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Original article: The importance of professional training: educational needs, assessment instruments and intervention tools

Accuracy and knowledge in 12-lead ECG placement among nursing students and nurses: a web-based Italian study

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Abstract. *Background and aim:* Electrocardiogram (ECG) is considered the most used diagnostic tool to identify many cardiological disease and conditions that require the monitoring and recording of heart's electric activity. The aim of this study is the validation and application of a web-survey, addressed to nursing students and nurses, in order to evaluate the degree of accuracy and the knowledge on the correct positioning of the 12-leads ECG. *Methods:* The study was a cross-sectional questionnaire-based study. The survey comprised 30 items, mainly multiple-choice questions. The participants were 484 nurses and nursing students. In the study, no exclusion criteria were adopted, but fill in the questionnaire any nurse on duty during the data collection period and/or any nursing student during the data collection period. Statistical analyses were performed using the SAS v. 9.4. In the study, no exclusion criteria were adopted. *Results:* A total of 484 nursing students and nurses comprising of 149 males (30.79%) and 335 females (69.21%) responded. In full findings showed good psychometric properties and good reliability. The Cronbach's alpha coefficient for the study is 0.76 (number of items = 17, number of obs= 484). The mean age of responders was 32.01 (Standard deviation (SD) 9.63). A logistic multivariate regression demonstrated significant differences. *Conclusions:* It is evident from our findings and those from other countries, that more education is required to ensure that mistaken interpretation, misdiagnosis, patient mismanagement and/or inappropriate procedures due to 12 leads ECG misplacement does not occur. (www.actabiomedica.it)

Key words: Electrocardiography, ECG lead placement, clinical skills, delivery of care, nursing education

Introduction

Electrocardiogram (ECG) is one of the most used diagnostic tools in the cardiovascular field (1, 2). It is considered the non-invasive gold standard for the identification of acute coronary syndromes, arrhythmia, chest pain, pneumothorax, and other conditions that require the monitoring and recording of heart's electric activity, and its plotting (3). The possibility of picking up heart's electric field is affected by many factors, such as: the properties of the dermal and epidermal skin layers, the properties of the electrolytic paste, the properties of the electrodes and their mechanical contact with the skin (4).

Moreover, the practical skills and knowledge of the health workers are important for the proper setting

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of the ECG Machine and the positioning of the leads (5-7). In fact, 12-leads ECG misplacement can lead to diagnostic errors (8, 9). It decreases the patient safety as any medical error, that represents a serious public health problem, such as medication errors (10-19).

Despite the availability of a large body of scientific literature on the correct positioning of the 12-leads ECG on the human body, different studies highlight the diffuse presence of three main artefacts in electrocardiograms (20):

- inaccurate identification of heart's point by the health worker;
- difficult identification of heart's point due to an excess of subcutaneous tissue (obesity);
- heart's anatomic conditions differing from the general population.

A normal sinus rhythm signal will be clearly displayed on the ECG monitor if the 12-lead ECG are correctly positioning and its contact with the skin is good. However, the appreciation of correct electrode positioning may not be recognized by some nursing students and registered nurses. So, the scientific literature identifies two different methods for identifying the correct landmarks for 12 lead ECG placement: the *Angle of Louis Method* and the *Clavicular Method* (21).

Both of them should be learned by nursing staff. As a matter of fact, the level of theoretical knowledge and the level of accuracy in 12-leads ECG placement must be high in nursing staff to reduce mistaken interpretation, misdiagnosis, patient mismanagement and/or inappropriate procedures (3).

Many Authors have investigated the level of accuracy and precision of the positioning of the 12-leads ECG by nurses and compared it with that of other health professionals (cardiologists and technicians) (5, 20). Rajaganeshan et al. (20) found that nurses are significantly worse than cardiac technicians, physicians are even worse and cardiologists worst of all. We sought to investigate these issues among nursing students and nursing hospital staff in our current study.

Aim of the study

The aim of this study was to quantify the level of accuracy and the level of knowledge between nursing students and registered nurses in 12-lead ECG placement.

