Systematic review of healthcare-associated *Burkholderia cepacia complex* outbreaks: presentation, causes and outbreak control

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SUMMARY

Background: Over the past decades, the *Burkholderia cepacia* complex (BCC) has been linked to multiple healthcare-associated outbreaks. No systematic analysis of these outbreaks has been carried out to date. The aim of this study was to conduct a systematic review of reports on nosocomial BCC outbreaks.

Methods: Published studies from 1971 until 9/12/2019 presenting nosocomial BCC outbreaks were identified using Embase, Pubmed and abstracts from professional meetings.

Results: We identified a total of 111 outbreak reports. Thirty-two percent of the affected institutions were academic hospitals and 43.8% community hospitals. The average outbreak duration was 198.6 ± 604.4 days. A total of 240 deaths (10% of the 2390 case patients) were reported but only 28 (1.2% of the 2390 case patients and 11.7% of the 240 deaths) were directly attributable to BCC. The source could be identified in 73.9% of the outbreaks; 53.2% were caused by contaminated medical solutions and medications, 12% were due to a contaminated disinfectant. In 28.2% of the outbreaks intrinsic product contamination was reported. Multidrug resistance was noted in 26.1% of the BCC strains. PFGE was the most frequently used typing method (43.2%) in the context of outbreak work-up.

Conclusion: Medical products are the most frequent source of BCC outbreaks, representing over half of the identified sources, with 12% of the outbreaks caused by disinfectant products. Intrinsic product contamination was detected frequently, suggesting a need for stricter regulation. While BCC-related mortality was low, our systematic review revealed significant heterogeneity in both investigations and reporting of BCC outbreaks.

Introduction

The *Burkholderia cepacia* complex (BCC) is a group of non-fermenting and oxidase-positive aerobic Gram-negative bacilli [1]. BCC is historically known as a deleterious pathogen in cystic fibrosis (CF) and chronic granulomatous disease (CGD) patients. Although considered of low virulence in the general population [2], it can cause serious illness in critically ill and immunocompromised patients. Nosocomial infections with BCC show no distinct clinical manifestation, and may present as asymptomatic colonization in CF patients, post-
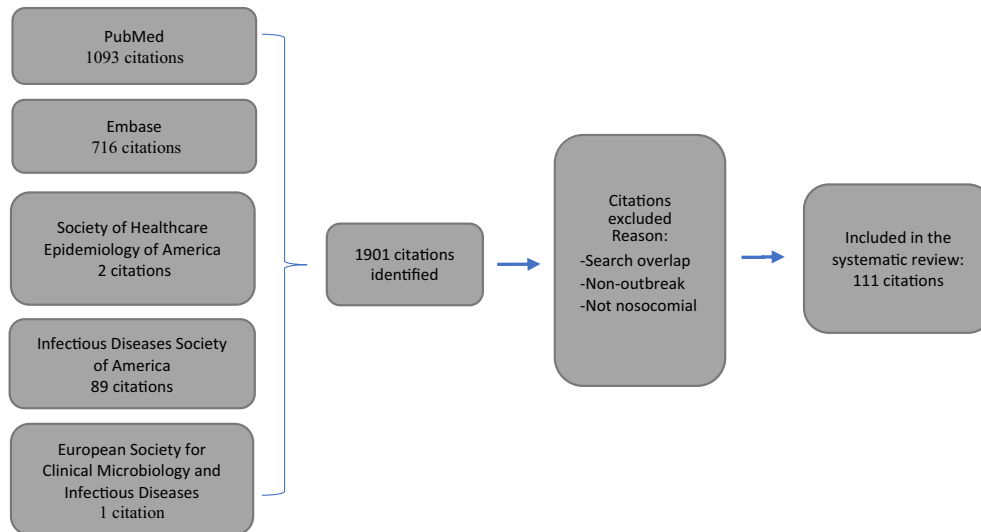
Figure 1. Flowchart of the review process with identified citations.

operative wound infection, pneumonia, urinary tract infection or septicemia [3].

BCC bacilli are commonly found in natural environments such as soil, water and plants or in food [4]. Although they do not grow very well in dry conditions, they have the ability to survive for months in moist environments.

Over the past decades, several outbreaks involving BCC were linked to environmental contamination, contaminated devices and contaminated solutions such as chlorhexidine solutions [5], mouthwash [6], moisturizing creams [7], inhaled solutions [8] or ultrasound gels [9]. Nonetheless, no systematic analysis of these healthcare-associated outbreaks has been carried out thus far.

