The BISON (Bloodstream Infections and Sepsis Outcomes measurement Network) initiative: systematic overview of outcomes used in systematic reviews on.

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on behalf of the European Society of Clinical Microbiology and Infectious Diseases working group on bloodstream infections and sepsis (ESGBIS).

Background

Sepsis and bloodstream infections (S/BSI) trials show diversity of endpoints in clinical trials; this hinders comparison and combination of trial results, wasting valuable scientific and clinical information.

Objectives

to estimate the potential research waste caused by a lack of agreement on outcome measures in S/BSI.

Methods

- **Design**: Overview of systematic reviews PROSPERO CRD42015016617
- Multidisciplinary panel
- **Databases:**
  - MEDLINE
  - Cochrane Library
  - Abstracts of Reviews of Effects
- **Inclusion criteria**
  - Systematic review for treatment efficacy, S/BSI, adult patients, publication >2004
- **Data**
  - for each SR: number of patients, number of RCTs, Outcomes
  - for each RCT: Population, Intervention, Control, Primary and additional Outcomes, Patients meta analysed
- **Outcome Classification**
  - Domains: Mortality, Admission Duration, Clinical, Laboratory/Functional, other

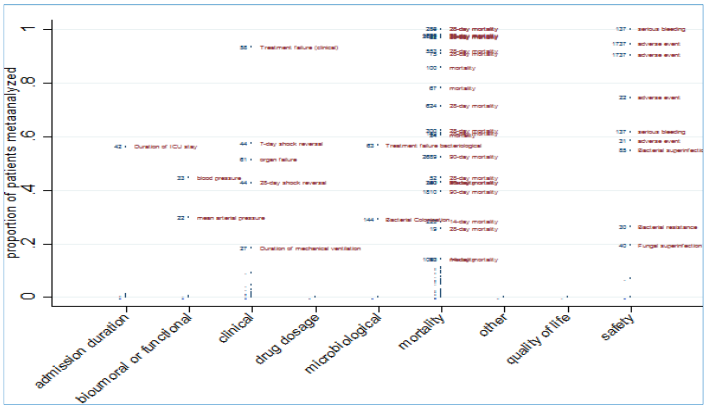
Results

Records identified through database searching (n=429)
Records after duplicates removed (n=426)
Full-text articles assessed for eligibility (n=65)
Studies included in quantitative synthesis
SR n=17, RCT n=200

	Characteristic	Category	N	%
Systematic reviews	Number of outcome planned	Median (IQR) range	3 (2-8)	1-10
	Total number of trials	Median (IQR) range	7 (4-16)	2-45
	Total number of patients		48264	NA
	Number of meta-analyses performed	Median (IQR) range	2 (1-4)	1-8
RCTs	Total number of patients	Median (IQR) range	67 (40-198)	10-2689
	Primary outcome	Mortality	112	56
		Clinical	52	26
		Bioumoral or functional	33	16·5
		Safety	3	1·5
	Number of outcomes planned	Median (IQR)	5 (3-7)	1-20
	Number of outcomes meta-analysed	Median (IQR)	2 (1-3)	0-7

rank	outcome	Frequency	Percent
1	mortality	103	35·8
2	28-day mortality	87	30·2
3	hospital mortality	19	6·6
4	ICU mortality	13	4·5
5	90-day mortality	10	3·5
6	mortality from sepsis/septic shock	10	3·5
7	14-day mortality	8	2·8
8	30-day mortality	7	2·4
9	12-month mortality	6	2·1
10	7-day mortality	6	2·1
11	60-day mortality	5	1·7
12	180-day mortality	2	0·7
13	21-day mortality	2	0·7
14	42-day mortality	2	0·7
15	12-month ICU mortality	1	0·4
16	12-month hospital mortality	1	0·4
17	28-day ICU mortality	1	0·4
18	28-day hospital mortality	1	0·4
19	6-month ICU mortality	1	0·4
20	6-month hospital mortality	1	0·4
21	intraoperative mortality	1	0·4
22	mortality in VAP	1	0·4

Proportion of patients included in meta-analyses, in 504 instances of outcomes in 17 SRs



Limitations

Highly selected reports: RCT included in SR Arbitrary classification of outcomed. Only outcomes described in SR have been assessed

Conclusions

Even from a sample of highly selected reports, there was a **large variation of outcomes reported**, even for a "strong" outcome as mortality: if all RCTs had used the same, usable reports for meta-analysis would increase by 11-100%, and patients by up to 100%.

Research waste in this setting is extremely relevant, and consensus on a core outcome set in the setting of S/BSI is needed.

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