Vedlegg

Vedlegg 1

Sjekkliste for vurdering av en kohortstudie

Hvordan bruke sjekklisten

Sjekklisten består av tre deler der de overordnede spørsmålene er:

- Kan du stole på resultatene?
- Hva forteller resultatene?
- Kan resultatene være til hjelp i praksis?

I hver del finner du underspørsmål og tips som hjelper deg å svare. For hvert av underspørsmålene skal du krysse av for «ja», «uklart» eller «nei». Valget «uklart» kan også omfatte «delvis».

Om sjekklisten

Sjekklisten er laget som et pedagogisk verktøy for å lære kritisk vurdering av vitenskapelige artikler. Hvis du skal skrive en systematisk oversikt eller kritisk vurdere artikler som del av et forskningsprosjekt, anbefaler vi andre typer sjekklister.
Se www.helsebiblioteket.no/kunnskapsbasert-praksis/kritisk-vurdering/sjekklister

Har du spørsmål om, eller forslag til forbedring av sjekklisten?
Send e-post til Redaksjonen@kunnskapsbasertpraksis.no.

(A) Kan du stole på resultatene?

1) Er formålet med studien klart formulert?   ☐ JA   ☐ UKLART   ☐ NEI

Tips:

Formålet bør være klart formulert med hensyn til

- populasjon (personene studien handler om)
- eksponering (f.eks. risikofaktorer)
- utfall
- om det klart fremgår hvorvidt studien forsøkte å finne en positiv eller negativ effekt (sammenheng)

2) Ble personene rekruttert til kohorten på en tilfredsstillende måte?   ☐ JA   ☐ UKLART   ☐ NEI

Tips: Se etter seleksjonsskjevhet (eng. selection bias) som kan begrense mulighetene for å generalisere funnene:

- Var kohorten (gruppen som ble studert) representativ for en definert populasjon (f.eks. befolkningsgruppe)?
- Var det noe spesielt med personene i kohorten?

Skal du fortsette vurderingen?

Tips:

Hvis du svarte NEI på et av spørsmålene over kan du kanskje like godt legge bort artikkelen og finne en annen.

3) Ble eksponeringen presist målt?   ☐ JA   ☐ UKLART   ☐ NEI

Tips:

- Er det måleskjevhet?
  - o Ble det brukt subjektive eller objektive målemetoder?
  - o Er målemetodene pålitelige (valide)?
- Er det klassifiseringsskjevhet?
  - Ble det brukt samme måte for å klassifisere personene til de ulike eksponeringsgruppene?

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4) Ble utfallet presist målt?   ☐ JA   ☐ UKLART   ☐ NEI

Tips:

- Er det måleskjevhet?
  - o Ble det brukt subjektive eller objektive målemetoder?
  - o Er målemetodene pålitelige (valide)?
  - o Var personene i kohorten og/eller de som målte utfallet blindet med hensyn til hvem som var eksponert? Uten blinding er det større risiko for bias (systematiske feil), særlig for subjektive utfallsmål som f.eks. smerte eller tilfredshet. Kan eventuell manglende blinding påvirke resultatene i denne studien?
- Er det klassifiseringsskjevhet?
  - Er det etablert et godt system for å fange opp alle utfall (eks. sykdomstilfeller)?
  - Ble samme målemetode brukt i alle gruppene?

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5) Forvekslingsfaktorer   ☐ JA   ☐ UKLART   ☐ NEI
a) Har forfatterne identifisert alle viktige forvekslingsfaktorer?

Tips: Aktuelle forvekslingsfaktorer (eng. confounding factors) kan være genetiske, miljømessige eller sosioøkonomiske. Nevn eventuelle forvekslingsfaktorer som ikke er gjort rede for i artikkelen.

b) Har forfatterne tatt hensyn til kjente, mulige forvekslingsfaktorer i design og/eller analyse?   ☐ JA   ☐ UKLART   ☐ NEI

Tips: Se etter restriksjoner i design eller teknikker, f.eks. stratifisering, regresjons- eller sensitivitetsanalyse, som er brukt for å kontrollere, korrigere eller justere for forvekslingsfaktorer.

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6) Oppfølging   ☐ JA   ☐ UKLART   ☐ NEI

a) Ble mange nok av personene i kohorten fulgt opp?