Material and methods

Study design and sample

The study was a cross-sectional questionnaire-based study. All participants (nursing students and registered nurses) completed a questionnaire online regarding theoretical knowledge and accuracy level in 12-lead ECG placement. In the study, no exclusion criteria were adopted. Nurses on duty during the data collection period and/or nursing students can fill the questionnaire.

Data collection

The data was collected between December 2018 and January 2019. Social media (such as Facebook) and mailing lists was used to collect data.

Data analysis

Statistical analyses were performed using the SAS v. 9.4 (SAS Institute Inc., Cary, NC, USA). The homogeneity of each subscale of theoretical knowledge and accuracy level toward 12-lead ECG placement (internal consistency) was verified with the Cronbach coefficient. To determine the regressors of the theoretical knowledge and accuracy level (dependent variables), multivariate logistic regression (backward method) analysis was employed. In logistic multivariate regression models were included age, gender, job, "where do you study/work?", years' work experience, years of studies, 12-lead ECG knowledge, importance of a lesson, importance of practice, the most recent training activity, mean of n. ECG/week as independent variables. Benjiamini-Hochberg (FDR) method was used for to correct the multiple comparisons. A $p<0.05$ was considered statistically significant.

Instrument development

A quantitative pilot study has been run in order to investigate the theoretical knowledge and the level of

accuracy of nursing students and nurses. The investigation tool has been created ad hoc, based on a literature review. The tool was then reviewed by a group of experts, in order assess its validity and to avoid the presence of any colloquialism that may cause difficulties of interpretation. A copy of questionnaire is available upon request.

The final questionnaire drawn up for this preliminary study comprised 30 items in Italian, mainly multiple-choice questions, arranged in 3 sections (Table 1):

- *Theoretical knowledge* (item 1,2,3,4,5.1, 5.2, 5.3, 5.4, 5.5, 5.6): assesses the participant's theoretical knowledge on the execution of an ECG with particular focus on the positioning of the 12-leads ECG;
- *Level of accuracy* (item 1, 2.1, 2.2, 2.3, 2.4, 2.5, 2.6): assesses the level of accuracy for the positioning of leads;
- *Sociodemographic and professional characteristics*: in addition to socio-demographic elements, the participants were also surveyed about 12-Lead ECG placement training and the number of ECGs interpreted during a week.

Ethics

The investigation conforms with the principles outlined in the Declaration of Helsinki. The approval of the Ethics Committee for the administration of the questionnaire with acknowledgement of notification for the study, was required – Prot. 162 /19.

Results

Internal consistency

Evaluation of the internal consistency of the subscales for knowledge and accuracy in 12-lead ECG placement questionnaire is carried out by calculating the Cronbach Alpha coefficient (22). Such parameter can be interpreted as an average of the correlation coefficients calculated for each possible division of items into two groups of equal dimensions. The assessment's reliability of a scale consists in the estimation of how much the score variation can be real or actual, rather than being due to chance or casual errors. The reliability's degree estimated from Cronbach's alpha is expressed as a proportion: for example, a 0.70 reliability's degree means that the measured variance can be considered 70% reliable (23; 24). The Cronbach's alpha coefficient for the study is 0.76 (N items = 17, N obs= 484).

However, the Cronbach's alpha coefficient for single section is:

- *Theoretical knowledge* (item 1, 2, 3, 4, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6): the Cronbach's alpha coefficient for theoretical Knowledge is 0.70 (N items = 10, N obs = 484);
- *Level of accuracy* (item 1, 2.1, 2.2, 2.3, 2.4, 2.5, 2.6): the Cronbach's alpha coefficient for level of accuracy is 0.80 (N items = 7, N obs = 484).

Table 1. Items of the instrument

Theoretical knowledge	*The standard 12-lead ECG consists of three standard bipolar leads, three unipolar leads and six precordial unipolar leads*
	The precordial derivations show the heart from the horizontal plane
	The electrode on the right leg is neutral (black colour).
	The Einthoven triangle is built on the bipolar derivations of the limbs.
	Indicate the correct positioning of the pre-cordial electrodes.
Level of accuracy	*Indicate which derivation you would place in the spaces indicated in the lines*
	At each white box write the name of the correct extension.

