



THE QUEEN'S
ANNIVERSARY PRIZES
FOR HIGHER AND FURTHER EDUCATION
2017



HSRU

Promoting Excellence in Health Services Research

Increasing the trial process evidence base without increasing research waste

Shaun Treweek

streweek@mac.com

@shauntreweek

HSRU is core funded by the Chief Scientist Office of the Scottish Government Health and Social Care Directorates. The author accepts full responsibility for this talk.



www.abdn.ac.uk/hsru

Follow us on  @hsru_aberdeen



Trials Change Lives

“Clinical trials are the backbone of primary research that informs clinical practice in the NHS in the UK”

*Prof Hywel Williams, Director,
Health Technology Assessment
Programme (NIHR)*



Listen to the
podcast

Clinical Trials for the NHS

Trials– important but not always efficient



HSRU

*'There is a peculiar paradox that exists in trial execution - we perform clinical trials to generate evidence to improve patient outcomes; however, we conduct clinical trials like anecdotal medicine.'**

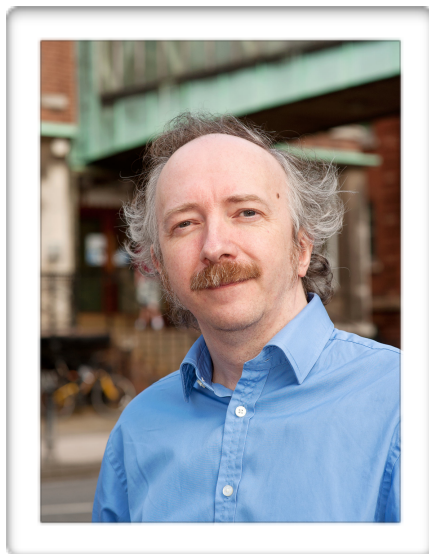
*Monica Shah in 'Site selection in global clinical trials in patients hospitalized for heart failure: perceived problems and potential solutions'. Heart Failure Review 2014; 19:135-52.

SWATs– why bother?



HSRU

It is essential that trials are done in the most effective and efficient ways and one way to do this is to use the same types of evaluation to investigate and improve the processes of how we do randomised trials.