The aim of this study was to conduct a systematic review of the scientific literature reporting on BCC outbreaks in order to better describe how investigations were done, what causes were identified and how these outbreaks were managed.

Methods

We followed the PRISMA statement when conducting this study. In order to find studies presenting nosocomial outbreaks associated with BCC, we used the databases "Embase" and "Pubmed", and reviewed conference abstracts from the "Society of Healthcare Epidemiology of America", the "European Conference of Clinical Microbiology and Infectious Diseases" and the "Infectious Diseases Society of America" up to 9/12/2019. Additional articles were added using the reference lists from each retrieved report. The time frame regarding publication ranged from 1971 [10] to 9/12/2019 [11]. Figure 1 summarizes the review process.

The following search terms and their combinations were used: «*Burkholderia*»; «*cepacia*»; «*Pseudomonas cepacia*» (an earlier terminology); «outbreak»; «nosocomial»; «healthcare-associated»; and «hospital-acquired».

We included publications presenting nosocomial outbreaks of BCC colonization and infections published until 9/12/2019. Case reports, case series and reports on outbreaks outside of healthcare institutions were excluded. Eligibility was assessed based on the abstract.

Relevant variables regarding publication, features of case patients, characteristics of the outbreaks, investigations carried out to find the source of outbreak, infection prevention and control (IPC) measures taken and characteristics of the bacterial isolates were collected. Findings were compiled in a spreadsheet and transferred to a statistical package for analysis (R Foundation for Statistical Computing, Vienna, Austria). As this project required no access to protected health information, no institutional review board was needed.

Since we did not find criteria for multi-drug resistance specific for BCC, we defined it according to the criteria proposed by Magiorakos [12] for the «*Pseudomonas*» category. BCC was considered multidrug-resistant (MDR) when resistant

Table 1
General characteristics of included reports of BCC outbreaks

Number of outbreak reports	111
Mean outbreak duration (days)	198.6 ± 604.4
Number of affected patients	2390
Number of affected hospitals	128
- *Academic hospitals*	41 (32%)
- *Community hospitals*	56 (43.8%)
- *Hospital type not reported*	31 (24.2%)
Overall fatalities	240
- *Number of outbreak reports with data on mortality*	77 (69.4%)
- *Number of deaths attributed to BCC[a]*	28
Multidrug resistance	
- *Number of outbreak reports with data on MDR[b]*	48 (43.2%)
- *Number of deaths attributed to MDR BCC (individual case patients)*	15/28
ICU[c] involvement	
- Number of *outbreaks* with ICU involvement	65 (58.6%)
- Number of *outbreaks* occurring exclusively in ICUs	39 (35.1%)

[a] BCC = *Burkholderia cepacia* complex.
[b] MDR = Multidrug resistance.
[c] ICU = Intensive care unit

Table 2
Elements of investigation of the BCC outbreaks

Patient's medical record	66 (59.5%)
Investigation on patient apart from blood cultures (i.e., respiratory samples, urine, faeces …)	55 (49.5%)
Environmental investigation	66 (59.5%)
Medical product testing	101 (91%)
Medical devices testing (*Bronchoscopes, anesthesia equipment, …*)	69 (62.1%)
Hospital department records analysis	30 (27%)
Investigation of medical staff (*observation of working methods, interview of medical staff, staff screening samples, …*)	59 (53.2%)
Review of IPC[a] procedures	40 (36%)
Case-control study to identify risk factors for colonization or infection	21 (18.9%)

[a] IPC = Infection prevention and control.

Table 3
Identified sources of the BCC outbreaks

Environmental source	9 (8.1%)
Medical device	19 (17.1%)
Medical preparation (including solutions, drugs, disinfectants)	66 (53.2%)
−*Contaminated disinfection products*	*15 (12%)*
•*Contaminated* chlorhexidine	*8 (6.5%)*
•*Contaminated* benzalkonium chloride	*3 (2.4%)*
−*Contaminated respiratory care products*	*11 (8.9%)*
•*Contaminated* albuterol	*5 (4%)*
−*Contaminated alcohol-free mouthwash*	*6 (4.8%)*
Intrinsically contaminated products	35 (28.2%)
Extrinsically contaminated products	55 (44.4%)
Unknown if intrinsically or extrinsically contaminated product	34 (27.4%)

against at least 3 classes of antibiotics. Bacteria described as multiresistant without further information in the respective study were included as such in this analysis.

