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«Research Methodology in Biomedicine, Biostatistics and Clinical Bioinformatics at University of Thessaly»

Master of Science Thesis:

Assessment of the reporting quality of RCTs for vaccination against HPV published from 2000 to 2019 based on the CONSORT statement

Αξιολόγηση της ποιότητας αναφορών των Τυχαιοποιημένων Κλινικών Δοκιμών για τον εμβολιασμό κατά του ιού HPV ,που δημοσιεύτηκαν από το 2000 ως το 2019 , βασισμένη στη δήλωση CONSORT .

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Abstract

Introduction and Purpose: Randomized Controlled Trials (RCTs) are the optimum means for the assessment of new interventions. The aim of the present study is to establish the reporting quality of RCTs for human papillomavirus (HPV) vaccination according to the CONSORT statement.

Methods: MEDLINE was searched for relevant studies. Among retrieved RCTs ten were randomly chosen for inclusion. CONSORT compliance was defined as the primary outcome. Secondary outcomes were adherence to the CONSORT statement per item, as well as investigation for possible determinants of the reporting quality. Non-parametric testing was conducted. CONSORT adherence ≥75% was defined as sufficient.

Results: Mean adherence (standard deviation) to the CONSORT statement was determined sufficient; 75% (7.5), Median = 75%, Minimum & Maximum compliance = 65% & 86% correspondingly. Reporting of item 24 was null, while items 10, 17b and 19 were inadequately assessed (30%). The rest of the items were more adequately reported (≥ 50%). Among analyzed factors (publication year, impact factor, sample size, number of authors, number of countries, number of sites) none proved to be significantly associated with the reporting quality.

Discussion: Reporting quality of RCTs for HPV vaccination is close to optimum. A larger study, involving all published RCTs, could provide more definite results.

Introduction

RCTs are the optimum means for the assessment of new interventions [1]. High quality RCTs are necessary in order to obtain robust results that can provide guidance for clinical decisions. On the other hand, RCTs of questionable quality might lead to erroneous results and inappropriate conclusions [2]. Therefore, ensuring that RCTs are of good quality is undoubtedly of utmost importance.

Data originating from RCTs are evaluated with regards to their quality and synthesized in order to acquire pooled estimates in meta-analyses. The conduction of both procedures requires adequate reporting by authors. At the same time, sufficient reporting enables investigators to replicate study designs and appraise the reproducibility of results, as well as provide homogeneous data that can be synthesized.

The Enhancing the Quality of Transparency of Health Research (EQUATOR) Network is involved in the recommendation of reporting guidelines regarding health research [3]. The CONsolidated Standards Of Reporting Trials (CONSORT) statement constitutes an extension of the EQUATOR network aiming at the improvement and evaluation of the reporting quality of RCTs [4]. The CONSORT statement was established in 1996 [5]. Since then, it was revised in 2001 [6] and 2010 [7], while an explanation and elaboration document accompanied both revisions [8, 9].

The CONSORT statement was embraced by a large number of scientific journals in order to ensure transparency of reporting [10]. A checklist of37 items (25 main items, of which 12 are divided into two sections), as well as a flow diagram of the participants consist the CONSORT statement. The main body of the checklist is relative to reporting of methodological features (17 items) and results (10 items). Introduction and discussion correspond to five items. The rest five items describe title, abstract, registration, protocol and funding information.

Human papillomavirus (HPV) is a virus considered as necessary component for the development of cervical cancer and an adjunctive component for several other malignancies [11]. Two particular genotypes, HPV 16 and 18 have been incriminated for the majority of cases of cervical cancer [12]. Notably, two other genotypes, HPV 6 and 11 have been associated with the majority of cases of genital warts [11]. The original targets of HPV vaccination were these four genotypes, but the antiviral range was expanded to include more associated genotypes [13].