Demographic details

A total of 484 nurses and nursing students responded to the invitation. The demographic details of the population are summarized in Table 2.

The self-administered questionnaire is distributed online to a random sample of nurses (n=387, 79.96%) and university undergraduate students (n=97, 20.04%).

Table 2. Demographics detail of nurses and nursing students

Items	n(%)
Age* (years)	32.01±9.63
Gender	
Male	149 (30.79)
Female	335 (69.21)
Job	
Student	97 (20.04)
Nurse	387 (79.96)
Where do you study/work?[a]	
North	229 (47.81)
Middle	172 (35.91)
South	78 (16.28)
Years' work experience[b]	
<1	55 (13.96)
1<years' work experience<3	91 (26.84)
3<years' work experience<5	58 (23.39)
5<years' work experience<10	74 (38.95)
>10	116 (61.06)
Years of studies	
First year, regular	10 (2.07)
Second year, regular	17 (3.51)
Third year, regular	57 (11.78)
Not in regular	9 (1.86)
I'm a nurse	391 (80.78)
12-lead ECG knowledge	
Poor	11 (2.27)
Insufficient	28 (5.78)
Good	91 (18.80)
Very good	199 (41.12)
Excellent	155 (32.02)
Importance of a lesson	
Very important	46 (9.50)
Important	59 (12.19)
Moderately important	108 (22.31)
Slightly important	157 (32.44)
Not important	114 (23.55)
Importance of practice	
Very important	23 (4.75)
Important	50 (10.33)
Moderately important	84 (17.35)
Slightly important	156 (32.23)
Not important	171 (35.33)
The most recent training activity	
Less than a month ago	63 (13.02)
1-6 month ago	57 (11.78)
6 month and 1 yeare ago	57 (11.78)
1-3 years ago	112 (23.14)
3-5 years ago	1 (0.21)
More than 5 years ago	194 (40.08)
Mean of n. ECG/week	
Less than 5 ECG	201 (41.53)
5-10 ECG/week	122 (25.21)
11-20 ECG/week	51 (10.54)
More than 21 ECG/week	110 (22.72)

*mean±SD
[a]Number of responders to the question: 479
[b]Number of responders to the question: 394

The participants included 149 males (30.79%) and 335 females (69.21%) from most of Regions of Italy. The mean age of responders was 32.01 (Standard Deviation 9.63). The majority of nursing sample have got more than ten years' work experience (61.06%), while nursing student sample are admitted to third year (11.78%).

Level of knowledge

Out of a maximum knowledge score of 10, the mean score achieved by participants was 6.90 (stand-

Table 3. Nursing staff and nursing students knowledge

	Knowledge
N	484
Mean	6,90
Standardized error	,097
Median	7,00
Standard deviation	2,125

ard deviation 2.12) and the median score was 7, with 21.7% (N = 105) achieving 90%. No responder has answered all the questions correctly (Table 3).

The associated variables with theoretical knowledge questions are: age, "where do you study/work?", years' work experience, 12-lead ECG knowledge, importance of a lesson. Table 4 showed the results about level of knowledge.

Among the ten questions on theoretical knowledge; age and 12-lead ECG knowledge are associated with question about the 12 leads ECG (question 1) (p=0.0008, p=0.0003 respectively) with OR=0.96, 95%CI (0.94-0.98) for age, indicating that increasing values of age correspond with decreasing odds of to answer correctly.