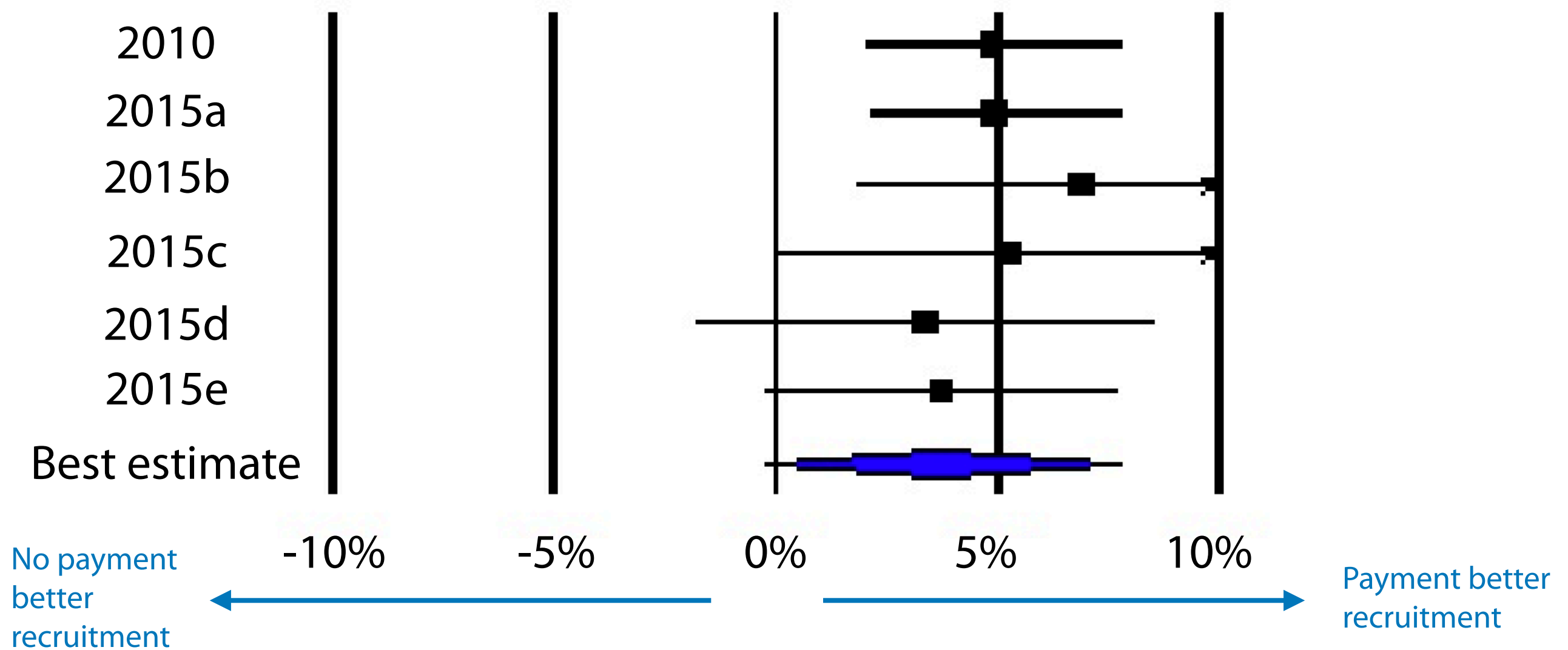


Mike Clarke,
Belfast, UK

E.g. SWAT– financial incentives



HSRU



GRADE

LOW

MODERATE

HIGH

The key question now is–



HSRU

Given what we know already, do we need to do another evaluation of a financial incentive?

The answer is important because if we keep doing evaluations willy-nilly, our attempt to reduce research waste will actually start to increase it.

The key question now is–



HSRU

Given what we know already, do we need to do another evaluation of a financial incentive?

The answer is important because if we keep doing evaluations willy-nilly, our attempt to reduce research waste will actually start to increase it.

NIHR | National Institute
for Health Research

HR^B
Health
Research
Board



TRIAL FORGE

GUIDANCE 2



HSRU

The screenshot shows a web browser displaying a Research Square article. The article title is "Trial Forge Guidance 2: How to decide if a further Study Within A Trial (SWAT) is needed". The status is "UNDER-REVIEW" and the journal is "TRIALS". The integrity check is "PASSED". The authors listed are Shaun Treweek, Simon Bevan, Peter Bower, Matthias Briel, Marion Campbell, Jacquie Christie, Clive Collett, Seonaidh Cotton, Declan Devane, Adel El Feky, Sandra Galvin, Heidi Gardner, Katie Gillies, Kerenza Hood, Jan Jansen, Roberta Littleford, Adwoa Parker, Craig Ramsay, Lynne Restrup, Frank Sullivan, David Torgerson, Liz Tremain, Erik von Elm, Matthew Westmore, Hywel Williams, Paula R Williamson, and Mike Clarke. The article was submitted on 18 October 2018. The DOI is <https://doi.org/10.21203/rs.1.1/v1>. The article has 0 comments and 0 PDF downloads.

How to decide if a further Study Within A Trial (SWAT) is needed. DOI: <https://doi.org/10.21203/rs.1.1/v1>

Our five criteria



HSRU

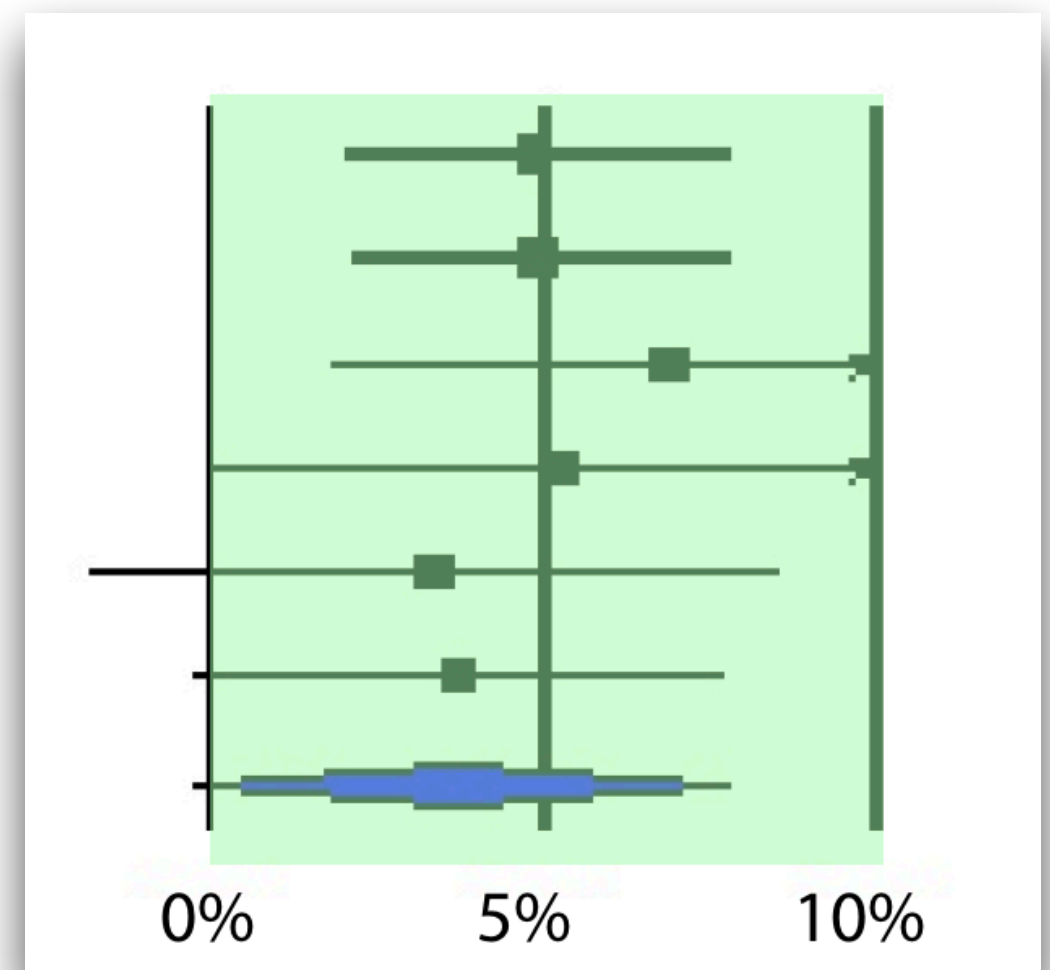
1. Cumulated evidence
2. GRADE
3. Context
4. Balance– participants
5. Balance– host trial

