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LAMPIRAN

Penulis	Tujuan	Desain Penelitian	Sampel	Durasi	Intervensi	Hasil	P value
R. Santos et al., 2019	untuk meningkatkan kemanjuran antibiotik dan antiseptik konvensional terhadap isolat klinis DFIs S. aureus	Cluster randomized trial	Sebanyak 53 stafilokokus dikumpulkan dari 49 pasien DFU, dari mana 23 isolat S. aureus penghasil biofilmkeluarga mereka	7 hari	antimikroba nisin-biogel diuji sendiri dan dalam kombinasi yang berbeda dengan antiseptik klorheksidin dan antibiotik klindamisin, gentamisin, dan vankomisin	antibakteri yang tinggi terhadap biofilm bentukan DFI S. aureus. Protokol gabungan yang menggunakan nisin-biogel dan klorheksidin menunjukkan kemanjuran tertinggi dalam penghambatan pembentukan biofilm, secara signifikan lebih tinggi (p <0,05) daripada yang disajikan oleh protokol berbasis antibiotik yang diuji. Mengenai pemberantasan biofilm, tidak ada perbedaan yang signifikan (p> 0,05) antara aktivitas kombinasi nisin-biogel ditambah klor-heksidin dan protokol berbasis antibiotik konvensional. klorheksidin dan nisinbiogel berpotensi diterapkan di pusat-pusat	*p<0.05*

						medis, berkontribusi untuk pengurangan pemberian antibiotik, tekanan seleksi pada patogen DFI dan penyebaran strain resistensi.	
Touzel et al., 2016	Untuk membangun model biofilm multi-spesies untuk menguji efektivitas formula yang mengandung klorheksidin dan klorheksidin dalam pemberantasan biofilm polimikroba	Randomized controlled trial		3 bulan	Klorheksidin diglukonat (CHD) ditambahkan ke bioreaktor pada berbagai konsentrasi. K. pneumoniae dan P. aeruginosa bertahan dalam biofilm multi-spesies	Chlorhexidine digluconate (CHD) ditambahkan ke bioreaktor pada berbagai konsentrasi. K. pneumoniae dan P. aeruginosa bertahan hidup dalam biofilm multi-spesies, hingga dan termasuk 4% PJK, sedangkan S. aureus berkurang hingga di bawah tingkat deteksi sebesar 1%. Menyeka kupon yang mengandung biofilm dari bioreaktor dengan tisu medis yang mengandung klorheksidin menghasilkan pengurangan> 3 hingga	*p:* 0,000

						<4 log10 setelah 24 jam, untuk semua spesies.	
Roukis, 2010,	untuk penyebab intrinsik dan ekstrinsik dengan menggunakan disinfektan topikal	Randomized controlled trial	Populasi 24 pasien yang diteliti hanya mencakup pasien dengan diabetes dan terbatas pada kaki	3 bulan	klorheksidin glukonat (4%)	pengurangan yang signifikan dari kedua jumlah organisme yang teridentifikasi dan kultur positif yang diperoleh untuk organisme bakteri aerob yang paling sering diisolasi termasuk yang sensitif terhadap metisilin dan yang resisten terhadap metisilin. S. epidermidis	p < 0.001
Johani et al., 2018	Uji kinerja solusi luka antimikroba topikal terhadap penggunaan biofilm mikroba model sistem pada waktu pemaparan yang relevan secara klinis	pada 10 pasien dengan ulkus kaki kronis tanpa penyembuhan diabetes rumit oleh biofilm	Experimental study	15 menit, setiap hari, selama 7 hari	Pencuci luka antimikroba topikal diuji di bawah tiga kondisi yang berbeda: (in vitro) 4% b / v Minyak melaleuca, polyhexamethylene biguanide, chlorhexidine, povidone iodine dan	Pada 15 menit pemajanan iodine povidone adalah satu- satunya solusi untuk tampil lengkap dan membunuh secara efisien biofilm S. aureus dan P. aeruginosa (6 dan 7 log10 pengurangan. CHG efektif melawan Biofilm S. aureus menunjukkan penghapusan lengkap semua	P < 0.01

					asam hipoklorus terhadap biofilm matang Staphylococcus aureus dan Pseudomonas aeruginosa; (ex vivo) asam hipoklorus diuji terhadap 3 hari biofilm P. aeruginosa dewasa; dan (in vivo) 4% w / v minyak Melaleuca.	bakteri (6log10) P=0,001), dan selanjutnya menunjukkan 3,96 log10 cfu reduksi terhadap biofilm P. aeruginosa (P =0,01). Efek	
Townsend et al., 2016	untuk menguji efektivitas formula yang mengandung klorheksidin	pasien dengan ulkus kaki, tidak dijelaskan berapa jumlah sampel yang digunakan	Experimental study	Tidak dijelaskan terkait durasi	-	biofilm yang representatif	p < 0.001

