Impact of numerical information on risk knowledge regarding human papillomavirus (HPV) vaccination among schoolgirls: a randomised controlled trial

Effekt von Zahlenangaben auf das Risikowissen von Schülerinnen zur Humanen Papillomavirus (HPV)-Impfung: eine randomisiert-kontrollierte Studie

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Abstract

Introduction: In Germany the implementation of human papillomavirus (HPV) vaccination for women aged 12–17 years was accompanied by various campaigns. Evidence-based information including numerical data was not provided. However, standard information leads to overestimation of cancer risk and effects of HPV vaccination. Confidence in children's ability to deal with numerical data is low, especially in disadvantaged pupils.
The aim of the present study was to compare the effects of a standard leaflet with an information leaflet supplemented with numerical data on 'risk knowledge' regarding HPV vaccination among schoolgirls.
Methods: Randomised-controlled short-term trial. All 108 schoolgirls of seven school classes were asked to participate and 105 agreed. Participants were vocational schoolgirls who were preparing for grade 10 graduation and who were members of the target group for HPV vaccination. The control group was asked to read a standard leaflet on HPV vaccination of the German Women's Health Network. The intervention group received the same leaflet, but it was supplemented with numerical information on cancer risk and assumed effects of the HPV vaccination on cancer prevention.
As baseline characteristics we surveyed: age, vaccination status, attitude towards HPV vaccination and aspects regarding migration background. The primary end point was 'risk knowledge'. Questionnaire surveys were performed under experimental conditions. Individual randomisation, participants, and intention-to-treat data analyses were blinded. The study was approved by the Ministry of Education and Culture of Schleswig-Holstein and the ethics committee of the Hamburg Chamber of Physicians.
Results: We analysed 'risk knowledge' for all 105 randomised participants. Baseline characteristics of the two groups were comparable. Numerical risk information recipients were more likely to give correct answers compared to standard information recipients: Mean value of risk knowledge score (0–5 points): 4.6±1.0 vs. 2.6±1.2 (mean difference 2.0 (95% CI 1.6–2.4)); (P<0.001). Post hoc distractor analysis of single items was performed. Incorrect answers of control participants indicated that cervical cancer risk was highly overestimated whereas total cancer risk was mostly underestimated, and possible impact of HPV vaccination on cancer prevention was overestimated.
Conclusion: Supplementing health information on HPV vaccination with numerical data improves 'risk knowledge' among schoolgirls.

Keywords: consumer health information, human papillomavirus vaccination, risk knowledge, evidence-based medicine

Zusammenfassung

Einführung: In Deutschland wurde die Implementierung der Humanen Papillomavirus (HPV)-Impfung für 12–17-jährige Mädchen von diversen Kampagnen begleitet. Evidenz-basierte Informationen, die Zahlenangaben beinhalten, wurden nicht zur Verfügung gestellt. Stattdessen führten die Standardinformationen zu einer Überschätzung des Krebsrisikos und den Effekten der HPV-Impfung. Das Vertrauen in die Fähigkeit von Kindern mit Risiken umzugehen ist gering, insbesondere wenn es sich um sozial benachteiligte Schüler handelt.

Das Ziel dieser Studie ist ein Vergleich der Effekte eines Standard-Flyers mit einem Informationsflyer, der Zahlenangaben beinhaltet, hinsichtlich des Risikowissens über die HPV-Impfung bei Schülerinnen.