On the 12-lead ECG knowledge we observe that only some comparisons are statistically significant

Table 4. Multivariate logistic regression for theoretical knowledge

Question about the 12-lead ECG (question 1)[b]			
Characteristic	OR (95%CI)	p	p-adjusted
Age (years)	0.96 (0.94-0.98)	**0.008**[a]	
12-lead ECG knowledge		**0.003**[a]	
Good vs. Very good	0.48 (0.25-0.92)	0.0265	0.053
Good vs. Excellent	0.24 (0.12-0.47)	<.0001	**0.0001**[a]
Good vs. Poor	1.73 (0.30-9.97)	0.5405	0.61
Good vs. Insufficient	0.86 (0.28-2.63)	0.7863	0.79
Very good vs. Excellent	0.49 (0.29-0.83)	0.0079	**0.04**[a]
Very good vs. Poor	3.58 (0.65-19.55)	0.1412	0.23
Very good vs. Insufficient	1.77 (0.63-4.98)	0.2776	0.40
Excellent vs. Poor	7.32 (1.31-40.87)	0.0232	0.053
Excellent vs. Insufficient	3.63 (1.26-10.44)	0.0169	0.053
Poor vs. Insufficient	0.49 (0.07-3.42)	0.4761	0.59
Question about the neutral lead ECG[c]			
Characteristic			
Age (years)	0.95 (0.93-0.98)	**0.001**[a]	
Question about V4-lead placement[d]			
Characteristic			
Where do you study/work?		**0.03**[a]	
Middle vs. North	0.76 (0.41-.41)	0.38	0.38
South vs. North	0.40 (0.20-0.79)	0.009	**0.03**[a]
Middle vs. South	1.92 (0.89-4.11)	0.09	0.13

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Table 4 ***(continued).*** Multivariate logistic regression for theoretical knowledge

Question about the 12-lead ECG (question 1)[b]			
Years' work experience		**0.0007**[a]	
<1 vs. (1<years' work experience<3)	0.89 (0.35-2.29)	0.82	0.82
<1 vs. (3<years' work experience<5)	1.21 (0.43-3.42)	0.72	0.80
<1 vs. (5<years' work experience<10)	1.74 (0.67-4.52)	0.26	0.43
<1 vs. >10	3.97 (1.62-9.73)	0.003	**0.01**[a]
(1<years' work experience<3) vs. (3<years' work experience<5)	1.35 (0.54-3.37)	0.52	0.65
(1<years' work experience<3) vs. (5<years' work experience<10)	1.94 (0.85-4.44)	0.12	0.23
(1<years' work experience<3) vs. >10	4.43 (2.08-9.45)	0.0001	**0.001**[a]
(3<years' work experience<5) vs. (5<years' work experience<10)	1.44 (0.56-3.68)	0.45	0.64
(3<years' work experience<5) vs. >10	3.28 (1.40-7.71)	0.006	**0.02**[a]
(5<years' work experience<10) vs. >10	2.28 (1.09-4.80)	0.03	0.07
12-lead ECG knowledge		**<0.0001**[a]	
Good vs. Very good	0.32 (0.15-0.68)	0.003	0.006
Good vs. Excellent	0.14 (0.06-0.34)	<.0001	**<0.0001**[a]
Good vs. Poor	10.01 (0.90-111.90)	0.06	0.08
Good vs. Insufficient	2.96 (0.78-11.34)	0.11	0.12
Very good vs. Excellent	0.44 (0.22-0.88)	0.02	**0.03**[a]
Very good vs. Poor	0.03 (0.003-0.35)	0.005	**0.008**[a]
Very good vs. Insufficient	0.11 (0.03-0.39)	0.0008	**0.002**[a]
Excellent vs. Poor	0.11 (0.001-0.16)	0.0006	**0.002**[a]
Excellent vs. Insufficient	0.05 (0.01-0.18)	<.0001	**<0.0001**[a]
Poor vs. Insufficient	0.30 (0.02-3.74)	0.35	0.35
Importance of a lesson		**0.03**[a]	
Very important vs. Important	0.26 (0.07-1.00)	0.05	0.15
Very important vs. Moderately important	0.52 (0.16-1.73)	0.29	0.41
Very important vs. Slightly important	0.69 (0.22-2.17)	0.52	0.58
Very important vs. Not important	1.38 (0.44-4.35)	0.58	0.58
Important vs. Moderately important	1.97 (0.67-5.81)	0.22	0.36
Important vs. Slightly important	2.61 (0.90-7.53)	0.08	0.15

