Checklist for Intervention research. Systematic Review Monitoring

Title .....

Author .....Device.....

Journal, publication date .....

Reviewer.....Date.....

Relevance	Yes	No	Unclear
1. Is the spectrum of patients representative of a general hospital ward population?	( )	( )	( )
2. Provides the investigated device or system decision support, analyzing the signals to present state a patients' health?	( )	( )	( )
3. Is the monitoring device wireless?	( )	( )	( )
4. Is the monitoring device contactless?	( )	( )	( )
5. Is the test device easily applicable in low care clinical practice?	( )	( )	( )

Validity

Quality/ design

5. Randomized allocation?	( )	( )	( )
6. Sampling: Cohort / Case-Control / Case series / other .....*			( )
7. Was the sample size calculation preformed?	( )	( )	( )
8. Was the method of recruitment/sampling systematically performed?	( )	( )	( )
9. Were primary and secondary outcome measures clearly predefined?	( )	( )	( )
10. Time span: How long was the intervention delivered?			( )
11. Who assessed/ acted on the initial results from the monitor?			( )
12. Who was blinded to the study condition assignment? Participants / care providers / those assessing outcomes *			( )
13. Statistical method to compare groups for outcomes:			( )

Quality / study execution

14. Population, setting:			( )
15. When was the study performed (Date)			( )
16. Participants. Baseline characteristics reported?	( )	( )	( )

	Patients	Age	Male			
Study group						
Usual care						

17. Index monitor, name:			( )
18. Method of respiratory observation (e.g. pulse oximetry):			( )
19. Measurement (e.g. humidity in expired air):			( )
20. Sensor placement (e.g. on the ear):.....			( )
21. Additional vital sign measurements (e.g. HR):.....			( )
22. Was standardized care applied at all times?	( )	( )	( )
23. Were any other health care changes made along with the introduction of the monitoring system?	( )	( )	( )
24. Primary endpoint			( )
Secondary endpoints			( )
25. Was the flow of participants through each stage clear: enrollment, assignment, allocation, intervention, follow-up?	( )	( )	( )
Enrollment: ..... (no. participants screened for eligibility)			( )
Assignment: ..... (no. participants assigned to a condition)			( )
Intervention exposure: ..... (no. participants receiving each intervention)			( )
Follow-up ..... (no. participants who completed follow-up)			( )

** delete what is not applicable*

		Yes	No	Unclear
26.	Was a summary of results provided for each primary- and secondary outcome?	( )	( )	( )
27.	Mortality			( )
28.	ICU admission			( )
29.	Length of hospital stay			( )
30.	Length of ICU stay			( )
31.	Cardiopulmonary arrests			( )
32.	Other:.....			( )

Quality / article

33.	Is the research question clearly stated?	( )	( )	( )
34.	Is the target population and study sample clearly described?	( )	( )	( )
35.	Is the intervention clearly described to allow replication?	( )	( )	( )
36.	Is the data acquisition described sufficiently?	( )	( )	( )
37.	Were the results/ outcomes clearly and correctly reported?	( )	( )	( )
38.	Were the indeterminate results (artifacts) and outliers reported?	( )	( )	( )
39.	Were the results discussed taking into account -the trial limitations?	( )	( )	( )
	-generalisability?	( )	( )	( )
	-benefit and harms?	( )	( )	( )

Checklist for diagnostic studies. Systematic Review Monitoring

Title .....

Author .....Device.....

Journal, publication date .....

Reviewer.....Date.....

Relevance	Yes	No	Unclear
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2. Provides the investigated device or system decision support, analyzing the signals to present state a patients' health?	( )	( )	( )
3. Is the monitoring device wireless?	( )	( )	( )
4. Is the monitoring device contactless?	( )	( )	( )
5. Is the test device easily applicable in low care clinical practice?	( )	( )	( )

Validity

Quality / design

6. Diagnostic accuracy / comparing accuracy between tests / methods-comparison*			( )
7. Sampling: Cohort / Case-Control / Case Series / other: ..... *			( )
8. Was a sample size calculation performed?	( )	( )	( )
9. Was the method of recruitment/sampling performed systematically?	( )	( )	( )
10. Were cutoff points (normal vs. abnormal) or categories of both reference test and investigated device determined previously?	( )	( )	( )
11. Were the reference measurements performed simultaneously with the index measurements (cross-sectional)?	( )	( )	( )
12. Blinding of the index monitor?	( )	( )	( )
13. Blinding of the reference monitor?	( )	( )	( )

Quality/ study execution

14. Population, setting:			( )
15. When was the study performed (Date)			( )
16. Participants, baseline characteristics reported?	( )	( )	( )

	Patients	Age	Male				
No. %							

17. Index monitor, name:			( )
18. Method of respiratory observation (e.g. pulse oximetry):			( )
19. Measurement (e.g. humidity in expired air):			( )
20. Sensor placement (e.g. on the ear):.....			( )
21. Additional vital sign measurements (e.g. HR):.....			( )
22. Reference test:.....			( )
23. Was standardized care applied at all times?	( )	( )	( )
24. Were any other health care changes made along with the introduction of the monitoring system?	( )	( )	( )
25. Is a cross tabulation reported?	( )	( )	( )

	Ref+	Ref-
Test+		
Test-		

26. Is diagnostic accuracy and statistical uncertainty reported?	( )	( )	( )

Sens	Spec	PPV	NPV	LR+	LR-

27. If comparability between tests is tested: Is a Bland Altman analysis done?	( )	( )	( )

Mean	SD	-limit	+limit

Quality / article

28. Is the research question clearly stated?	( )	( )	( )
29. Is the target population and study sample clearly described?	( )	( )	( )
30. Is the index monitor clearly described?	( )	( )	( )
31. Is the reference monitor clearly described?	( )	( )	( )
32. Is the data acquisition described sufficiently?	( )	( )	( )
33. Were the results/ outcomes clearly and correctly reported?	( )	( )	( )
34. Were the indeterminate results (artifacts) and outliers reported?	( )	( )	( )
35. Is clinical applicability of study findings reported?	( )	( )	( )

** delete what is not applicable.*