LAMPIRAN 2. TOOLS PENILAIAN KUALITAS ARTIKEL
CASP RCT

11 questions to help you make sense of a trial

How to use this appraisal tool

Three broad issues need to be considered when appraising a randomised Controlled trial study: Are the

results of the study valid? (Section A)
What are the results? (Section B)
Will the results help locally? (Section C)

The 11 questions on the following pages are designed to help you think about these issues systematically. The first two questions are screening questions and can be answered quickly. If the answer to both is "yes", it is worth proceeding with the remaining questions.

There is some degree of overlap between the questions, you are asked to record a "yes", "no" or "can't tell" to most of the questions. A number of italicised prompts are given after each question. These are designed to remind you why the question is important. Record your reasons for your answers in the spaces provided.

These checklists were designed to be used as educational pedagogic tools, as part of a workshop setting, therefore we do not suggest a scoring system. The core CASP checklists (randomised Controlled trial & *systematic review*)
were based on JAMA 'Users' guides to the medical literature 1994 (adapted from Guyatt GH, Sackett DL, and Cook DJ), and piloted with health care practitioners.

For each new checklist a group of experts were assembled to develop and pilot the checklist and the workshop format with which it would be used. Over the years overall adjustments have been made to the format, but a recent survey of checklist users reiterated that the basic format continues to be useful and appropriate.

Referencing: we recommend using the Harvard style citation, i.e.:

Critical Appraisal Skills Programme (2017). CASP (insert name of checklist i.e. Randomised Controlled Trial) Checklist. [online] Available at: *URL*. Accessed: *Date Accessed.*

(A) Are the results of the trial valid?

Screening Questions

1. Did the trial address a clearly focused issue? **□Yes** **□Can't tell** **□No**

HINT: An issue can be 'focused' In terms of

- The population studied
- The intervention given
- The comparator given
- The *outcome*s considered

2. Was the assignment of patients to treatments **□Yes** **□Can't tell** **□No randomised?**

HINT: Consider

- How was this carried out?

- Was the allocation sequence concealed from researchers and patients?

---

3. Were all of the patients who entered conclusion? □**Yes** □**Can't tell** □**No the trial properly accounted for at its**

HINT: Consider

- Was the trial stopped early?
- Were patients analysed in the groups to which they were randomised?

Is it worth continuing?

Detailed questions

4. Were patients, health workers and study □Yes □Can't tell □No personnel '*blind*' to treatment?

HINT: Think about

- Patients?
- Health workers?
- Study personnel?

---

5. Were the groups similar at the start of the trial? □Yes □Can't tell □No

HINT: Look at

- Other faktors that might affect the *outcome* such as age, sex, social class

6. Aside from the experimental intervention, were the groups treated equally? ☐ **Yes** ☐ **Can't tell** ☐ **No**

(B) What are the results?

7. How large was the treatment effect?

HINT: Consider

- What *outcome*s were measured?
- Is the primary *outcome* clearly specified?
- What results were found for each *outcome*?

8. How precise was the estimate of the treatment effect?

HINT: Consider

- What are the confidence limits?

(C) Will the results help locally?

9. Can the results be applied in your context? ☐ **Yes** ☐ **Can't tell** ☐ **No (or to the local population?)**

HINT: Consider whether

- Do you think that the patients covered by the trial are similar

enough to the patients to whom you will apply this?, if not how to they differ?

10. Were all clinically important *outcome*s considered? ☐ **Yes** ☐ **Can't tell** ☐ **No**

HINT: Consider

a. Is there other information you would like to have seen?
b. If not, does this affect the decision?