Methoden: Randomisiert-kontrollierte Kurzzeitstudie. Es wurden alle 108 Schülerinnen aus sieben Schulklassen auf die Teilnahme angesprochen und 105 stimmten zu. Die Teilnehmerinnen waren Berufsfachschülerinnen, die den Abschluss der 10. Klasse anstrebten und zur Zielgruppe für eine HPV-Impfung gehörten. Die Kontrollgruppe wurde gebeten, den Standardflyer des Nationalen Netzwerks Frauen und Gesundheit zu lesen. Die Interventionsgruppe erhielt den gleichen Flyer, der jedoch mit numerischen Informationen zum Krebsrisiko und zu den angenommenen Effekten der HPV-Impfung auf die Krebsprävention ergänzt worden war. Als Basischarakteristika wurden Alter, Impfstatus, Einstellung zur HPV-Impfung und Aspekte bezüglich des Migrationshintergrunds erhoben. Der primäre Endpunkt war Risikowissen. Die Fragebogenerhebungen erfolgten unter experimentellen Bedingungen. Die individuelle Randomisierung, die Teilnehmerinnen und die intention-to-treat Datenanalyse waren verblindet. Die Studie wurde vom Ministerium für Bildung und Kultur des Landes Schleswig-Holstein und der Ethikkommission der Hamburger Ärztekammer genehmigt.

Ergebnisse: Risikowissen wurde für alle 105 randomisierten Teilnehmerinnen analysiert. Die Basischarakteristika der beiden Gruppen waren vergleichbar. Die Schülerinnen, die den Flyer mit Zahlenangaben erhielten, gaben häufiger korrekte Antworten im Vergleich zur Kontrollgruppe mit der Standardinformation: Mittelwert des Risikowissens (0–5 Punkte): 4,6±1,0 vs. 2,6±1,2 (Differenz 2,0 (95% CI 1,6–2,4)); (P<0,001). Post hoc wurde eine Distraktorenanalyse der einzelnen Items durchgeführt. Die inkorrekten Antworten der Teilnehmerinnen der Kontrollgruppe zeigten, dass das Zervixkarzinom-Risiko stark überschätzt wurde, das Risiko für Krebserkrankungen im Allgemeinen meist unterschätzt wurde und der mögliche Einfluss der HPV-Impfung auf die Krebsprävention überschätzt wurde.

Schlussfolgerung: Die Ergänzung eines Informationsflyers zur HPV-Impfung mit Zahlenangaben verbesserte das Risikowissen von Schülerinnen.

Schlüsselwörter: Gesundheitsinformationen, Humane Papillomviren-Impfung, Risikowissen, Evidenz-basierte Medizin

Introduction

In Germany HPV vaccination for young women 12–17 years of age started in 2007. The implementation was accompanied by various campaigns. Pharmaceutical industry was strongly involved including presentations in school classes [6]. Neumeyer-Gromen et al. have analysed German media reports and public brochures from 2007–2009 to study whether available information facilitates informed choice in HPV vaccination. They found that only 41% of the identified sources provided numbers on effectiveness and 2% on absolute risk reductions for the cancer surrogate dysplasia. Also, none of the numbers was correct [14].

Adolescents' participation in decision making lacks essential prerequisites for informed choice including availability of evidence-based patient information. This means information that is unbiased, complete and understandable [2]. Incomplete and biased information may lead to worrying misconceptions as reported in a number of recent publications.

About one year after the introduction of the UK vaccination programme, Hilton et al. explored schoolgirls' knowledge and understanding about HPV infection and its link to cervical cancer, beliefs about safer sex, and personal risk in relation to HPV, understandings and concerns about HPV vaccination, vaccination experiences, and understanding of the importance of cervical cancer screening. Participants (n=87) of this focus group study were between 12–18 years old. Typically girls referred to the HPV vaccination as the cancer jab. Results showed that knowledge on HPV was low and partly incorrect [9].

Schmeink et al. interviewed 698 female and male students aged 18–25 years. After implementation of the national HPV vaccination programme in the Netherlands, more than 50% had never heard of HPV [15]. In a web-based survey with 396 female American college students, Dillard et al. explored general knowledge on HPV vaccination. Results showed that HPV related knowledge averaged only 65% overall [5]. In addition, an Australian focus group and interview study found lack of knowledge about HPV vaccination (HPV infection, transmission, cervical cancer connection, HPV vaccine, recommendations) among parents and girls [4].