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Table 4 ***(continued).*** Multivariate logistic regression for theoretical knowledge

Question about the 12-lead ECG (question 1)[b]			
Important vs. Not important	5.22 (1.73-15.76)	0.003	**0.03**[a]
Moderately important vs. Slightly important	1.32 (0.63-2.79)	0.46	0.58
Moderately important vs. Not important	2.65 (1.16-6.03)	0.02	0.10
Slightly important vs. Not important	2.00 (0.96-4.16)	0.06	0.15

[a]Only p in bold are statistically significant

[b]The model includes the independent variables: job, "where do you study/work?", years' work experience, years of studies, importance of a lesson, importance of practice, the most recent training activity, mean of n. ECG/week

[c]The model includes the independent variables: job, "where do you study/work?", years' work experience, years of studies, 12-lead ECG knowledge, importance of a lesson, importance of practice, the most recent training activity, mean of n. ECG/week

[d]The model includes the independent variables: age, job, years of studies, importance of practice, the most recent training activity, mean of n. ECG/week

(good vs. excellent: OR=0.24, 95%CI (0.12-0.47), p-adjusted=0.0001; very good vs. excellent: OR=0.49, 95%CI (0.29-0.83), p-adjusted=0.039). The habitants in Middle (Italy?) area have almost 3 times the probability to respond correctly compared to North residents (OR=2.73, 95%CI (1.48-5.01), p-adjusted=0.0036).

Working for less than a year, between one and three years, between three and five years compared to greater and/or equal of 10 years have, all, high probability to answer correctly (OR=3.97, 95%CI (1.62-9.73), p-adjusted=0.01; OR=4.43, 95%CI (2.08-9.45), p-adjusted=0.001 and OR=3.28, 95%CI (1.40-7.71), p-adjusted=0.02).

Level of accuracy

Out of a maximum accuracy score of 7, the mean score achieved by participants was 6.77 (standard deviation 0.83) and the median score was 7, with 89.5% (N = 435) achieving 100%. Nobody individual did not answer any questions correctly (see Table 5).

Table 6 showed the results about level of accuracy. The variables associated to accuracy level of the question number A1 about the correct peripheral leads placement are age and job (p=0.04 and p=0.004). As in models with theoretical knowledge level the age has the same characteristics (OR=0.94, 95%CI (0.89-0.99)). The student vs. nurses show less accuracy (OR=0.07, 95%CI (0.01-0.44)). Therefore, the student answer correctly with a very low probability (7%).

The regression analysis with the question about the correct V1-lead placement (question A2.1) has not

Table 5. Nursing staff and nursing students accuracy

	Accuracy
N	484
Mean	6,77
Standardized error	,038
Median	7,00
Standard deviation	,835

Table 6. Multivariate logistic regression for accuracy level

Question about the leads placed on the extremities[c]		
Characteristic	OR (95%CI)	p
Age (years)	0.94 (0.89 to 0.99)	**0.04**[a]
Job		**0.004**[a]
Student vs. Nurse	0.07 (0.01 to 0.44)	

[a]Only p in bold are statistically significant

[c]The model includes the independent variables: "where do you study/work?", years' work experience, years of studies, 12-lead ECG knowledge, importance of a lesson, importance of practice, the most recent training activity, mean of n. ECG/week

regressors statistically significant. Only one variable is associated to the question A2.2 question about the correct V2-lead placement: 12-lead ECG knowledge (p=0.006). Job and importance of practice (p=0.01 and p=0.007, respectively) are associated to the question about V3-lead placement (question A2.3). The model with the question about V4-lead placement (question A2.4) has the following regressors: "where do you study/work?"(p=0.02), 12-lead ECG knowledge (p=0.04) and importance of practice (p=0.02). 12-lead ECG knowledge (p=0.001 and p=0.0006) is associated to the question about V5-lead placement (question A2.4) and V6-lead placement (question A2.5), respectively.