The performance of RCTs regarding vaccination tends to present several undeniable difficulties that impede the conduction of multiple studies. The most prominent adversity is the considerable period of follow-up required to elucidate the potential usefulness, as well as the safety profile of the newly assessed intervention. In this context, well designed RCTs with adequate reporting quality are of even superior importance.

To the best of the author's knowledge, reporting quality of RCTs for vaccination against HPV has not been investigated so far. Therefore, the present study investigates the reporting quality of RCTs for HPV vaccination according to the CONSORT statement.

Methods

The present study consists a retrospective analysis of the reporting quality of RCTs for HPV vaccination according to the CONSORT statement.

Search Method

The MEDLINE database was comprehensively searched. The final literature search was performed on July 31, 2019. The search strategy included the MeSH Term ‘hpv vaccines’ and ‘hpv vaccination’ as well as ‘Human papillomavirus vaccination’ as free text words. Additionally, the filter ‘Randomized Controlled Trial’ was utilised. The implemented search strategy was:

> (hpv vaccination) OR (hpv vaccines[MeSH Terms]) OR (Human papillomavirus vaccination)

Eligibility Criteria

Studies were included according to the following criteria:

- they were RCTs (prospective studies with random assignment of their human population to two or more intervention groups)
- they were published before July 31, 2019
- one treatment arm was randomized to HPV vaccination regardless of the other(s) treatment arm(s)

Studies were excluded according to the following criteria:

- irrelevant studies
- other study designs
- studies not published in English

- pilot studies
- conference abstracts

Titles and abstracts were initially assessed, while full texts were screened if needed to clarify if a study fulfilled the inclusion criteria.

Data Extraction – Outcome measures

It was the author's intention to include a sample of 10 studies. Retrieved studies would berandomly included, according to the following plan. Each study would receive a corresponding number and then studies would be chosen based on a random number table.

The 2010 CONSORT checklist was utilized (Table 1). In total, 37 items (12 of 25 items are divided into two sections) were equally assessed as reported or not reported. With the exception of other information (Registration, Protocol, and Funding) items had to be described at the corresponding section (Introduction, Methods, Results, Discussion) to be rated as reported. The complementary appendices were evaluated only if a relevant reference was included in the main text (apart from item 8a which had to be included in the main text according to the CONSORT guidelines).When an item was reported more than once, it was rated as not reported in the presence of inconsistency of reports.

Additionally, information with respect to publication year, Journal Impact Factor -IF- for the publication year, settings, number of authors, sample size and intervention under investigation were collected.

The proportion of adherence per study to the CONSORT statement was defined as the primary outcome measure. Secondary outcome measures were the proportion of

CONSORT compliance per item and the investigation of the relationship between reporting quality and possible determinants.

Table 2 CONSORT checklist

Section/Topic	Item No	Checklist item
Title and abstract	1a	Identification as a randomised trial in the title
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)
Introduction - Background and objectives	2a	Scientific background and explanation of rationale
	2b	Specific objectives or hypotheses
Methods		
Trial design	3a	Description of trial design and allocation ratio
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons
Participants	4a	Eligibility criteria for participants
	4b	Settings and locations where the data were collected
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed
	6b	Any changes to trial outcomes after the trial commenced, with reasons
Sample size	7a	How sample size was determined
	7b	When applicable, explanation of any interim analyses and stopping guidelines
Randomisation:		
Sequence generation	8a	Method used to generate the random allocation sequence
	8b	Type of randomisation; details of any restriction (such as blocking and block size)
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned
Implementation	10	Who generated the random allocation sequence Who enrolled participants Who assigned participants to interventions
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how
	11b	If relevant, description of the similarity of interventions
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses

Results		
Participant flow (a diagram is strongly recommended)	13a	People evaluated for potential enrolment Participants randomly assigned Participants who completed treatment as allocated, by study group Participants who completed follow-up as planned, by study group Participants included in main analysis, by study group
	13b	For each group, losses and exclusions after randomisation,together with reasons
Recruitment	14a	Dates defining the period of recruitment and of follow-up
	14b	Why the trial ended or was stopped
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group and the estimated effect size and its precision
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)
Discussion		
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses
Generalisability	21	Generalisability (external validity, applicability) of the trial findings
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence
Other information		
Registration	23	Registration number and name of trial registry
Protocol	24	Where the full trial protocol can be accessed, if available
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders

Statistical Analysis

Statistical analyses were carried out with SPSS Statistics Software Version 26. Adherence to the CONSORT statement was defined as sufficient or insufficient using the arbitrary threshold of 75%. Statistic measures of central tendency and dispersion were used to describe CONSORT compliance. Continuous parameters were assessed non-parametrically for probable association with sufficient reporting quality, according to Mann-Whitney U test, in view of the small number of studies included and the existence of not significant outliers. Year of publication was assessed as a dichotomous variable (before 2010 and after 2010 – year of CONSORT revision) by Fisher's exact test. A p-value of 0.05 was set to be significant

Results

Literature search provided 317 studies (Figure 1) . After retrieving relevant RCTs, 10 studies were obtained according to the methodological plan described above [15-24]. The features of the retrieved studies are presented at Table 2.

Table 2 Study characteristics

Study	Year Published	Journal's IF*	Settings	Sample size	Vaccine	Number of authors
Ferris et al.	2017	5.515	9 countries 34 sites	1,661	4-valent	13
Huh et al.	2017	53.254	18 countries 105 sites	14,215	9-valent	28
Wheeler et al.	2016	19.864	12 countries	4,407	2-valent	36
Vesikari et al.	2015	2.587	6 countries 24 sites	600	9-valent	10
Apter et al.	2015	2.277	14 countries	18,644	2-valent	27
Coskuner et al.	2014	3.151	1 country 3 sites	91	4-valent	5
Reisinger et al.	2007	0.132	10 countries 47 sites	1,781	4-valent	12
Mao et al.	2006	3.891	1 country 16 sites	2,391	1-valent	10
Poland et al.	2005	4.638	1 country 15 sites	480	1-valent	10
Vandepapelie`re et al.	2005	7.092	8 countries 26 sites	457	1-valent	7

*Impact factor(according to Journal IF published each summer by Clarivate Analytics)

CONSORT compliance was estimated per RCT: Ferris et al.: 73%, Huh et al.: 86%, Wheeler et al.: 81%, Vesikari et al.: 76%, Apter et al.: 84%,Coskuner et al.:

68%,Reisinger et al.: 76%, Mao et al.: 65%,Poland et al.: 78%,Vandepapelie`re et al.: 65%. Mean adherence (standard deviation –SD-) to the CONSORT statement was determined satisfactory; 75% (7.5). Median = 75%, Minimum & Maximum compliance = 65% & 86% correspondingly.