In preparing the protocol of the present study, few studies were identified which explored children's perception of risk information. In fact, confidence in children's ability to deal with numerical data is low, especially in disadvantaged pupils. Ulph et al. studied children's perception of different presentations of probability information. In principal, children between 7 and 11 years of age can understand probability information. Pie charts were helpful to support understanding of presentations [20].

In 2008, the British General Medical Council explicitly demanded the participation of adolescents in decision making, which requires evidence-based information [7]. In the UK the Gillick guidelines provide a legal framework for professionals who have to judge on adolescents' ability to consent to medical treatment [8]. However, in practice, the interpretation of the guideline varies [21]. Based on an interview study with stakeholders, Wood et al. suggest to allow “Gillick competent” adolescents to consent or to refuse, even if this contradicts their parents' opinion [21].

The target group of HPV vaccination demands and urgently needs numerical information on disease risk [19]. Stöckli et al. analysed three HPV information brochures for adolescents and conducted focus groups with Swiss pupils aged 14–19 years. One of the analysed HPV information was the leaflet of the German Women's Health Network which was used in the control group of the present study [13]. They reported that none of the information provided numerical data on cervical cancer risk. However, the information drew certain pictures on the disease risks. Pupils highly overestimated cervical cancer risk with overall ratings between 24% and 35%, and estimates up to 90%. One information leaflet induced another serious confusion. Participants equalised the cervical cancer risk to the risk of HPV infection, which was stated to be 70%. In fact, lifetime cervical cancer risk is approximately 1%. The authors concluded that those developing information should beware of these communication pitfalls. Their study shows that standard information without numerical data causes harm by evoking misconceptions of disease risks [19]. Communicating numbers could prevent false conclusions [19].

Therefore, the aim of the present study was to compare the effects of an information leaflet including numerical data to standard information without numerical data on ‘risk knowledge’ regarding HPV vaccination in disadvantaged schoolgirls of full-time vocational schools.

Methods

In 2009, 3 vocational schools, in Schleswig Holstein, Germany, were asked to participate in the project and facilitate access to the target group of HPV vaccination in full-time vocational classes. All schools agreed and facilitated access to eligible classes. Classes were recruited until sample size was reached.

Participants

All 108 schoolgirls of seven classes were asked to participate and 105 gave informed consent. Participants were full-time vocational schoolgirls who were preparing for grade 10 graduation and who were members of the target group for HPV vaccination in Germany (age 15–17).

We randomly assigned the 105 schoolgirls to receive either one of the two information formats on HPV vaccination. Individual randomisation was done for all participants by an external person. Allocation was concealed. ID numbers were either even or odd numbers representing either one study group and leading to an even distribution in each class. Students, trial staff and also the statistician, were unaware of the study arm to which participants had been assigned.

Intervention and comparison

The intervention consisted of the modified standard leaflet of the German Women's Health Network, which is part of the European Women's Health Network and aims to enhance women's health. This standard leaflet comprised one A4 size paper, printed on both sides, and did not include numerical risk information (Attachment 1). For the intervention group the standard leaflet was supplemented with numerical information on cancer risk and on benefit of the HPV vaccination in terms of cervical cancer prevention [13] (Attachment 2). The control group was asked to read the standard leaflet on HPV vaccination. The modified leaflet was pilot tested with members of the target group (n=5) for comprehensibility, readability, and acceptability.