11. Are the benefits worth the harms and costs? ☐ **Yes** ☐ **Can't tell** ☐ **No**

HINT: Consider

c. Even if this is not addressed by the trial, what do you think?

JBI Critical Appraisal tools (Checklist for Quasi experimental tools)

JBI Critical Appraisal Checklist for Quasi-Experimental Studies
(non-randomized experimental studies)

*Reviewe*r_____Date _____

Author _____Year_____Record Number _____

	Yes	No	Unclear	Not applicable
1. Is it clear in the study what is the 'cause' and what is the 'effect' (i.e. there is no confusion about which variable comes first)?	□	□	□	□
2. Were the participants included in any comparisons similar?	□	□	□	□
3. Were the participants included in any comparisons receiving similar treatment/care, other than the exposure or intervention of interest?	□	□	□	□
4. Was there a kontrol group?	□	□	□	□
5. Were there multiple measurements of the *outcome* both pre and post the intervention/exposure?	□	□	□	□
6. Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?	□	□	□	□
7. Were the *outcome*s of participants included in any	□	□	□	□

comparisons measured in the same way?

8. Were *outcome*s measured in a reliable way? □ □ □ □

9. Was appropriate statistical analysis used? □ □ □ □

Overall appraisal: Include □ Exclude □ Seek further info □

Comments (Including reason for exclusion)

_____

_____

LAMPIRAN 3. TOOLS PENILAIAN RISIKO BIAS

Cochrane Collaboration's tool for assessing risk of bias (adapted from Higgins and Altman13)

Bias domain	Source of bias	Support for judgment	*Review* authors' judgment (assess as low, unclear or high risk of bias)
Selection bias	Random sequence generation	Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups	Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence
	Allocation concealment	Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen before or during enrolment	Selection bias (biased allocation to interventions) due to inadequate concealment of allocations before assignment
Performance bias	*Blind*ing of participants and personnel*	Describe all measures used, if any, to *blind* trial participants and researchers from knowledge of which intervention a participant received. Provide any information relating to whether the intended *blind*ing was effective	Performance bias due to knowledge of the allocated interventions by participants and personnel during the study
Detection bias	*Blind*ing of *outcome* assessment*	Describe all measures used, if any, to *blind outcome* assessment from knowledge of which intervention a participant received. Provide any information relating to whether the intended *blind*ing was effective	Detection bias due to knowledge of the allocated interventions by *outcome* assessment
Attrition bias	Incomplete *outcome* data*	Describe the completeness of *outcome* data for each main *outcome*, including attrition and exclusions from the analysis.	Attrition bias due to amount, nature, or handling of incomplete *outcome* data

		State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomised participants), reasons for attrition or exclusions where reported, and any reinclusions in analyses for the *review*	
Reporting bias	Selective reporting	State how selective *outcome* reporting was examined and what was found	Reporting bias due to selective *outcome* reporting
Other bias	Anything else, ideally Prespecified	State any important concerns about bias not covered in the other domains in the tool	Bias due to problems not covered elsewhere

*Assessments should be made for each main *outcome* or class of *outcome*s

LAMPIRAN 4. PENILAIAN *OXFORD CENTRE FOR EVIDENCE BASED MEDICINE- LEVEL OF EVIDENCE*

Oxford Centre for Evidence-based Medicine – Levels of Evidence (March 2009)

What are we to do when the irresistible force of the need to offer clinical advice meets with the immovable object of flawed evidence? All we can do is our best: give the advice, but alert the advisees to the flaws in the evidence on which it is based.

The CEBM 'Levels of Evidence 1' document sets out one approach to systematising this process for different question types.

(For definitions of terms used see our glossary)

Level	Therapy / Prevention, Aetiology / Harm	Prognosis	Diagnosis	Differential diagnosis / symptom prevalence study	Economic and decision analyses
1a	SR (with homogeneity*) of RCTs	SR (with homogeneity*) of inception cohort studies; CDR" validated in different populations	SR (with homogeneity*) of Level 1 diagnostic studies; CDR" with 1b studies from different clinical centres	SR (with homogeneity*) of prospective cohort studies	SR (with homogeneity*) of Level 1 economic studies
1b	Individual RCT (with narrow Confidence Interval"¡)	Individual inception cohort study with > 80% follow-up; CDR" validated in a single population	Validating** cohort study with good" " " reference standards; or CDR" tested within one clinical centre	Prospective cohort study with good follow-up****	Analysis based on clinically sensible costs or alternatives; systematic review(s) of the evidence; and including multi-way

