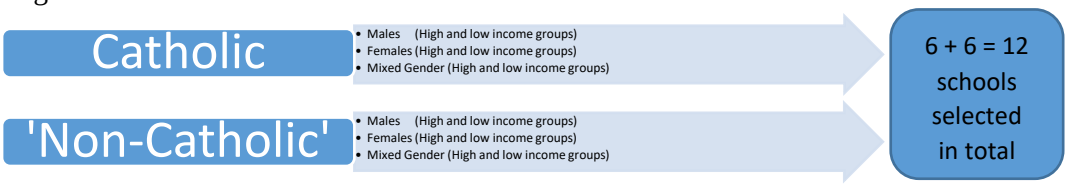
Individual focus groups will be created for the following 3 separate groups of stakeholders;
- Year 12 secondary school students (15-17 years old)
- Secondary school teachers
- Nurses involved in the administration of HPV vaccinations in secondary schools.

As 90% of qualitative themes are likely to be discoverable within 3-6 focus groups for each demographic characteristic[53,54] with ideal focus group size of 4-10 participants per group[53,55,56], the initial plan will be to aim for this number, acknowledging that additional groups may be required if data saturation is not reached, as recommended by Glaser and Strauss[53,54]. Two researchers from the research team, with interview training and experience, will be present during the focus groups; one to moderate and the second researcher to observe and take notes. Initial focus group discussion guides (Appendix 1) have been produced based on the recommendations of three primary research studies[53,55,57] but guides may be iteratively modified. Piloting of focus groups will be conducted internally with colleagues of the research team. A de-brief will occur immediately after each focus group to enable the guide to be iteratively modified to investigate arising issues in more depth. Focus groups of this nature generally last between 1-2 hours[53,55,57].

Sampling Strategy

As previously established, religion[7,8], socioeconomic factors[10], gender[9] and ethnicity[10,11,12] are all factors which have been found to influence the uptake of HPV vaccinations. In order to capture this range of diverse characteristics, Stratified Random Sampling will be used. Stratified Random Sampling is appropriate in qualitative research where the aim of the study is to generalise the findings from the sample to a population as it enables the researchers to select a sample that is random, large and representative[58,59]. The Department of Education in Northern Ireland lists 197 secondary schools which have been categorised by both religion and percent of pupils entitled to free meals[60]. The

percent of pupils entitled to free school meals provides a strong indicator of socioeconomic spread within any school. Female only, male only and mixed gender schools will be included to ensure gender diversity. Consequently, two strata will initially be created; 1 stratum where ≥ 50% of students are of Catholic religion and the second stratum where ≥ 50% of students are of 'Non-Catholic' religion.



A randomisation generator will then randomly choose schools from each of the 2 groups, until each group has selected 2 boys' schools, 2 girls' schools and 2 mixed gender schools with one higher income school and one lower income school in each group. This will result in the selection of 12 schools in total. Lower income groups will be defined as schools where >50% of students are entitled to free school meals and higher income groups will be defined as schools where ≤ 50% of students are entitled to free school meals. Two researchers will conduct this process together to retain randomisation integrity. Although ethnicity is another important characteristic, only around 29% of pupils in secondary school in Northern Ireland are considered to be of minority ethnic origin[61]. Therefore, data regarding ethnicity will be captured through demographic Information completed prior to each student focus group (Appendix 2).

Procedure for Contacting Schools

A phone call will be made to the principal or vice principal in each of the 12 randomised schools. This phone call will provide a brief overview of the study (Appendix 3), asking teachers if they would be willing to consider participating in this research. If they agree to consider participation in this study, then further information (Appendix 4) regarding the study will be sent via e-mail or post depending on preference. If there is no response by the return date, a follow-up phone call will be made to the principal/vice principal to confirm their interest in participation. If any school declines to participate in the study, then another school with the same characteristics will be drawn until 12 schools have agreed to participate. If a school agrees to participate in the study, then information, with permission, will be obtained regarding contact information for the community nurse team involved with the vaccination programme.