Results

General characteristics of nosocomial BCC outbreaks

We included 111 outbreak reports in our analysis (Table 1; Supplementary File 1). Twenty outbreaks occurred in Europe, 38 in North America (Canada and USA), 29 in Asia, 10 in the Middle East, 11 in South America and 3 in Australia or New Zealand. As a result of multi-institutional outbreaks, 128 hospitals were affected: 32% were academic institutions, 43.8% were community hospitals and for 24.2% institutions no details about their structure were offered. A third of the affected hospitals had ≥ 500 bed capacity, 28.1% had a bed capacity ≤ 500, and no information about hospital size could be obtained in 37.5%. ICU involvement was reported from 58.6% of the affected institutions. Outbreaks limited exclusively to the ICU occurred in 35.1% of the reports.

The total number of affected patients was 2,390. The average duration of an outbreak was 198.6 ± 604.4 days, with a median duration of 93.5 days and a range between 3 and 2,661 days. Regarding mortality, 45.1% of the studies reported occurrence of deaths. The total number of reported deaths was 240 (10% of 2,390 case patients). However, only 28 deaths (1.2% of 2,390 case-patients and 11.7% of 240 deaths) could directly be attributed to BCC.

A single article reported that cystic fibrosis (CF) patients were affected by a BCC cluster. In 23.4% of the outbreak reports it was made explicit that no CF patients were involved and the remaining 75.7% contained no statement at all. No chronic granulomatous disease (CGD) patients were mentioned in any of the articles. A total number of 137 immunocompromised patients were reported out of 12.6% of the publications; seven publications reported no involvement of immunocompromised patients and 90 made no statement at all.

Regarding the assessment of bacteriological characteristics "Pulsed field gel electrophoresis" (PFGE) was used in 43.2%, "random amplification of polymorphic DNA" (RAPD) in 7.2%, ribotyping in 6%, "multilocus sequence typing" (MLST) in 5.4%

and "whole genomic sequencing" (WGS) in 2.7%. No bacteriological typing was done in 4.5% of the reported outbreaks and 28.8% of the studies did not mention typing at all. Clonal relationship of strains was proven positive in 52.2%, negative in 14.4% and remained undetermined in 32.4%. Due to the inclusion of outbreaks where multiple BCC species were detected, the total number of strains involved in this analysis was 121. *B. cepacia* accounted for 43.8% of the strains, *P. cepacia*[1] for 17.4%; *B. cenocepacia* for 12.4%; *B. stabilis* for 7.5%; *B. contaminans* for 4.1%; *B. multivorans* for 1.7%; *B. ambifaria*, *B. pseudomallei* and *B. vietnamiensis* for 0.8%. The species identity of 10.7% of the strains was not identified.

Multidrug-resistant BCC strains were reported in 26.1% of the studies. Non-resistant strains accounted for 17.1% of the outbreaks and no information was given in 56.8%. Of the 240 overall deaths, 80 occurred during outbreaks caused by MDR strains and 46 during outbreaks caused by non-resistant strains (and there was no information for the remainder). Fifteen of the 28 deaths attributed to BCC were linked to MDR strains and four to non-resistant BCC. However, we recommend regarding these results with caution. On the one hand, the analyzed studies frequently failed to disclose the exact method of isolate testing. Moreover, the reporting of the activity of individual antimicrobials was diverse, which made comparisons cumbersome. In order to facilitate comparison between isolates across studies, we recommend using CLSI breakpoints.

Investigation and management of nosocomial BCC outbreaks

Regarding investigation and management of outbreaks (Table 2), 91% of the outbreak investigations concerned medical products such as medications or disinfectants. Medical devices such as bronchoscopes were tested in 62.1% of the cases. Analysis of patient medical records was reported in 59.5%, environmental sampling in 59.5% and investigation of medical staff in 53.2% of the outbreaks.

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[1] All BCC species were first described as *P. cepacia*. We kept *P. cepacia* as an entity for the outbreak reports using this obsolete nomenclature.

Table 4
Infection prevention and control measures taken during the BCC outbreaks

Recall of incriminated product/cessation of incriminated procedure	56 (50.5%)
Use of alternative product	25 (22.5%)
Working procedure adapted	29 (26.1%)
Cleaning/disinfection of ward/unit	23 (20.7%)
Enhanced infection control procedures	40 (36%)
Isolation of patients	11 (9.9%)
Notification of public health authorities	36 (32.4%)

Source

The source of the outbreak could be identified in 73.9% of the cases and remained unknown in 26.1% (Table 3). The total number of sources reaches 124 because of outbreaks linked to contamination of multiple products. Fifty-three percent of the outbreaks were caused by a medical preparation, with contaminated disinfection products accounting for 12% of the outbreaks. Intrinsic product contamination was reported in 28.2% of the outbreaks. Contamination of medical devices and environmental contamination caused 17.1% and 8.1% of the outbreaks, respectively.