Our five criteria: #1



HSRU

1. Cumulated evidence: the cumulative meta-analysis shows that the effect estimate for each outcome essential to make an informed decision has not converged.



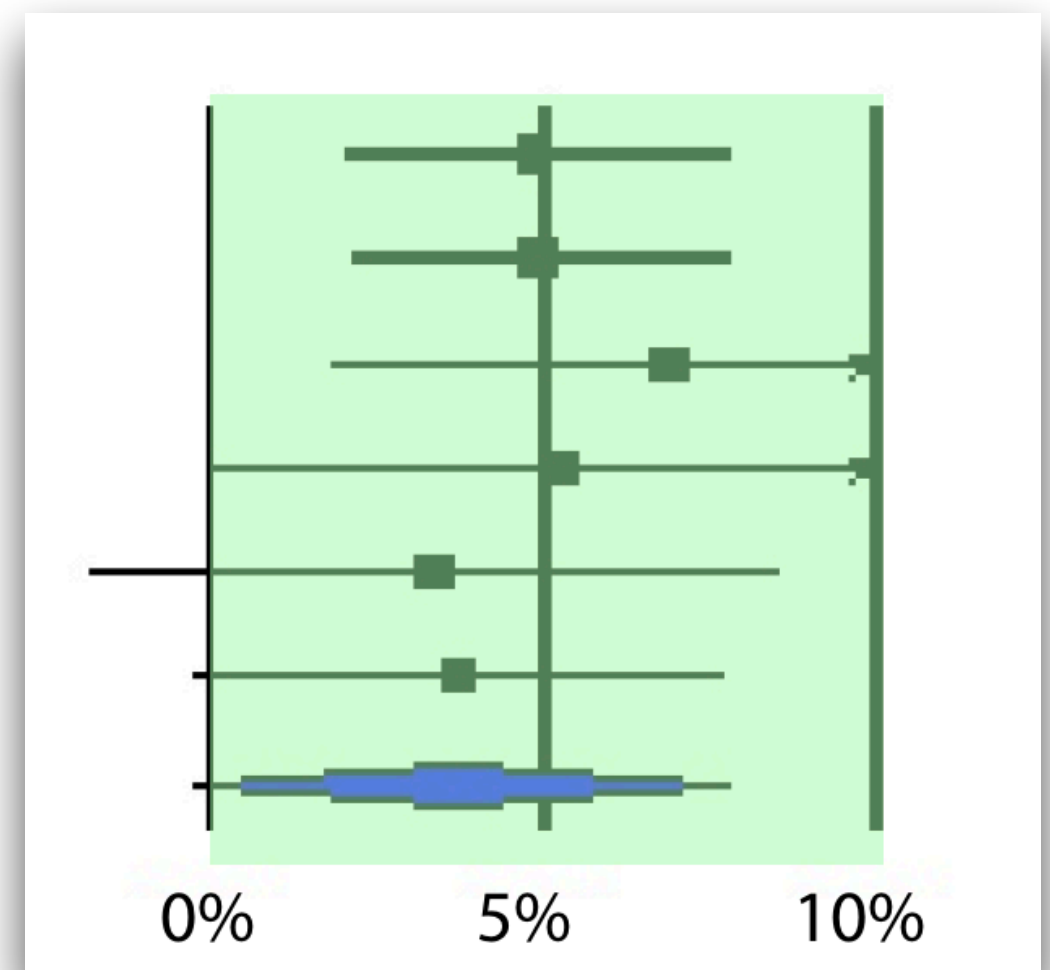
Our five criteria: #1



HSRU

1. Cumulated evidence: the cumulative meta-analysis shows that the effect estimate for each outcome essential to make an informed decision has not converged.

Criterion met



Our five criteria: #2



HSRU

-
1. GRADE: the GRADE certainty in the evidence for all outcomes is lower than 'high'.



Our five criteria: #2



HSRU

-
1. GRADE: the GRADE certainty in the evidence for all outcomes is lower than 'high'.



Criterion met

Our five criteria: #3



HSRU

-
1. Context: the range of host trial contexts evaluated to date does not translate easily to the context of the proposed SWAT.

P– Participants
I– Intervention
C– Comparator
O– Outcomes
T– Timing

Our five criteria: #3



HSRU

-
- Six SWATs, all UK. Five done by the same group.
 - Five in primary care, one in community.
 - Three trials involved hypertension, one arthritis, one excess uric acid in urine, one smoking
 - Five done in drug trials (comparators were an active drug). Other done in mobile phone supported smoking cessation intervention trial, comparator no support.
 - All SWATs measured recruitment.
 - Five SWATs involved a £100 (\$130) payment, higher than is usual in the UK at least.

Our five criteria: #3



HSRU

-
- Six SWATs, all UK. Five done by the same group.
 - Five in primary care, one in community.
 - Three trials involved hypertension, one arthritis, one excess uric acid in urine, one smoking
 - Five done in drug trials (comparators were an active drug). Other done in mobile phone supported smoking cessation intervention trial, comparator no support.
 - All SWATs measured recruitment.
 - Five SWATs involved a £100 (\$130) payment, higher than is usual in the UK at least.

Criterion partially met, maybe

Our five criteria: #4



HSRU

-
1. Balance– participants: the balance of benefit and disadvantage to participants in the host trial and/or the SWAT is not clear.

Our five criteria: #4



HSRU

-
1. Balance– participants: the balance of benefit and disadvantage to participants in the host trial and/or the SWAT is not clear.

Criterion partially met

Our five criteria: #5



HSRU

-
1. Balance– host trial: the balance of benefit and disadvantage to the new host trial is not clear.

Our five criteria: #5



HSRU

-
1. Balance– host trial: the balance of benefit and disadvantage to the new host trial is not clear.

Criterion not met

Do we need more evaluations of financial incentives for recruitment?



HSRU

Users: trial teams

Outcome: recruitment

1. Cumulated evidence: **Criterion met**
2. GRADE: **Criterion met**
3. Context: **Criterion partially met, maybe**
4. Balance– participants: **Criterion partially met**
5. Balance– host trial: **Criterion not met**

Do we need more evaluations of financial incentives for recruitment?



HSRU

Users: trial teams

Outcome: recruitment

1. Cumulated evidence: **Criterion met**
2. GRADE: **Criterion met**
3. Context: **Criterion partially met, maybe**
4. Balance– participants: **Criterion partially met**
5. Balance– host trial: **Criterion not met**

On balance, yes, more evaluations needed

Summary



HSRU

1. We need more trial process evidence.
2. SWATs are one way of filling evidence gaps.
3. ..but we need to stop once the gap has been filled.
4. Avoiding that needs criteria; now we have some.
5. We aim to use the criteria in Trial Forge. Others can too.



HSRU

Promoting Excellence in Health Services Research



TRIAL FORGE

www.trialforge.org

If you have any further questions please contact:

Shaun Treweek, HSRU, University of Aberdeen, UK

Email: streweek@mac.com

Twitter: [@shauntreweek](https://twitter.com/shauntreweek); [@Trial_Forge](https://twitter.com/Trial_Forge)

HSRU is core funded by the Chief Scientist Office of the Scottish Government Health and Social Care Directorates. The author accepts full responsibility for this talk.



www.abdn.ac.uk/hsru

Follow us on  [@hsru_aberdeen](https://twitter.com/hsru_aberdeen)



HSRU