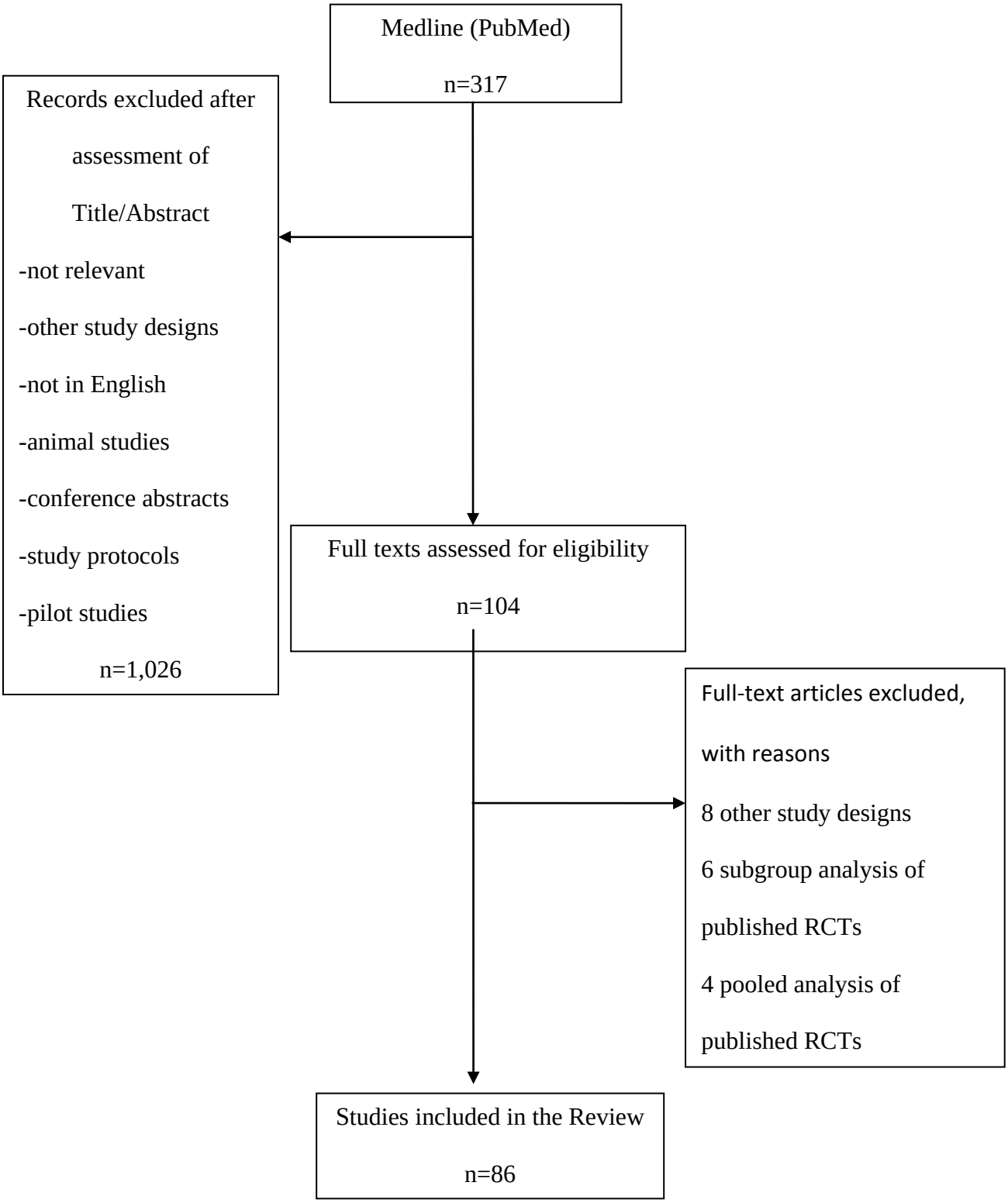
Compliance per item is illustrated at Table 3. Item 24 was evaluated negatively in all studies. Items 10, 17b and 19 were assessed as reported solely in 30% of the studies. Item 22 was evaluated positively in half of the studies, whereas a satisfactory reporting quality was observed for most of the rest items (≥60%).

With respect to associated parameters, fisher's exact test did not reveal any significant association regarding publication year and sufficient reporting quality ($p = 0.548$). Similarly, Mann-Whitney U test did not indicate any significant association concerning continuous parameters and sufficient reporting (number of countries; $p = 0.131$, number of sites; $p = 0.386$, IF; $p = 0.67$, sample size; $p = 0.171$). The number of authors came closer to statistical significance ($p = 0.084$).