Infection prevention and control measures

Half of the reports mentioned a recall of an incriminated product or cessation of an incriminated procedure. Enhanced infection control procedures were explicitly reported in 36%, and notification to public health authorities in 32.4% of the cases. Isolation of patients was explicitly mentioned in 9.9% of the reports. The infection prevention and control measures are summarized in table 4.

Discussion

To our knowledge, this is the first systematic review of healthcare-associated *Burkholderia cepacia* complex outbreaks presented to date. We were able to elicit several noteworthy aspects of the affected patients, their clinical outcomes, the investigation for causes of an outbreak and the outbreak management.

Identification of the outbreak source represents a keystone when deciding about the most appropriate infection prevention and control (IPC) response. In a quarter of the reported outbreaks, the source could not be identified, emphasizing the fact that the cause of a BCC outbreak can be difficult to elucidate and depends on the thoroughness of the investigation. In a review of nosocomial Salmonella outbreaks, Lee *et al.* [13] found similar results with a non-identification rate of 21% of the outbreak source. Regarding BCC, this could be either linked to difficulties in identifying these bacteria in the laboratory or due to their potential to colonize a large number of products, devices, as well as the environment. This finding also highlights the difficulty of establishing proper infection control and prevention measures when the source is not identified.

On the other hand, we could determine that contaminated medical solutions and medications were responsible for over half of the outbreaks, with contaminated disinfectants accounting for 12% of the identified sources. Unlike MRSA outbreaks where healthcare workers and patients play an important role as source or vectors [14] our data suggest that BCC outbreaks are actually less often associated with manually contaminated environment (8.1%) or medical devices (17.1%) but rather with contaminated products. Consequently, the investigation of a BCC outbreak should always include medical products. Furthermore, contamination-prone products should be carefully reviewed in each affected department, in order to avoid ongoing administration to patients.

Regarding environmental investigations, we recommend applying a step-wise approach so as to be cost-efficient. Special consideration should be given to water-related surfaces such as sinks and faucets, as BCC tends to develop particularly well in moist environments. Medical device investigations should target respiratory care devices as BCC has a propensity to colonize the respiratory system. Therefore, oxygen delivery devices (nasal cannula, face masks), bronchoscopes and anesthesia equipment should be scrutinized.

Intrinsic contamination was demonstrated in 28.2% of the outbreaks, meaning that bacterial colonization had occurred during the manufacturing process of the product that caused the outbreak. The distinction between intrinsic and extrinsic contamination is crucial in the response to nosocomial outbreaks, mainly because concerned manufacturers and institutions should be warned as soon as possible in order to avoid further infections by recalling the contaminated product. Official notification allows the manufacturer to assess production methods and improve the manufacturing process. Our findings also highlight the issue concerning the lack of legislation surrounding quality control and reintroduction of concerned products, an issue recently addressed by Becker *et al.* [15]. None of the analyzed reports specified what happened after the recall of the product. It therefore remains unknown if the concerned products were definitively removed from the market or if they were reintroduced after modifications. It is also unclear if the manufacturing process was assessed and if contamination prevention at the production site was enhanced. In Europe, there is currently no legislation for an independent control mechanism and quality improvements in a given production site are exclusively the manufacturer's responsibility [16]. Weaker enforcement of legal requirements may lead to less thorough investigations and preventive measures and, consequently, to more contaminations. We strongly recommend the creation of legislation regarding the control of manufacturing and reintroduction after the recall of contaminated products with an independent third party, an idea already formulated by Becker and colleagues [15] and Sommerstein *et al.* [16] in recent years.

Only 77 of the 111 outbreaks reports disclosed data regarding mortality with a total number of deaths reaching 240, which represents 10% of the 2390 case-patients. However, mortality attributable to BCC revealed only 28 fatalities, representing a mere 1.2% of the 2,390 case-patients and 12.7% of the 240 deaths. Fifteen of the 28 BCC attributed deaths were caused by MDR strains. In comparison, the mortality rate in *A. baumannii* outbreaks may reach 47.1% and in *P. aeruginosa* outbreaks 23.3% [17]. Campos *et al.* [18] reported a mortality for KPC *K. pneumoniae* infections ranging from 27.8% to 66.7%. The published data therefore suggest a rather low mortality and indicate that the problematic aspects of BCC outbreaks do not necessarily lie in the resulting mortality but rather in the

cost generated by longer hospital stays, the medical management of affected patients and laborious outbreak investigations.

