

Current infection control measures regarding Heater Cooler Units (HCU) in Germany after the mycobacteria chimaera outbreak 2014–2026

Umgang mit Heater Cooler Units (HCU) in Deutschland im Gefolge des Mycobacterium chimaera-Ausbruchs 2014–2026

Abstract

Introduction: The 2014–2016 outbreak of cardiac surgery–associated infections with non-tuberculous mycobacteria (NTM) linked to heater-cooler units (HCUs) led to widespread implementation of environmental monitoring and technical/organizational control measures in Germany. We aimed to describe current infection prevention practices, with a focus on ongoing water and air surveillance related to HCUs in German cardiac surgery centres.

Method: An anonymous online survey was distributed to directors of all German cardiac surgery departments by the Deutsche Gesellschaft für Thorax-, Herz- und Gefäßchirurgie e.V. (DGTHG). The survey collected administrative information on procedure volumes, HCU types and placement, disinfection practices, and the use and frequency of routine microbiological water sampling for NTM and air sampling in the operating room. No patient-level data were collected.

Results: Twelve departments responded, ranging from small (≈300 cardiopulmonary bypass procedures/year) to very large centres (≈2,800/year), and representing major HCU manufacturers used in Germany. During the outbreak phase, all centres introduced routine NTM water sampling (monthly to yearly) and 4/12 also performed routine air sampling every 3–6 months. By 2026, two centres had discontinued water sampling, and most of the others reduced sampling frequency; air sampling was not implemented or was later abandoned in most institutions (only 3/12 continued). Between 2014 and 2016, 4/12 of centres detected NTM in water and 1/12 reported NTM in air samples; in the most recent 12 months, no positive water or air samples were reported. The proportion of centres positioning HCUs outside the operating room increased from 4/12 during the outbreak phase to 5/12 in 2026.

Discussion: German cardiac surgery departments report a clear de-escalation of environmental monitoring for HCUs since the initial outbreak response, particularly for air sampling, while technical measures such as positioning exhaust away from the surgical field and, where feasible, locating HCUs outside the operating room have increased. Given persistent reports of HCU water colonization in the literature, continued water monitoring appears reasonable, with reduced intervals (e.g., every 3–6 months) in centres with consistently negative results, and targeted air sampling primarily when NTM are detected in water to support risk assessment and device management.

Keywords: heater cooler unit, mycobacterium chelonae, water contamination, water disinfection, cardiac surgery

**Sebastian
Schulz-Stübner^{1,2,3}**

- 1 German Consulting Center for Infection Prevention and Control (BZH GmbH), Freiburg i. Brsg., Germany
- 2 Department of Anesthesiology and Critical Care Medicine, University of Freiburg, Faculty of Medicine, Freiburg im Brsg., Germany
- 3 Institute for Public Health and Health Research at the Freiburg University of Education, Freiburg im Brsg., Germany

Zusammenfassung

Einleitung: Der Ausbruch von Infektionen durch nichttuberkulöse Mykobakterien (NTM) in den Jahren 2014–2016 im Zusammenhang mit Herzoperationen unter Einsatz von Heater-Cooler Units (HCU) führte in Deutschland zur Einführung umfangreicher technischer und organisatorischer Präventionsmaßnahmen sowie zu regelmäßigen Umweltuntersuchungen (Wasser- und Luftproben). Ziel dieser Arbeit war es, den aktuellen Stand der infektionspräventiven Maßnahmen in deutschen herzchirurgischen Fachabteilungen mit besonderem Fokus auf das fortgeführte mikrobiologische Monitoring von HCU (Wasser/OP-Luft) zu erfassen.

Methode: Es wurde eine anonyme Online-Befragung über die Deutsche Gesellschaft für Thorax-, Herz- und Gefäßchirurgie e.V. (DGTHG) an die Leiterinnen und Leiter deutscher herzchirurgischen Fachabteilungen versandt. Erfragt wurden u.a. Fallzahlen (Eingriffe mit Herz-Lungen-Maschine), eingesetzte HCU-Typen und deren Aufstellort, Desinfektions-/Aufbereitungspraktiken sowie Art und Frequenz routinemäßiger mikrobiologischer Wasseruntersuchungen (insbesondere NTM) und Luftproben im Operations(OP)-Saal. Es wurden ausschließlich administrative Daten erhoben; Patientendaten wurden nicht erfasst.