Focus Groups with Students

Students from selected schools will meet the inclusion criteria if they;
- are in Year 12 in secondary education
- are between the ages of 15-17 years old.
- have provided the appropriate consent (see Ethical Issues section for details)

The teachers, who will act as the gatekeepers, will be asked to promote participation through their classes and to display a poster (see Appendix 5) in suitable areas throughout the school. Through liaison with the gatekeeper, the PhD student researcher will provide verbal and written information to students, offering students the opportunity to ask questions. The following documentation will be provided at this time;

- a Participant Information Sheet [Students] (PIS) (Attachment 1)
- a Participant Information Sheet [Parents/Legal Guardians] (Attachment 2)
- a Student Demographic Information form (Appendix 2)
- a Student/Parent Consent form (Attachment 3)

During this information session, the PhD student researcher's contact details would be provided and subsequently students and their parents can then contact the researcher via e-mail to ask further

questions, set-up a video call or obtain a copy of any of the relevant documents. Parents will also be informed of this study through means deemed suitable by each school e.g. school app, newsletter etc. The PhD student researcher would then collect consent forms from the students a minimum of one week after the initial information has been provided. The preferred method for conducting focus groups with students is Face-to-Face (FTF) focus groups. FTF focus groups will take place in the school setting as this location is convenient for students, requiring no additional effort or cost and students may feel more secure and at ease in this environment. However, in consideration of the on-going COVID-19 outbreak, it is anticipated that circumstances may prevent FTF focus groups and therefore if FTF focus groups are not possible, due to government/school guidelines, computer-mediated (CM) focus groups will be conducted instead. Mounting evidence suggests that CM focus groups have the ability to generate the same number and variety of themes as FTF focus groups[62,63] and are suitable when discussing sensitive subjects, offering an environment for increased freedom of expression[64]. FTF focus groups or CM focus groups with students will be video-recorded with their consent. CM focus groups will be recorded via the online software Blackboard Collaborate™. The aims, format and Discussion Guide for student focus groups, are detailed in full in Appendix 1. An ice-breaker quiz for students is included which is detailed in Appendix 6.

FTF Student Focus Groups Format

Students will be invited to help themselves to a range of food and drink options including vegan, gluten-free and dairy-free options. The seats will be arranged in a circle around a table and the moderator will sit within the circle while the observer will sit a distance away from the circle. Once everyone is seated, the format of the session will be explained as previously described. Established support services (Appendix 7) and a Distress protocol (Appendix 8) is in place for any student who may become upset during this session.

CM Student Focus Groups Format

If FTF focus groups are not possible, then the students will receive a link to enable them to join a Blackboard Collaborate™ video call. The researcher will request that the students attempt this link with the researcher prior to the real focus group session to ensure effective connectivity. A link will be sent to participants with a time and date to join the discussion. Blackboard Collaborate™ software will enable powerpoint slides to be visible to all participants throughout the focus group. A distress protocol is in place for any student who may become upset during this session (Appendix 9).

Focus Groups with School Teachers

Teachers from participating schools will be invited to take part in a CM focus group with a maximum of 10 teachers, from a number of schools throughout Northern Ireland.
Inclusion criteria for teachers from selected secondary school includes;
- teachers with qualified teaching status who teach Relationship and Sexuality Education (RSE); Personal, Social and Health Education (PSH); and/or Biological Science
- Vice principal of the school
- Principal of the school

CM focus group format was chosen as it enables the research team to reach a wide geographical range of participants increasing opportunity for recruitment[57,65]. Participant information sheets and Consent forms will be distributed by post and electronically, to the vice principal/principal requesting that they distribute them to eligible teachers. The Vice principal and Principal of the school will also be invited to participate in these focus groups. The PIS will include background information of the topic and the aims of the focus group (See Attachment 4). A consent form will accompany this PIS (Attachment 5). Teachers will be asked to e-mail the researcher if they are interested in participating in a focus group. Prior to the focus group, those who consent to participate will be asked to review 3 resources which

are published by Public Health Agency in Northern Ireland (see Appendix 7). This will provide teachers with an overview of the current information regarding HPV. Demographic information for teachers will also be captured (See Appendix 10) prior to the focus groups. The aims, format and Discussion Guide for teacher focus groups, are detailed in full in Appendix 1.

Focus Groups with Nurses involved in School Vaccination Programme

A CM focus group format was chosen for nurses for the reasons previously stated.

The inclusion criteria for nurses in this study include;

- any qualified nurse who is currently involved in the delivery of the HPV vaccination programme in selected secondary schools in Northern Ireland.

The nursing team will be contacted initially by phone where a brief overview of the study will be explained asking if they would be willing to consider participating in the research (sample transcript; Appendix 11). Subsequently, an information letter (Appendix 12) will be posted or e-mailed to the team, along with copies of the PIS (Attachment 6) and Consent form (Attachment 7). The letter will explain that those interested in participating should e-mail the research team to set up a video call where the PhD research student will provide full details of the study. If there is no response by the return date, a follow-up phone call will be made to the team to confirm their interest in participation. Once participants consent, a doodle poll will then be used to select suitable dates and times for the CM focus group(s). The aims, format and Discussion Guide for nurse focus groups, are detailed in full in Appendix 1.

