



Review

Systematic review and meta-analysis of the risk of microbial contamination of parenteral doses prepared under aseptic techniques in clinical and pharmaceutical environments: an update

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SUMMARY

Background: Administration of parenteral doses with microbial contamination can lead to infective morbidity or death.

Aim: To test whether aseptic preparation of parenteral doses or additives to sterile doses undertaken in dedicated pharmaceutical rather than clinical environments reduces the risk of microbial dose contamination.

Methods: Data identified from a systematic review were examined using random effects meta-analyses, and *t*-tests were used to compare dose contamination frequencies.

Findings: In all, 16,552 doses from 34 studies (33 records) were identified. For all the data combined there was a significantly higher frequency of contamination of doses prepared in clinical than in pharmaceutical environments {3.7% [95% confidence interval (CI): 2.2, 6.2; *N* = 10,272 doses] vs 0.5% (95% CI: 0.1, 1.6; *N* = 6280 doses); *P* = 0.007}. Contamination of doses was significantly higher when prepared as individual lots than as part of a batch in pharmaceutical environments [2.1% (95% CI: 0.7, 5.8; *N* = 168 doses) vs 0.2% (95% CI: 0.1, 0.9; *N* = 6112 doses); *P* = 0.002]. There was a significantly higher frequency of dose contamination if additions were made to sterile parenteral doses in clinical environments [risk ratio: 2.121 (95% CI: 1.093, 4.114); *P* = 0.026]. The overall quality of the studies was judged to be low.

Conclusion: Reported rates of parenteral dose contamination were orders of magnitude higher than accepted reference standards, which may increase infection risk. The limited evidence on contamination rates supports dose preparation in pharmaceutical rather than clinical environments, and does not support batch preparation in clinical environments.

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Introduction

Administration of a parenteral dose with microbial contamination may result in infective morbidity and death. Recent examples include: postoperative sepsis after inadequate aseptic handling of intravenous anaesthetic; loss of vision or

further surgery due to endophthalmitis as a consequence of contaminated intravitreal injections in the USA; an outbreak of bloodstream infections requiring withdrawal of relevant stock due to contaminated intravenous analgesia in Taiwan; and deaths in newborns as a consequence of contaminated parenteral nutrition in France and the UK.^{1–4} This means it is

Table 1

The terms and number of results for the literature search undertaken on February 10th, 2014 to identify parenteral doses prepared under aseptic techniques in clinical and pharmaceutical environments

Database	Search row	Search terms	Results (N)
Medline (OvidSP)	1	(syringe or syringes).mp. or syring*.tw.	21,041
	2	(bag or bags).mp. or bag*.tw.	18,909
	3	(infusion or infusions).mp. or infus*.tw.	258,728
	4	(vial or vials).mp. or vial*.tw.	6066
	5	(microbial or microbiological).mp. or micro*.tw.	2,017,452
	6	(bacterium or bacteria).mp. or bact*.tw.	598,873
	7	(fungus or fungi).mp. or fung*.tw.	134,157
	8	(contaminated or contamination).mp. or contam*.tw.	166,465
	9	prepared.mp. or prep*.tw. or manufactured.mp. or manuf*.tw. or compounded.mp. or compound*.tw.	1,110,191
	10	(1 and 5) or (1 and 6) or (1 and 7) or (1 and 8) or (2 and 5) or (2 and 6) or (2 and 7) or (2 and 8) or (3 and 5 and 9 ^b) or (3 and 6 and 9 ^c) or (3 and 7) or (3 and 8) or (4 and 5) or (4 and 6) or (4 and 7) or (4 and 8)	19,123
	11	limit 10 to English language	17,662
Embase Classic and Embase (OvidSP)	1	(syringe or syringes).mp. or syring*.tw.	32,435
	2	(bag or bags).mp. or bag*.tw.	30,560
	3	(infusion or infusions).mp. or infus*.tw.	352,153
	4	(vial or vials).mp. or vial*.tw.	10,079
	5	(microbial or microbiological).mp. or micro*.tw.	2,221,231
	6	(bacterium or bacteria).mp. or bact*.tw.	952,057
	7	(fungus or fungi).mp. or fung*.tw.	252,530
	8	(contaminated or contamination).mp. or contam*.tw.	253,438
	9	prepared.mp. or prep*.tw. or manufactured.mp. or manuf*.tw. or compounded.mp. or compound*.tw.	1,697,262
	10	(1 and 5) or (1 and 6) or (1 and 7) or (1 and 8) or (2 and 5) or (2 and 6) or (2 and 7) or (2 and 8) or (3 and 5 and 9 ^b) or (3 and 6 and 9 ^c) or (3 and 7) or (3 and 8) or (4 and 5) or (4 and 6) or (4 and 7) or (4 and 8)	23,099
	11	limit 10 to English language	20,824
The Cochrane Library (Wiley Online Library) ^a	#1	"syringe" or "syringes" or syring*	1364
	#2	"bag" or "bags" or bag*	4467
	#3	"infusion" or "infusions" or infus*	36,233
	#4	"vial" or "vials" or vial*	1325
	#5	"microbial" or "microbiological" or micro*	66,334
	#6	"bacterium" or "bacteria" or bact*	25856
	#7	"fungus" or "fungi" or fung*	2759
	#8	"contaminated" or "contamination" or contam*	3453
	#9	"prepared" or prep* or "manufactured" or manuf* or "compounded" or compound*	64,682
	#10	(#1 and #5) or (#1 and #6) or (#1 and #7) or (#1 and #8) or (#2 and #5) or (#2 and #6) or (#2 and #7) or (#2 and #8) or (#3 and #5 and #9 ^b) or (#3 and #6 ^c) or (#3 and #7) or (#3 and #8) or (#4 and #5) or (#4 and #6) or (#4 and #7) or (#4 and #8)	3760

^a All document search.

^b The combination of search terms 3 and 5 yielded 57,265 results in Medline, 33,340 results in Embase, and 7464 results in the Cochrane Library, and 4848, 671, and 876 results respectively when search term 9 was also included in the combination.

^c The combination of search terms 3 and 6 returned 6363 results in Medline and 9036 results in Embase, and 689 and 784 results respectively when search term 9 was included in the combination. The third search term was not required for the combination of search terms 3 and 6 in the Cochrane Library since 1565 results were returned.

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