Ergebnisse: Zwölf Fachabteilungen nahmen an der Befragung teil; die Antworten umfassten ein breites Spektrum von kleinen (ca. 300 Eingriffe/Jahr) bis sehr großen Fachabteilungen (ca. 2.800 Eingriffe/Jahr) sowie die in Deutschland gängigen Hersteller von HCU. In der Ausbruchphase etablierten alle Zentren routinemäßige NTM-Wasserproben (Intervalle monatlich bis jährlich); 4 der 12 Teilnehmenden führten zusätzlich Luftproben im OP im Abstand von 3–6 Monaten durch. Im Jahr 2026 hatten zwei Fachabteilungen die Wasserbeprobung vollständig beendet, in den übrigen wurde sie überwiegend in der Frequenz reduziert; Luftbeprobungen wurden in den meisten Fachabteilungen nicht eingeführt oder später wieder aufgegeben (fortgeführt in 3/12). Positive NTM-Nachweise wurden für 2014–2016 in 4/12 Kliniken im Wasser und in 1/12 in der OP-Luft berichtet; in den letzten 12 Monaten wurden keine positiven Wasser- oder Luftbefunde angegeben. Der Anteil der Zentren mit außerhalb des OP-Saals aufgestellten HCU stieg von 4/12 (Ausbruchsphase) auf 5/12 in 2026.

Diskussion: Die Ergebnisse zeigen eine deutliche Deeskalation des Umweltmonitorings von HCU seit der unmittelbaren Ausbruchsreaktion, insbesondere hinsichtlich routinemäßiger Luftproben. Gleichzeitig wurden technische Maßnahmen (z. B. Ableitung der Abluft weg vom OP-Feld und – sofern möglich – Verlagerung der HCU außerhalb des OP-Saals) häufiger umgesetzt. Vor dem Hintergrund fortbestehender Berichte über NTM-Kolonisation von HCU-Wassersystemen erscheint eine fortgeführte Wasserbeprobung weiterhin sinnvoll; bei stabil negativen Befunden kann eine Verlängerung der Intervalle (z.B. auf 3–6 Monate) vertretbar sein. Luftproben sind aus Risikomanagementsicht vor allem dann zu erwägen, wenn NTM im Wasser nachgewiesen werden, um die potenzielle Aerosolisierung zu beurteilen und das weitere Gerätemanagement zu unterstützen.

Schlüsselwörter: Heater cooler unit, Mycobacterium chelonae, Wasserkontamination, Wasserdeseinfektion, Herzchirurgie

Introduction

At the beginning of 2015 In Switzerland, the Netherlands, and Germany, 10 patients were diagnosed with endocarditis and foreign-body infections caused by *Mycobacterium (M.) chimaera*, a non-tuberculous mycobacterium (NTM) of the *M. avium* complex group. Epidemiological and microbiological studies linked these infections to intraoperatively used heater cooler units (HCU) via aerosol formation originating from contaminated water in the cooler system in cases with heart-lung machine (HLM) use [1], [2].

The exact diagnosis with corresponding microbiological detection of the pathogen was made in the affected patients after a relatively long latency period of 1.5 to 3.6 years since NTM are slow-growing and because in cases of suspected endocarditis specific microbiological diagnostics targeted at NTM are not routinely performed.

A corresponding risk assessment was published by the European Center for Disease Prevention and Control (ECDC) on April 30, 2015 [3], triggering a response for strict infection control measures and introduction of water and air sampling by cardiac surgery centres throughout Germany, often with strict regulation by local authorities responsible for medical product control, based mainly on preliminary recommendations by the Swiss national health authority (Bundesamt für Gesundheit, BAG), which have evolved since then [4].

We sought to determine the current state of environmental sampling in German cardiac surgery departments with a survey.

Methods

The anonymous survey was distributed online to all directors of German cardiac surgery departments using the membership directory of the German Society for Thoracic and Cardiovascular Surgery e.V. (DGTHG). Only administrative data and no patient information was collected, so the survey is not considered human research.