Tips:

- Var det få som falt fra?
- Var frafallet likt fordelt i de ulike gruppene?
- Skiller de som falt fra seg fra de som ble fulgt opp og analysert i studien?

b) Ble personene fulgt opp lenge nok?   ☐ JA   ☐ UKLART   ☐ NEI

Tips: Det må ha gått lang nok tid for eventuelle positive og negative utfall til å oppstå

Basert på svarene dine på punkt 1 – 6 over, mener du at resultatene fra denne studien er til å stole på?   ☐ JA   ☐ UKLART   ☐ NEI

(B) Hva er resultatene?

7) Hva er resultatene i denne studien?

Tips:

- Hva er hovedresultatet?
- Hvor sterk er sammenhengen (eng. association) mellom eksponering og utfall (se på Risk Ratio RR)?
- Hva er den absolutte risikoreduksjonen (ARR)?

8) Hvor presise er resultatene og hvor presist er risikoestimatet?

Tips: Se på

- P-verdien
- Bredden av konfidensintervallet

9) Tror du på resultatene?   ☐ JA   ☐ UKLART   ☐ NEI

Tips:

- Store effekter er vanskelige å se bort fra
- Kan resultatene skyldes skjevhet, tilfeldige feil eller forveksling?
- Har designet og metodene i studien så mange feil at resultatene ikke er til å stole på?
- Vurder mot Bradford Hill-kriteriene* (f.eks. tidsrelasjon, dose-respons, biologisk gradient, konsistens)

*https://en.wikipedia.org/wiki/Bradford_Hill_criteria

(C) Kan resultatene være til hjelp i praksis?

10) Kan resultatene overføres til praksis?   ☐ JA   ☐ UKLART   ☐ NEI

Tips:

- Vurder om personene i studien er annerledes enn personene du møter i praksis
- Er de lokale forholdene forskjellige fra stedet der studien ble gjort?

11) Sammenfaller resultatene i denne studien med resultatene fra annen forskning?   ☐ JA   ☐ UKLART   ☐ NEI

Tips: Vurder andre tilgengelige studier som systematiske oversikter, randomiserte kontrollerte studier, kasuskontrollstudier og andre kohortstudier – er det sammenfallende resultater eller sammenhenger?

Viktig!

En enkelt observasjonsstudie, f.eks. kasuskontrollstudie, gir sjelden tilstrekkelig kunnskap til å anbefale endringer i praksis. For spørsmål om årsak og prognose er imidlertid observasjonsstudier det beste studiedesignet.

Tilliten til resultatet fra en observasjonsstudie vil bli styrket hvis et eller flere av disse kriteriene oppfylles:

- det er en stor effekt
- alle forvekslingsfaktorer ville redusere effekt
- det er en klar dose-responsgradient

For mer informasjon, se:

Factors that can increase the quality of the evidence. I: GRADE Handbook [Internet]. GRADE Working Group. Updated October 2013. Tilgjengelig fra: http://gdt.guidelinedevelopment.org/app/handbook/handbook.html#h.gwd531rylwaj

Vedlegg: Utregning av effektestimater

		Utfall JA (syk)	Utfall NEI (frisk)
Eksponert	Y	a	b
Ikke eksponert	X	c	d

Risiko for utfall

$$Y = a/(a+b)$$
$$X = c/(c+d)$$

Relativ risiko/Relative Risk/Risk Ratio (RR)

Relativ risiko (RR) er ratioen mellom de to risikoene. Risikoen i intervensjonsgruppen delt på risikoen i kontrollgruppen.

$$RR = Y/X$$

Odds Ratio (OR)

Odds Ratio (OR) er sjansen (oddsen) for et utfall i eksponeringsgruppen dividert med sjansen for det samme utfallet i kontrollgruppen.

$$OR = (a/b)/(c/d)$$

Relativ risikoreduksjon/Relative Risk Reduction (RRR)

Relativ risikoreduksjon er prosent reduksjon i risiko i intervensjonsgruppen sammenlignet med kontrollgruppen

$$RRR : 1-RR = 1-Y/X \times 100 \%$$

Vedlegg 2

JBI CRITICAL APPRAISAL CHECKLIST FOR ANALYTICAL CROSS SECTIONAL STUDIES

Reviewer_____Date_____

Author_____Year_____ Record Number_____

		Yes	No	Unclear	Not applicable
1.	Were the criteria for inclusion in the sample clearly defined?	☐	☐	☐	☐
2.	Were the study subjects and the setting described in detail?	☐	☐	☐	☐
3.	Was the exposure measured in a valid and reliable way?	☐	☐	☐	☐
4.	Were objective, standard criteria used for measurement of the condition?	☐	☐	☐	☐
5.	Were confounding factors identified?	☐	☐	☐	☐
6.	Were strategies to deal with confounding factors stated?	☐	☐	☐	☐
7.	Were the outcomes measured in a valid and reliable way?	☐	☐	☐	☐
8.	Was appropriate statistical analysis used?	☐	☐	☐	☐