Our analysis showed much variation regarding the quality of investigation of the outbreaks. Based on the information gathered from the reports, one can assume that a large part of the outbreaks were investigated without use of standardized infection control guidelines or a dedicated IPC team. This situation can lead to a delayed identification of outbreaks, delayed implementation of infection control measures and delayed identification of the source. In order to optimize identification and investigation of an outbreak, we recommend following national or international guidelines such as the one proposed by the U.S. Centers for Disease Control and Prevention (CDC) for outbreak investigation [19]. Furthermore, the creation of an "outbreak response team", which is a frequent approach in academic hospitals, guided by pre-established investigation guidelines, could diminish the duration of an outbreak, thus containing the costs.

Concerning the assessment of bacteriological characteristics, we observed a great heterogeneity regarding the method of BCC typing. Although almost half of the studies used PFGE, more than a quarter of the analyzed articles did not mention the typing method at all, making it difficult to interpret their ability to accurately identify the species. Identification of BCC can represent a real challenge with a risk of misidentification [20], especially with phenotypic tests such as those used in readily available commercial systems [21]. In recent years, whole genome sequencing (WGS) has been shown to have the highest level of discrimination in identifying BCC species [22] and we strongly advocate for its use. It is, however, a costly and time-consuming technique used so far only in a minority of laboratories, pointing to the need for an alternative if WGS is not available. Fehlberg *et al*. [23] and Lambiase *et al*. [24] analyzed the accuracy of MALDI-TOF in identifying BCC species and described a good correlation with classical molecular methods such as PCR, making it a sensitive, rapid and cost-friendly alternative.

The most often cited IPC measures were recall of a product, use of an alternative product, and enhanced infection control procedures in terms of cleaning and disinfection. Surprisingly, isolation of patients was explicitly mentioned in only 9.9% of the reports; we believe this value to be underestimated due to a lack of explicit reporting. In order to determine the size of an outbreak, identify additional carrier patients and risk factors for colonization or infection, we recommend conducting a case-control study, an approach reportedly carried out in only 18.9% of the outbreaks summarized here. Of note, our data also revealed that less than a third of the institutions notified public health authorities, probably partially linked to the fact that notifiable diseases differ between countries. However, we suspect that a large part of the publications did not explicitly mention this step in their report. Nonetheless, involvement of public health authorities, as recommended by the American CDC should be one of the first measures taken in order to optimize collaboration, activate contingency plans and avoid the risk of nationwide outbreaks due to intrinsically contaminated products.

A systematic review is by definition a post hoc analysis of other authors' reports. Therefore, the quality of the data compiled in such an analysis depends on the quality of the work of other investigators. Our study revealed significant heterogeneity in terms of BCC outbreak investigation and the presentation of findings, making it difficult to develop a general statement about the thoroughness of investigations. This heterogeneity complicates our analysis and limits the quality of the results presented here. This particular aspect was highlighted previously regarding *A. baumannii* and *P. aeruginosa* outbreaks [17]. Outbreak reports play a central role regarding the investigation, infection prevention and control measures and overall understanding of outbreaks and their dynamics. As others have stated before, we would welcome a standardization of how outbreaks are reported in the literature in order to optimize the quality of reported data [25]. The popularization of the Worldwide Database for Nosocomial Outbreaks (www.outbreak-database.com) proposed by Lee *et al*. could be a first step in this direction [13].

In summary, we identified more than 100 reports of BCC outbreaks in the healthcare setting. Medical products are the most frequent source of such outbreaks, representing over half of the identified sources, with 12% of the outbreaks caused by disinfectant products. Intrinsic product contamination was detected frequently, suggesting a need for stricter regulation. While BCC-related mortality was low representing only 11.7% of the reported deaths, our systematic review revealed significant heterogeneity in terms of both investigation and reporting of BCC outbreaks.

CRediT authorship contribution statement

Emmanuel Häfliger: Conceptualization, Data curation, Methodology, Formal analysis, Writing - original draft, Writing - review & editing. **Andrew Atkinson:** Methodology, Formal analysis, Supervision, Writing - review & editing. **Jonas Marschall:** Conceptualization, Methodology, Supervision, Writing - original draft, Writing - review & editing.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.infpip.2020.100082.

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