					sensitivity analyses
1c	All or none§	All or none case-series	Absolute SpPins and SnNouts” “	All or none case-series	Absolute better-value or worse-value analyses ” ” ” “
2a	SR (with homogeneity*) of cohort studies	SR (with homogeneity*) of either retrospective cohort studies or untreated control groups in RCTs	SR (with homogeneity*) of Level >2 diagnostic studies	SR (with homogeneity*) of 2b and better studies	SR (with homogeneity*) of Level >2 economic studies
2b	Individual cohort study (including low quality RCT; e.g., <80% follow-up)	Retrospective cohort study or follow-up of untreated control patients in an RCT; Derivation of CDR” or validated on split-sample§§§ only	Exploratory** cohort study with good” ” ” reference standards; CDR” after derivation, or validated only on split-sample§§§ or databases	Retrospective cohort study, or poor follow-up	Analysis based on clinically sensible costs or alternatives; limited review(s) of the evidence, or single studies; and including multi-way sensitivity analyses
2c	“Outcomes” Research; Ecological studies	“Outcomes” Research		Ecological studies	Audit or outcomes research
3a	SR (with homogeneity*) of case-control studies		SR (with homogeneity*) of 3b and better studies	SR (with homogeneity*) of 3b and better studies	SR (with homogeneity*) of 3b and better studies
3b	Individual Case-		Non-consecutive study; or	Non-consecutive	Analysis based on

	Control Study		without consistently applied reference standards	cohort study, or very limited population	limited alternatives or costs, poor quality estimates of data, but including sensitivity analyses incorporating clinically sensible variations.
4	Case-series (and poor quality cohort and case-control studies§§)	Case-series (and poor quality prognostic cohort studies***)	Case-control study, poor or non-independent reference standard	Case-series or superseded reference standards	Analysis with no sensitivity analysis
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on economic theory or "first principles"

Produced by Bob Phillips, Chris Ball, Dave Sackett, Doug Badenoch, Sharon Straus, Brian Haynes, Martin Dawes since November 1998. Updated by Jeremy Howick March 2009.

Notes

Users can add a minus-sign "-" to denote the level of that fails to provide a conclusive answer because:

- ***EITHER*** a single result with a wide Confidence Interval
- ***OR*** a Systematic Review with troublesome heterogeneity.

Such evidence is inconclusive, and therefore can only generate Grade D recommendations.

*	By homogeneity we mean a systematic review that is free of worrisome variations (heterogeneity) in the directions and degrees of results between individual studies. Not all systematic reviews with statistically significant heterogeneity need be worrisome, and not all worrisome heterogeneity need be statistically significant. As noted above, studies displaying worrisome heterogeneity should be tagged with a "-" at the end of their designated level.
"	Clinical Decision Rule. (These are algorithms or scoring systems that lead to a prognostic estimation or a diagnostic category.)
"¡	See note above for advice on how to understand, rate and use trials or other studies with wide confidence intervals.
§	Met when all patients died before the Rx became available, but some now survive on it; or when some patients died before the Rx became available, but none now die on it.
§§	By poor quality cohort study we mean one that failed to clearly define comparison groups and/or failed to measure exposures and outcomes in the same (preferably blinded), objective way in both exposed and non-exposed individuals and/or failed to identify or appropriately control known confounders and/or failed to carry out a sufficiently long and complete follow-up of patients. By poor quality case-control study we mean one that failed to clearly define comparison groups and/or failed to measure exposures and outcomes in the same (preferably blinded), objective way in both cases and controls and/or failed to identify or appropriately control known confounders.
§§§	Split-sample validation is achieved by collecting all the information in a single tranche, then artificially dividing this into "derivation" and "validation" samples.
" "	An "Absolute SpPin" is a diagnostic finding whose Specificity is so high that a Positive result rules-in the diagnosis. An "Absolute SnNout" is a diagnostic finding whose Sensitivity is so high that a Negative result rules-out the diagnosis.