Procedure

In Germany, any studies performed within public schools require approval from the federal state government. In contrast to other federal states, Hamburg always requires informed consent given by parents. According to the German data protection act, the target group is judged to be mature enough to give informed consent regarding the present study. Therefore, in September 2009 we addressed the three vocational schools in Schleswig Holstein that offered full-time vocational classes in the field of health and were situated close to Hamburg. The schools were addressed and information on the project was provided. Seven classes were consecutively included until the sample size was reached.
Schoolgirls who were present at school the day of the study were addressed. Male students were offered the intervention but they were not included.
After a short introduction of the project by one of the authors (AS or MA), envelopes were consecutively distributed. According to IDs, participants were then seated either in the window section or the non-window section of the classroom to avoid contamination among the groups. The time frame comprised 90 minutes. After the schoolgirls exhaustively worked through the flyer, they completed the knowledge questionnaire.
After completion of the study, participants had the chance to ask questions and discuss relevant issues on HPV vaccination.

Outcome measure

The primary outcome measure was 'risk knowledge'. Age, vaccination status, attitude towards HPV vaccination, information accessed for HPV, native language and parents' countries of birth were surveyed as baseline characteristics.
The knowledge questionnaire was based on the 'informed choice' knowledge questionnaire developed by Marteau et al. and adapted to HPV vaccination [11]. It comprised 6 items (Table 1). The first 2 items referred to general knowledge and were assumed to be easy to answer. They were intended to motivate adolescents to work on the questionnaire.
Items were coded according to a predefined coding sheet. Each correct response scored either 0.5 points (2 items on general knowledge) or 1.0 point (4 items on 'risk knowledge') leading to a maximum score of 5 points. Missing responses were counted as wrong answers.
Attitudes were surveyed applying the attitude item of the 'informed choice' instrument by Marteau et al. (scale: 1 (positive) – 4 (negative)) [11].
We had decided not to survey components of the outcome measure at baseline, before distribution of the information leaflets, for methodological reasons. Applying the same questionnaires twice within one session would have biased results.

Hypothesis

We expected risk knowledge to be poor with standard information and that the intervention would improve 'risk knowledge' by 30% of the scale range among schoolgirls.

Statistical analysis

The primary analysis was performed by intention-to-treat. Baseline variables are presented as means and standard deviation (SD) or frequency distributions. Fisher's exact tests for categorical variables and unpaired t-tests for continuous variables were used to explore comparability of the study groups at baseline.
The data columns considering 'risk knowledge' did not contain any missing values because only correct answers were counted as 'risk knowledge'. Knowledge scores were analysed as continuous variables and analysed based on mean-scores (SD). Groups were compared using unpaired t-test.
The software package SPSS 16.0 was used for statistical calculations.

Sample size

Sample size calculation: We assumed that the control group would achieve 10% (0.5 points) of the maximum score. We considered an increase of 30% (1.5 points) in 'risk knowledge' as an important improvement. Aiming for a power of 90% at an alpha error of 5% each study group should therefore include 47 participants.

Results

Baseline characteristics of the two groups were comparable (Table 2). Attitudes towards HPV vaccination showed no significant differences between intervention and control group. Mean values (SD) were 1.7 (0.8) and 1.7 (0.6) respectively, $p=0.95$ (scale 1 (positive) – 4 (negative)) (Table 1). We analysed 'risk knowledge' for all 105 randomised participants (Figure 1). Numerical information recipients were much more likely to give correct answers compared to standard information recipients: mean value of 'risk knowledge' score (scale 0–5 points): 4.6 ± 1.0 vs. 2.6 ± 1.2; difference 2.0 (95% CI 1.6–2.4; $p<0.001$) (Table 3).
Post hoc analyses of single items were performed. Incorrect answers of control participants indicated that cervical cancer risk was highly overestimated whereas total cancer risk was mostly underestimated, and possible impact of HPV vaccination on cancer prevention was overestimated. Results of the multiple choice knowledge items are shown in Table 1. 89% of adolescents of the intervention group correctly estimated their lifetime risk to get cervical cancer versus 29% in the control group. Only 12% of the participants in the intervention group overestimated their risk, compared to 50% in the control group. Comparable results are shown for the risk of dying from cervical cancer.