Procedure for Gaining Consent for Focus Groups

Participants will have a minimum of one week from the time that they are provided with the initial information to the time that they are asked to give their consent. Prior to conducting each CM focus group, participants will be required to have an individual Blackboard Collaborate™ video call with the researcher to review the PIS and Consent form and have the opportunity to ask questions. Participants will be asked to specify if they have any individual needs that should be considered in the running of the focus group and every effort will be made to accommodate these needs to ensure focus groups are fully inclusive. In the case of CM focus groups, participants should return consent form(s), by e-mail, to the researcher prior to the focus group. The Demographic Information will be captured via Qualtrics, which is licensed through Ulster University and offers a secure and anonymous format for providing this information. A link for the Qualtics questionnaire will be sent to the participants via e-mail. The link will explain that by completing the questionnaire, participants' are consenting to using this demographic information for this research. Additionally, implicit written consent for video-recording of the session will be required in the individual Consent forms. The presence of a second researcher facilities being with a participant who is experiencing distress or needs time out from the group. Blackboard Collaborate Ultra offers breakout rooms. The moderator can move a participant to a breakout room and join them in order to continue a private conversation and gain contact details in order to implement the distress protocol. The researchers will also stress to participants at the outset that any participant wishing to leave the focus group can do so freely at any time, without any explanation being required. See Discussion Guide questions (Appendix 1). Upon completion of each focus group, the sessions will be transcribed verbatim. After each focus group is complete, the researchers will have a debrief in order to support each other and to address any issues that may need attention for subsequent focus groups.

Personal and Public Involvement (PPI)

This proposal was reviewed by a peer reviewer and two secondary school prior to submission to the Ulster University Institute of Nursing and Health Sciences Research Governance Filter Committee. Participants who indicated on the signed consent form that they wished to be informed of the study findings, will be provided with a written summary of the study outcomes by e-mail or post (depending on their selected preference).

Impact of Study

The results of this study will help to inform the need, practicalities and overall design of a school-based intervention for middle adolescents to improve HPV vaccination uptake, knowledge and risk awareness. These findings, along with evidence from the literature, will inform the design of an intervention which will be piloted by the research team in the next phase of this project. The direct impact of this intervention may result in increased HPV uptake in this population, increased knowledge of HPV and changed behaviours to reduce risk of HPV-associated cancers. Results will be disseminated through peer-reviewed journals including 'Radiography' and apt conferences.

Ethical approval

This research study has obtained ethical approval from the Ulster University Institute of Nursing and Health Sciences Research Governance Filter Committee and is awaiting approval from ORECNI through the IRAS system. Given that one of the populations involved in this study is adolescents, additional safeguarding is needed to ensure the protection of young participants. Distress protocols have been established (Appendix 8 and 9) and a Disclosure Protocol is in place (Appendix 15) to safeguard all participants. Additionally, support services have been established for all participants as previously described (Appendix 7). Young persons ≥ 16 years old, can be presumed to have the capacity to self-consent without parental consent[69] and therefore for 16 and 17 year old students, only a student consent form is needed. In the case of a young person who is 15 years old, the research team will require both student consent and parental consent to enable participation. If a 15-year-old student is interested in participating but does not have parental consent, they would need to organise an assessment of competency with their school counsellor who would return the completed competency checklist[70] to a member of the research team (Appendix 16). This aligns with the guidelines published by NIDirect, which explains that the final decision to participate is legally the adolescents' as long as they are deemed to understand the issues in giving consent[71,72]. Given that parental lack of acceptance of HPV vaccination is one of the main barriers for high HPV vaccination uptake[25,26], it is important to enable competent young adolescents to participate in this research if they choose to do so with full knowledge of the implications. If the school and research team are made aware of any conflict arising between a student and parent from this study, the school counsellor should act as a mediator to ensure that the issue is dealt with sensitively and in confidence. Data will be captured and stored in accordance with the UK Data Protection Act 2018 and General Data Protection Regulation (GDPR). All data will be recorded on a password-protected Ulster University computer. Only the research team members involved with the study will have access to the data. All study information and data collected will be anonymised through allocation of a unique study number. On completion of the study, data will be kept for 10 years and will then be destroyed in compliance with the UK Data Protection Act 2018 and GDPR guidelines. Access to data will be limited to members of the research team and members of the Research Governance departments in Ulster University and the NHS trusts in Northern Ireland. Although there is always a small potential of coercion during any research recruitment, all researchers are GCP trained and there is a vast amount of relevant experience within the team (see CVs for full details) minimizing this risk significantly. Only the researchers involved with the study will have access to any participant details throughout the study, maximising participant confidentiality.

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