“¡”¡	Good, better, bad and worse refer to the comparisons between treatments in terms of their clinical risks and benefits.
” ” “	Good reference standards are independent of the test, and applied blindly or objectively to applied to all patients. Poor reference standards are haphazardly applied, but still independent of the test. Use of a non-independent reference standard (where the ‘test’ is included in the ‘reference’, or where the ‘testing’ affects the ‘reference’) implies a level 4 study.
” ” ” “	Better-value treatments are clearly as good but cheaper, or better at the same or reduced cost. Worse-value treatments are as good and more expensive, or worse and the equally or more expensive.
**	Validating studies test the quality of a specific diagnostic test, based on prior evidence. An exploratory study collects information and trawls the data (e.g. using a regression analysis) to find which factors are ‘significant’.
***	By poor quality prognostic cohort study we mean one in which sampling was biased in favour of patients who already had the target outcome, or the measurement of outcomes was accomplished in <80% of study patients, or outcomes were determined in an unblinded, non-objective way, or there was no correction for confounding factors.
****	Good follow-up in a differential diagnosis study is >80%, with adequate time for alternative diagnoses to emerge (for example 1-6 months acute, 1 – 5 years chronic)

Grades of Recommendation

A	consistent level 1 studies
B	consistent level 2 or 3 studies ***or*** extrapolations from level 1 studies
C	level 4 studies ***or*** extrapolations from level 2 or 3 studies
D	level 5 evidence ***or*** troublingly inconsistent or inconclusive studies of any level

“Extrapolations” are where data is used in a situation that has potentially clinically important differences than the original study situation.

Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence

Question	Step 1 (Level 1*)	Step 2 (Level 2*)	Step 3 (Level 3*)	Step 4 (Level 4*)	Step 5 (Level 5)
How common is the problem?	Local and current random sample surveys (or censuses)	Systematic review of surveys that allow matching to local circumstances**	Local non-random sample**	Case-series**	n/a
Is this diagnostic or monitoring test accurate? (Diagnosis)	Systematic review of cross sectional studies with consistently applied reference standard and blinding	Individual cross sectional studies with consistently applied reference standard and blinding	Non-consecutive studies, or studies without consistently applied reference standards**	Case-control studies, or "poor or non-independent reference standard**	Mechanism-based reasoning
What will happen if we do not add a therapy? (Prognosis)	Systematic review of inception cohort studies	Inception cohort studies	Cohort study or control arm of randomized trial*	Case-series or case-control studies, or poor quality prognostic cohort study**	n/a
Does this intervention help? (Treatment Benefits)	Systematic review of randomized trials or *n*-of-1 trials	Randomized trial or observational study with dramatic effect	Non-randomized controlled cohort/follow-up study**	Case-series, case-control studies, or historically controlled studies**	Mechanism-based reasoning
What are the COMMON harms? (Treatment Harms)	Systematic review of randomized trials, systematic review of nested case-control studies, *n*-of-1 trial with the patient you are raising the question about, or observational study with dramatic effect	Individual randomized trial or (exceptionally) observational study with dramatic effect	Non-randomized controlled cohort/follow-up study (post-marketing surveillance) provided there are sufficient numbers to rule out a common harm. (For long-term harms the duration of follow-up must be sufficient.)**	Case-series, case-control, or historically controlled studies**	Mechanism-based reasoning
What are the RARE harms? (Treatment Harms)	Systematic review of randomized trials or *n*-of-1 trial	Randomized trial or (exceptionally) observational study with dramatic effect			
Is this (early detection) test worthwhile? (Screening)	Systematic review of randomized trials	Randomized trial	Non-randomized controlled cohort/follow-up study**	Case-series, case-control, or historically controlled studies**	Mechanism-based reasoning

*** Level may be graded down on the basis of study quality, imprecision, indirectness (study PICO does not match questions PICO), because of inconsistency between studies, or because the absolute effect size is very small; Level may be graded up if there is a large or very large effect size.**

**** As always, a systematic review is generally better than an individual study.**

How to cite the Levels of Evidence Table

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** OCEBM Table of Evidence Working Group = Jeremy Howick, Iain Chalmers (James Lind Library), Paul Glasziou, Trish Greenhalgh, Carl Heneghan, Alessandro Liberati, Ivan Moschetti, Bob Phillips, Hazel Thornton, Olive Goddard and Mary Hodgkinson*