Table 1: Distractor analyses of multiple choice items of the knowledge questionnaire (correct answers in bold). Values are numbers (percentages)* of participants

	Intervention group (n=53)	Control group (n=52)	p-value
Questions regarding general knowledge of HPV:			
1. What is the HPV vaccine supposed to prevent?			p=1.000
Hepatitis	0 (0)	0 (0)	
Human-Papilloma-Virus	**52 (98)**	**52 (100)**	
AIDS	0 (0)	0 (0)	
All sexually transmitted diseases	0 (0)	0 (0)	
2. How can I get infected with HPV?			p=1.000
Drinking from the same glass	0 (0)	0 (0)	
Visiting a swimming pool	0 (0)	0 (0)	
Having sex	**53 (100)**	**52 (100)**	
Sharing a lipstick	0 (0)	0 (0)	
Questions regarding cervical cancer risk without vaccination:			
3. How many out of 1000 women will get cervical cancer in their lifetime?			p<0.001
4	0 (0)	4 (8)	
10	**47 (89)**	**15 (29)**	
140	4 (8)	21 (40)	
800	2 (4)	5 (10)	
4. How many out of 1000 women will die from cervical cancer?			p<0.001
3	**48 (91)**	**21 (40)**	
10	0 (0)	12 (23)	
100	5 (9)	12 (23)	
750	0 (0)	1 (2)	
Questions regarding cervical cancer risk with vaccination:			
5. How many out of 1000 women will die from cervical cancer if they were vaccinated before they first had sex (in consideration of the present screening conditions in Germany)?			p<0.001
0	3 (6)	16 (31)	
1	**47 (89)**	**27 (52)**	
60	2 (4)	4 (8)	
280	0 (0)	0 (0)	
6. How many out of 1000 women will die from other cancer diseases?			p<0.01
80	3 (6)	18 (35)	
230	**48 (91)**	**19 (37)**	
570	1 (2)	9 (17)	
800	1 (2)	1 (2)	

* values may not sum up to 100% due to missing values

Table 2: Baseline characteristics of participants (n=105)

	Intervention group (n=53)	Control group (n=52)	p-value
Age			
Mean (SD) years	16.6 (1.3)	17.0 (1.5)	.158
Range	15–21	15–22	
First language			
German	45	41	.607
Other	6	10	
Parents' countries of birth			
Fathers			.329
Germany	42	33	
Russia	2	5	
Turkey	4	6	
Other	2	7	
Mothers			.401
Germany	36	34	
Russia	2	5	
Turkey	5	6	
Other	8	6	
HPV vaccination status			.020
Completely vaccinated	29	21	
Incompletely vaccinated	7	2	
Not vaccinated	14	17	
Attitude towards HPV vaccination*			
Mean (SD)	1.7 (0.8)	1.7 (0.6)	.947
Information accessed on HPV vaccination before the study			
Yes	39	33	.064

* scale 1 (positive) – 4 (negative)

Table 3: Primary outcome 'risk knowledge' (scale 0–5 points)

	Intervention group (n=53)	Control group (n=52)	Mean difference
Risk Knowledge Mean (SD)	4.6 (1.1)	2.6 (1.2)	2.0 (95% CI 1.6 to 2.4) p<0.001

9% vs. 48% of adolescents overestimated their risk in the intervention and control group, respectively. Finally, 6% (intervention group) vs. 31% (control group) stated that no woman out of 1,000 vaccinated women will die from cervical cancer, which indicates overestimation of HPV vaccination efficacy.

In addition, we surveyed the sources used by adolescents to find health information on HPV vaccination. The sources most frequently accessed were doctors (33 vs. 29), parents (23 vs. 15) and friends (16 vs. 11) for intervention and control group, respectively. Journals (4 vs. 9), television (7 vs. 9), internet (6 vs. 5), and school (8 vs. 5) were less frequently mentioned as a source of information by intervention and control group participants.