Table 3 Compliance per CONSORT item

Item	Compliance n (%)	Item	Compliance n (%)
1a	9/10 90%	12a	7/10 70%
1b	10/10 100%	12b	7/10 70%
2a	10/10 100%	13a	9/10 90%
2b	10/10 100%	13b	8/10 80%
3a	10/10 100%	14a	10/10 100%
3b	6/10 60%	14b	8/10 80%
4a	7/10 70%	15	10/10 100%
4b	7/10 70%	16	10/10 100%
5	10/10 100%	17a	10/10 100%
6a	10/10 100%	17b	3/10 30%
6b	7/10 70%	18	6/10 60%
7a	6/10 60%	19	3/10 30%
7b	8/10 80%	20	7/10 70%
8a	10/10 100%	21	6/10 60%
8b	10/10 100%	22	5/10 50%
9	9/10 90%	23	6/10 60%
10	3/10 30%	24	0/10 0%
11a	7/10 70%	25	8/10 80%
11b	6/10 60%		

Figure 1 Prisma flow chart of the literature search



Discussion

The present study aimed to evaluate the reporting quality of RCTs for HPV vaccination according to the CONSORT statement. For the mentioned purpose it was decided that a random sample of ten studies would be analyzed. Reporting quality was determined sufficient, overall. Individually, six from the ten studies registered a sufficient reporting quality.

Title and abstract reporting, as well as introduction items were sufficiently reported. The increasing number of publications renders the reporting of the first two items very significant. Most readers will potentially resort to study abstract in order to decide to acquire or not the full text. It is even probable that some readers will utilize abstract to obtain information, without assessing the full text [24]. Therefore, abstract reporting should be considered of major importance.

Although methodological items generally consist the primary field of underreporting, retrieved studies exhibited satisfactory reporting for most of the methodological items [25]. Item 10 (implementation of randomization), constitutes an exception, with solely 30% of the studies describing this item. Similar reporting patterns with deficient reporting of item 10 were described by Chen et al. and Agha et al. [26, 27]. From the results section, reporting of items 17b (presentation of binary outcomes) and 19 (adverse events) was mainly suboptimal. A similar trend was indicated by Chen et al. and Adie et al. [26, 28].

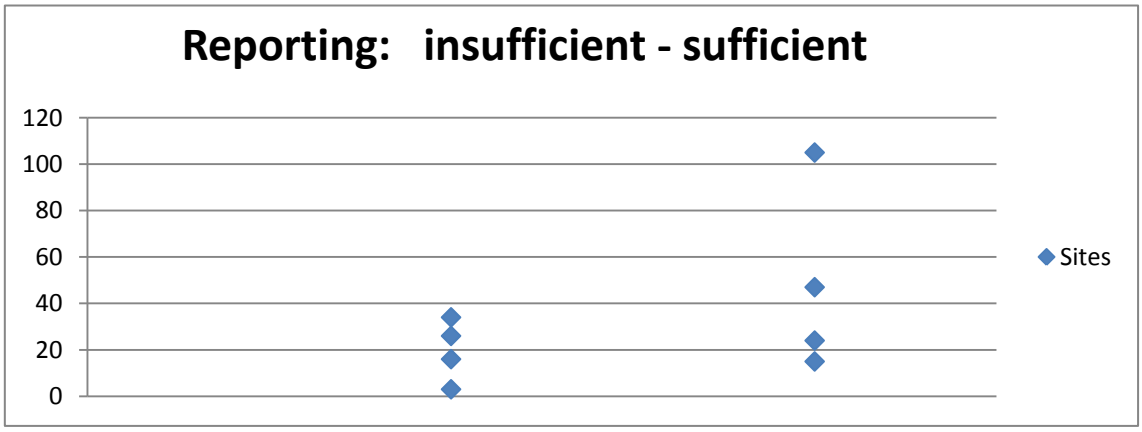
Items 20-22 are generally considered as subjectively assessed (alongside items 2a and 2b). Most studies tend to reveal high reporting rates of the mentioned items. The present study, contrarily to most papers, determined a moderate reporting quality of the