Discussion

The practical skills and knowledge of the health workers are important for the proper setting of the ECG Machine and the positioning of the leads (5-7). In fact, 12-leads ECG misplacement can lead to diagnostic errors (8; 9). Although mean knowledge levels and accuracy level for 12 leads ECG placement was reasonable (73.2% and 98.1% of the sample answered correctly on a half of the question about knowledge and accuracy, respectively), only 6.8% and 89.5% of nursing staff and nursing students scored 100% in each category, respectively. These figures suggest that nursing students and nurses are not aware about own level of knowledge and therefore establishment of training activities in Italy may help in accuracy 12-leads ECG placement.

Research has been conducted in other countries with special training in 12 leads ECG placement to explore nursing staff and nursing student's knowledge and accuracy about the appreciation of correct electrode positioning (7, 20, 25). Medani et al. (5) shown that the knowledge of correct ECG placement was very poor among nurses, physicians and technicians. Medani et al. (5) evaluated the efficacy of an educational intervention. According their findings, the educational intervention showed a "dramatic improvement in accuracy of ECG recording". It is evident from our findings and those from other countries, that more education is required to ensure that mistaken interpretation, misdiagnosis, patient mismanagement and/or inappropriate procedures due to 12 leads ECG misplacement do not occur.

Regarding to accuracy, a study conducted by Bickerton et al. (25) shown that then accuracy in 12 lead ECG placement varies from 16 to 90% standards and guidelines on electrode placement are not being adhered to.

These studies reveal that nursing staff and nursing student's knowledge and accuracy about 12 leads ECG placement is frequently incomplete. Moreover, our nursing sample shown lack of attention to education in 12-leads ECG placement. Indeed, only 13.02% of the sample attended a training activity on this topic less than a month ago. An educational method to learn the 12-leads ECG placement is needed as several authors showed (25, 26). A study conducted by Jefries et al. (27), shown that there is no significant difference between two methods for teaching the skill of performing a 12-Lead ECG: interactive, multimedia CD-ROM or traditional methods.

Conclusion

The findings we obtained in this study by analyzing data from web survey show a poor theoretical knowledge among nursing students and nurses, while the percentage of level of accuracy is very good. Our survey is the first, to our knowledge, to be conduct in Italy that explores health professional knowledge and accuracy about 12 leads ECG placement and it contributes to the international picture about a new educational programme to learning the correct positioning that is emerging.

A limitation of our study regards data collection methods. The Authors got started a web-survey. This method is a key of success to investigate a large group of Italian people but, at the same time, the Authors do not know the percentage of non-response. So people are voluntary enrolled in the survey. This may determine a selection bias because responders could have better attitudes towards health research and training activities.

Furthermore, in models that include the question number 3, 4, 5, 6, 7 (theoretical knowledge) no

show the ORs and 95%CI why both ORs and 95%CI are rather wide and can seem unlikely, but because the numbers of the negative answers are very small but it's acceptable.

As strengths, this study investigates knowledge and accuracy on a large group of nurse and nursing students living in all region of Italy. To our knowledge, this is the first study that assessing knowledge and level of accuracy among nursing students and nurse in Italy with a so large sample size and a multicenter approach.

Conflict of interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1-2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1-2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	3-4
Methods			
Study design	4	Present key elements of study design early in the paper	4-5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4-5
3Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	4-5
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4-5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*4-5*
Bias	9	Describe any efforts to address potential sources of bias	-
Study size	10	Explain how the study size was arrived at	4-5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	-

Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	4-5
		(*b*) Describe any methods used to examine subgroups and interactions	
		(*c*) Explain how missing data were addressed	
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	4-5
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6-9
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	6-9
		(b) Indicate number of participants with missing data for each variable of interest	6-9
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	6-9
		(*b*) Report category boundaries when continuous variables were categorized	6-9
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	6-9
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	6-9
Discussion			
Key results	18	Summarise key results with reference to study objectives	8-9
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	8-9
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	8-9
Generalisability	21	Discuss the generalisability (external validity) of the study results	8-9
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	10

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.