Overall appraisal: Include ☐   Exclude ☐   Seek further info ☐

Comments (Including reason for exclusion)

_____

_____

_____

EXPLANATION OF ANALYTICAL CROSS SECTIONAL STUDIES CRITICAL APPRAISAL

Analytical cross sectional studies Critical Appraisal Tool

Answers: Yes, No, Unclear or Not/Applicable

1.   Were the criteria for inclusion in the sample clearly defined?

The authors should provide clear inclusion and exclusion criteria that they developed prior to recruitment of the study participants. The inclusion/exclusion criteria should be specified (e.g., risk, stage of disease progression) with sufficient detail and all the necessary information critical to the study.

2.   Were the study subjects and the setting described in detail?

The study sample should be described in sufficient detail so that other researchers can determine if it is comparable to the population of interest to them. The authors should provide a clear description of the population from which the study participants were selected or recruited, including demographics, location, and time period.

3.   Was the exposure measured in a valid and reliable way?

The study should clearly describe the method of measurement of exposure. Assessing validity requires that a 'gold standard' is available to which the measure can be compared. The validity of exposure measurement usually relates to whether a current measure is appropriate or whether a measure of past exposure is needed.

Reliability refers to the processes included in an epidemiological study to check repeatability of measurements of the exposures. These usually include intra-observer reliability and inter-observer reliability.

4.   Were objective, standard criteria used for measurement of the condition?

It is useful to determine if patients were included in the study based on either a specified diagnosis or definition. This is more likely to decrease the risk of bias. Characteristics are another useful approach to matching groups, and studies that did not use specified diagnostic methods or definitions should provide evidence on matching by key characteristics

5.   Were confounding factors identified?

Confounding has occurred where the estimated intervention exposure effect is biased by the presence of some difference between the comparison groups (apart from the exposure investigated/of interest). Typical confounders include baseline characteristics, prognostic factors, or concomitant exposures (e.g. smoking). A confounder is a difference between the comparison groups and it influences the direction of the study results. A high quality study at the level of cohort design will identify the potential confounders and measure them (where possible). This is difficult for studies where behavioral, attitudinal or lifestyle factors may impact on the results.

6.   Were strategies to deal with confounding factors stated?

Strategies to deal with effects of confounding factors may be dealt within the study design or in data analysis. By matching or stratifying sampling of participants, effects of confounding factors can be adjusted for. When dealing with adjustment in data analysis, assess the statistics used in the study. Most will be some form of multivariate regression analysis to account for the confounding factors measured.

7. Were the outcomes measured in a valid and reliable way?

Read the methods section of the paper. If for e.g. lung cancer is assessed based on existing definitions or diagnostic criteria, then the answer to this question is likely to be yes. If lung cancer is assessed using observer reported, or self-reported scales, the risk of over- or under-reporting is increased, and objectivity is compromised. Importantly, determine if the measurement tools used were validated instruments as this has a significant impact on outcome assessment validity.

Having established the objectivity of the outcome measurement (e.g. lung cancer) instrument, it's important to establish how the measurement was conducted. Were those involved in collecting data trained or educated in the use of the instrument/s? (e.g. radiographers). If there was more than one data collector, were they similar in terms of level of education, clinical or research experience, or level of responsibility in the piece of research being appraised?

8. Was appropriate statistical analysis used?

As with any consideration of statistical analysis, consideration should be given to whether there was a more appropriate alternate statistical method that could have been used. The methods section should be detailed enough for reviewers to identify which analytical techniques were used (in particular, regression or stratification) and how specific confounders were measured.

For studies utilizing regression analysis, it is useful to identify if the study identified which variables were included and how they related to the outcome. If stratification was the analytical approach used, were the strata of analysis defined by the specified variables? Additionally, it is also important to assess the appropriateness of the analytical strategy in terms of the assumptions associated with the approach as differing methods of analysis are based on differing assumptions about the data and how it will respond.