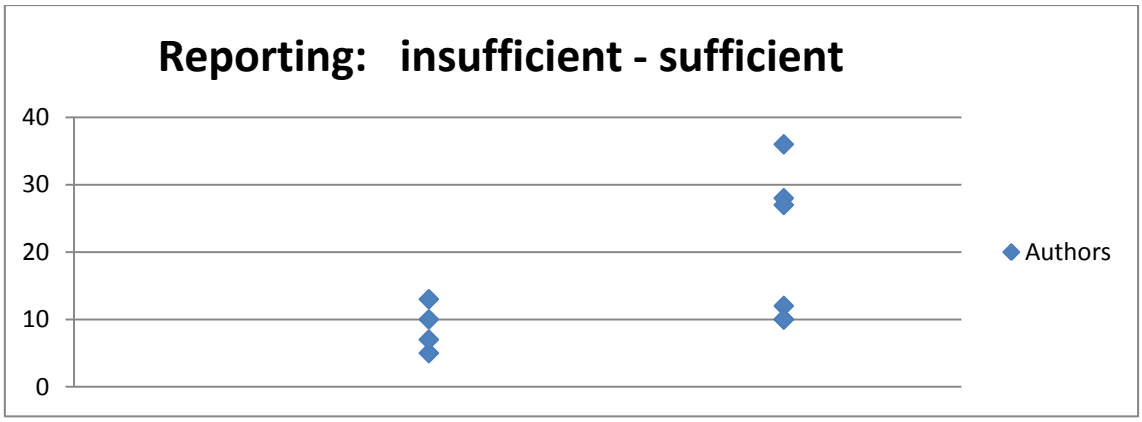
mentioned items. Among items regarding other information, item 24 (study protocol) was negatively appraises in all studies while items 23 and 25 were reported more adequately. Similar results with underreporting of the study protocol were reproduced by Liampas et al [29].

None of the factors investigated for possible association with reporting quality proved significant. Publication year [30] and IF [31] have been associated with the quality of reporting by other studies. Number of authors [32], settings [33] and sample size [34] have been examined as probable determinants, but obtained results were conflicting. The number of authors came closer to statistical significance ($p = 0.084$) in the present study, indicating the possible value of scientific collaboration [33].

To the best of the author's knowledge the present study was the first to assess the reporting quality of RCTs for HPV vaccination according to the CONSORT statement. Nevertheless, it is important to highlight certain limitations. Assessment of CONSORT adherence was performed by a single investigator and literature search involved only one database and a sample of all published RCTs. Furthermore, the investigator was not blinded to study's, authors' and journal's information. Additionally, only studies published in English were considered eligible. Finally, only a sample of published RCTs was analysed.

Conclusively, reporting quality of RCTs for HPV vaccination is close to optimal. A larger study involving all published RCTs could provide more definite results.





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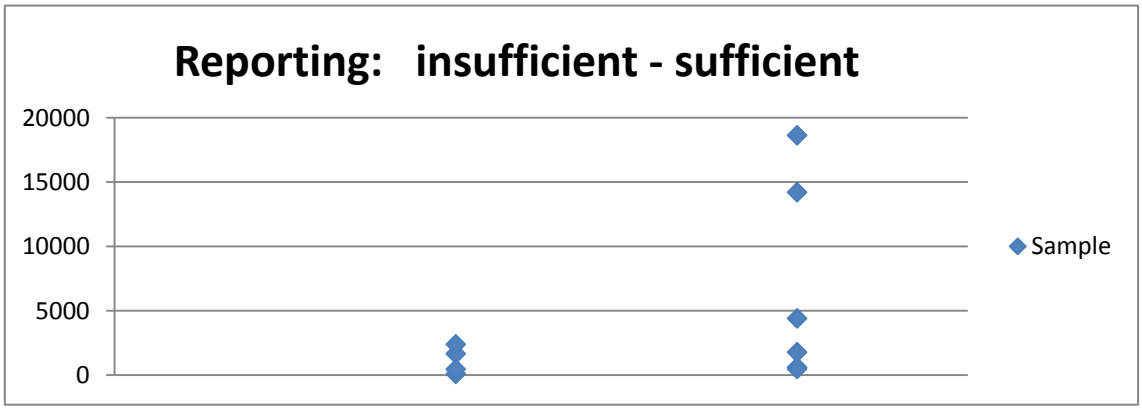

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