Results

12/78 departments filled in the survey. However, the distribution of responses ranged from small (300 procedures with HLM use) to very large centres (2,800 procedures with HLM use) and included types of HCU from the major manufacturers on the German market.

During the outbreak phase between 2014 and 2026 all departments introduced routine water sampling for NTM (ranging from monthly to yearly intervals) and 4/12 departments routine air sampling every 3–6 months. Two departments abandoned water sampling completely in 2026, and one institution prolonged the frequency of testing.

Air sampling was abandoned by one of the four departments originally employing it, and the frequency was ex-

tended from 6 to 12 months by one unit and maintained by the remaining two.

From 2014 to 2016, NTM were found by 4/12 departments in water samples and in one department in air samples. In 2025 no positive water or air samples were reported.

The number of centres with the HCU positioned outside the OR increased from 4/12 during the outbreak phase to 5/12.

Table 1 shows the summary of the survey's responses. Additional free text comments remarked that

- “after switching to HCU 40, indoor air sampling became obsolete”,
- “we had no outbreaks between 2014 and 2016. Following the new construction, there are no longer any HCUs directly in the operating rooms, so we no longer conduct regular indoor air sampling for mycobacteria there”,
- “we had very small amounts of atypical mycobacteria in the drinking water, but we already had a hygiene protocol in place and cleaned the hypothermia devices regularly. Therefore, we never had a serious hygiene problem, just a lot of hassle”.

Discussion

Schreiber et al. [5] in 2021 reviewed the literature related to the outbreak and found nine studies in which *M. chimaera* isolates from LivaNova (former Sorin) heater-cooler units (HCU) had a high level of genetic similarity but were genetically distant from isolates from HCUs produced by other manufacturers. Except for a single study, the remaining eight studies reported a high level of genetic proximity between the majority of *M. chimaera* isolates derived from cardiac surgery-associated patients and LivaNova HCUs. In-depth analysis revealed involvement of three distinct *M. chimaera* subgroups in the outbreak (1.1, 1.8, 2.1), with 1.1 suggested as causative of the outbreak. Samples taken at the LivaNova production site supported contamination with strains of subgroups 1.1 and 1.8. In the combined analysis of 526 publicly available whole genome sequencing (WGS) data sets, nearly all isolates from cardiac surgery-associated patients contained strain 1.1 (50/52), and at least one of the outbreak strains was found in almost all LivaNova HCUs (241/257, 93.8%), with strain 1.1 present in 198/257 (77.0%).

Schreiber et al. [6] further investigated the longitudinal development of NTM in water samples from five Liva Nova HCUs. Non-tuberculous mycobacteria were isolated in 319 (48.0%) of a total of 665 water samples. 21 water samples grew more than one mycobacterial species. The most frequently detected species were *M. chimaera* (n=247/319, 77.4%), *M. gordonae* (46/319, 14.4%) and *M. paragordonae* (34/319, 10.7%). Detection rates increased prospectively for any NTM (odds ratio (OR) per year in use: 1.60, 95% confidence interval (CI) 1.17–2.24,

Table 1: Summary of the survey questions and results (n=12 hospitals)