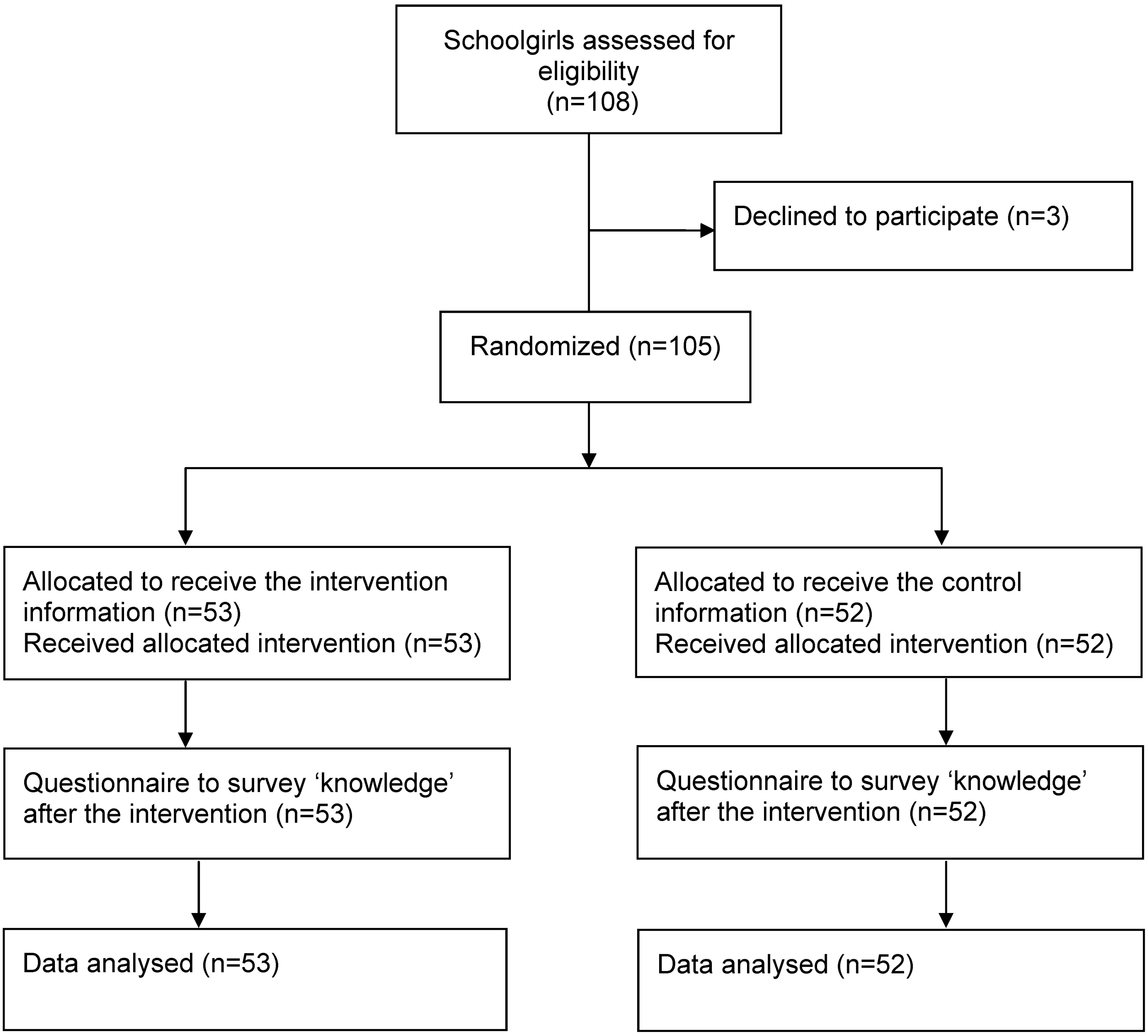

Figure 1: Flow of participants through trial

Discussion

Our study shows that risk knowledge is low and misconceptions about cervical cancer risk and HPV vaccination are high among schoolgirls when using standard patient information. Numerical information on HPV vaccination improved risk knowledge.