Vedlegg 3

Name:_____   Date: _____

Pittsburgh Sleep Quality Index (PSQI)

Instructions: The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. **Please answer all questions.**

1. During the past month, what time have you usually gone to bed at night? _____
2. During the past month, how long (in minutes) has it usually taken you to fall asleep each night? _____
3. During the past month, what time have you usually gotten up in the morning? _____
4. During the past month, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spent in bed.) _____

5. During the past month, how often have you had trouble sleeping because you…	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
a. Cannot get to sleep within 30 minutes				
b. Wake up in the middle of the night or early morning				
c. Have to get up to use the bathroom				
d. Cannot breathe comfortably				
e. Cough or snore loudly				
f. Feel too cold				
g. Feel too hot				
h. Have bad dreams				
i. Have pain				
j. Other reason(s), please describe:				
6. During the past month, how often have you taken medicine to help you sleep (prescribed or "over the counter")?				
7. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?				
	No problem at all	Only a very slight problem	Somewhat of a problem	A very big problem
8. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?				
	Very good	Fairly good	Fairly bad	Very bad
9. During the past month, how would you rate your sleep quality overall?				

	No bed partner or room mate	Partner/room mate in other room	Partner in same room but not same bed	Partner in same bed
10. Do you have a bed partner or room mate?				
	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
If you have a room mate or bed partner, ask him/her how often in the past month you have had:				
a. Loud snoring				
b. Long pauses between breaths while asleep				
c. Legs twitching or jerking while you sleep				
d. Episodes of disorientation or confusion during sleep				
e. Other restlessness while you sleep, please describe:				

Scoring the PSQI

The order of the PSQI items has been modified from the original order in order to fit the first 9 items (which are the only items that contribute to the total score) on a single page. Item 10, which is the second page of the scale, does not contribute to the PSQI score.

In scoring the PSQI, seven component scores are derived, each scored 0 (no difficulty) to 3 (severe difficulty). The component scores are summed to produce a global score (range 0 to 21). Higher scores indicate worse sleep quality.

Component 1: Subjective sleep quality—question 9

Response to Q9	Component 1 score
Very good	0
Fairly good	1
Fairly bad	2
Very bad	3

Component 1 score:_____

Component 2: Sleep latency—questions 2 and 5a

Response to Q2	Component 2/Q2 subscore
$\leq$ 15 minutes	0
16-30 minutes	1
31-60 minutes	2
> 60 minutes	3

Response to Q5a	Component 2/Q5a subscore
Not during past month	0
Less than once a week	1
Once or twice a week	2
Three or more times a week	3

Sum of Q2 and Q5a subscores	Component 2 score
0	0
1-2	1
3-4	2
5-6	3

Component 2 score:_____

Component 3: Sleep duration—question 4

Response to Q4	Component 3 score
> 7 hours	0
6-7 hours	1
5-6 hours	2
< 5 hours	3

Component 3 score:_____

Component 4: Sleep efficiency—questions 1, 3, and 4

Sleep efficiency = (# hours slept/# hours in bed) X 100%
  # hours slept—question 4
  # hours in bed—calculated from responses to questions 1 and 3

Sleep efficiency	Component 4 score
> 85%	0
75-84%	1
65-74%	2
< 65%	3

Component 4 score:_____

Component 5: Sleep disturbance—questions 5b-5j

Questions 5b to 5j should be scored as follows:

Not during past month	0
Less than once a week	1
Once or twice a week	2
Three or more times a week	3

Sum of 5b to 5j scores	Component 5 score
0	0
1-9	1
10-18	2
19-27	3

Component 5 score:_____

Component 6: Use of sleep medication—question 6

Response to Q6	Component 6 score
Not during past month	0
Less than once a week	1
Once or twice a week	2
Three or more times a week	3

Component 6 score:_____

Component 7: Daytime dysfunction—questions 7 and 8

Response to Q7	Component 7/Q7 subscore
Not during past month	0
Less than once a week	1
Once or twice a week	2
Three or more times a week	3

Response to Q8	Component 7/Q8 subscore
No problem at all	0
Only a very slight problem	1
Somewhat of a problem	2
A very big problem	3

Sum of Q7 and Q8 subscores	Component 7 score
0	0
1-2	1
3-4	2
5-6	3

Component 7 score:_____

Global PSQI Score: Sum of seven component scores:_____

Citation: Buysse, DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ: The Pittsburgh Sleep Quality Index (PSQI): A new instrument for psychiatric research and practice. Psychiatry Research 28:193-213, 1989