Strengths and limitations

Primary analysis was on intention-to-treat and pupils were blinded to group affiliation. The study participants were disadvantaged students who were preparing for their first graduation in vocational full-time schools.

The trial also has limitations. Outcome measures had to be surveyed right after the intervention for data privacy protection reasons. The knowledge test had not been validated. Hence, lack of discrimination of single items might have obscured existing differences. In this study however, we detected a difference in risk knowledge. Furthermore, surveying adverse effects is an important issue. In this study follow up data collection was neither feasible nor intended. However, as demonstrated in the present and previous studies standard information on HPV vaccination rather than risk communication with numerical data appears to evoke adverse effects in adolescents' risk perception [19]. Overestimation of personal cancer risk and unrealistic expectations of medical intervention are clearly undesired outcomes of health information. Finally, the numerical information flyer was not rigorously developed according to defined criteria for evidence-based patient information and was also limited by the leaflet format [2]. Participants of the intervention group reported a slightly higher access to information on HPV. As evidence-based consumer information including numerical data was not available at the time of our study, this imbalance could have hardly influenced the results on risk knowledge.

Meaning of the study results

Our results extend the findings of other trials. Few studies addressed adolescents regarding risk knowledge on HPV vaccination. It is of note, that none of these studies surveyed risk knowledge on cervical cancer risk and effects of HPV vaccination on cancer prevention. In contrast to these recent international studies, schoolgirls in our study showed good knowledge regarding general aspects of HPV in both study groups as the first two items of the questionnaire were correctly answered by all except one participants [4], [5], [9].

Risk knowledge is an important component in decision making, but there are some other aspects of relevance. Connolly et al. emphasized that in case of vaccination decisions accurate and credible information on risks and benefits alone is not enough [3]. Decision makers need help to structure and transfer the relevant information into a well-reasoned decision. The authors suggest internet-based decision aids to face this issue [3]. They discuss a hierarchy of decision aids to offer health information of different levels of complexity in order to meet the individuals' needs, and suggest 3 different levels: simple recommendation; supported recommendation; interactive and assisted personal decision model [3].

On the other hand, Web 2.0 information has been shown to be influenced by anti-vaccination movements. Kata has outlined the rhetorical tactics of these movements [10]. Betsch et al. also discussed opportunities and challenges of Web 2.0 related to vaccination information. They identified users who are particularly vulnerable to finding and using misleading information [1]. This group especially comprises persons with low numeracy and low health literacy [1]. Therefore, improving risk literacy in young people is a prerequisite to informed decision making.

Conclusion

Those designing and implementing vaccination programmes must respect the ethical right to evidence-based information for the target groups including adolescents. Results support the ethical guidelines' demand for evidence-based, reliable and easy to understand information on benefit and harm of medical interventions. Campaigns, using incomplete and misleading presentations of information are delusive and should be abandoned. In the meantime, the HPV flyer used in the intervention group is available on the internet [13]. Finally, as emphasized by various authors, adolescents need health literacy to be prepared for the critical appraisal of health information. Various projects have addressed this important issue [12], [18], [17].

Notes

Data

Data for this article are available in the Dryad Repository: http://dx.doi.org/10.5061/dryad.2pm60 [16]

Competing interests

The authors declare that they have no competing interests.

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Ethical approval

The study was approved by the Ministry of Education and Culture, Schleswig Holstein, and by the local ethics committee of the Hamburg Chamber of Physicians (PV3344).

Trial registration

Current Controlled Trials ISRCTN86240771

Attachments

Available from
http://www.egms.de/en/journals/gms/2013-11/000183.shtml

1. 000183_leaflet control group.pdf (706 KB)
   Standard leaflet without numerical risk information
2. 000183_leaflet intervention group.pdf (713 KB)
   Leaflet for the intervention group supplemented with numerical risk information

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