Procedures with ECC*/year	600	800	1,100	2,800	350	600	550	700	500	400	300	650
Procedures with ECC- standby/year	250	150	800	2,000	600	10	180	1,000	250	10	100	350
Patients with NTM- infection 2014-2016	0	0	0	0	0	0	0	0	0	0	0	0
Nosocomial?	0	0	0	0	0	0	0	0	0	0	0	0
HCU**-Typ 2014-2016	Stöckert 3T	T3	Stöckert T3	Stöckert HCU 3T Liva-va	3T HCU Liva-va	HCU 30 Geringe	Maquet	HCU 40	HCU 40	Sorin 3T & HCU40	HCU 30 Maquet	Liva-va 3T HCU
Located inside the OR?	+	+	-	-	+	-	+	+	+	+	-	+
Routine water tests	+	+	+	+	+	+	+	+	+	+	+	+
Frequency (months)	1	1	12	3	3	1	3	3	3	3	1	2
Detection of NTM***	-	-	-	+	-	+	-	+	-	-	+	-
Routine-OR air samples	+	-	-	-	+	-	+	+	-	-	-	-
Frequency (months)	6	0	0	0	6	0	3	6	0	0	0	0
Detection of NTM	-	-	-	+	-	-	-	-	-	-	-	-
HCU-Typ 2026	Geringe HCU 40	HCU 40	Stöckert T3	Stöckert HCU 3T Liva-va	HCU40 Geringe	HCU40 Geringe and 3T Liva-va	Maquet	HCU 40	HCU 40	HCU 40	HCU 40	Liva-va 3T HCU
Located inside the OR?	+	+	-	-	-	-	+	+	+	+	-	+
Frequency of water tests 2026 (months)	0	0	12	6	3	1	3	3	3	3	1	1
Detection of NTM in the last year?	-	-	-	-	-	-	-	-	-	-	-	-
Frequency of air samples in 2026 (months)	12	0	/	0	0	0	3	6	0	0	0	0
Detection of NTM in the last year?	-	-	-	-	-	-	-	-	-	-	-	-

* ECC = extracorporeal circulation ** HCU = heater cooler unit ***NTM = non tubercular mycobacteria. + = yes; - = no

$P < 0.001$) and for *M. chimaera* (OR per year in use: 1.67, 95% CI 1.11–2.57, $P < 0.01$).

However, colonization with *M. chimaera* and other NTM has been reported for HCUs produced by several manufacturers.

Dittomaso et al. [7]) describe ongoing problems with the disinfection procedures recommended by the manufacturer. A total of 308 HCU water samples (264 samples from 17 Stockert 3T HCUs and 44 samples from 12 Maquet HCU40 devices) were analysed in their study, 65.5% of which yielded NTM. The most frequently colonized device with NTM was the Stoeckert 3T (88.2%), with a frequency of positive samples of 59.5% (157/264). The Maquet HCU40 devices less frequently yielded NTM (33.3%), with a frequency of positive water samples of 6/44. Disinfection procedures were effective in reducing bacteria except for NTM species. NTM were detected in both pre-disinfection (50.1%) and post-disinfection (55.7%) samples, and no significant association was found between disinfection and NTM results both in Stoeckert 3T and Maquet HCU40 devices.

Schlotthauer et al. [8] confirmed this impression and presented data on the occurrence of *M. chimaera* and other mycobacterial pathogens in different HCUs from one surgical center in Germany over a 42-month period. Water samples and swabs from seven different HCUs were taken between 2015 and 2018, and mycobacteria were detected in 50.6% (78/154) of water samples and in 4/19 of swabs. *M. chimaera* accounted for the most detected pathogen (77/83 isolates in water samples), but other species such as *M. goodii* were also found. Despite strict adherence to an intensified, regular manufacturer recommended disinfection procedure, the majority of HCUs remained positive for mycobacteria until the end of the study.

Kuster et al. [9] reported the results of their surveillance measures including water and air sampling. Since 01/2016, four Maquet HCU40 (Getinge) HCUs have been in operation at the University Hospital Basel. Monthly water cultures for Gram-negative bacteria and mycobacteria were performed, including samples from two filling lines equipped with 0.2 µm water filters. Intermittent monthly air sampling for mycobacteria was conducted. Between 01/2016 and 05/2018, various non-fermenting bacteria were cultured. *M. chelonae* was first isolated in 06/2018 from HCU water tanks. Mycobacteria cultures from the filling lines remained negative. The first air sample positive for *M. chelonae* was collected in 12/2019. Despite intensified disinfection measures from 01/2022 onwards, *M. chelonae* could be cultured in air samples, collected at 30 cm and 120 cm height adjacent to three of the four running HCUs in 07/2022. Whole genome sequencing identified a cluster of isolates differing by a maximum of four single nucleotide polymorphisms. Despite extensive investigations, the source of *M. chelonae* remains undetermined. To date, no infections with *M. chelonae* have been related to the contaminated HCUs at the authors institution.

In our survey positive results of water samples (3/12) and air samples (1/12) were only reported during the outbreak phase and not over the last 12 months. The frequency of sampling was reduced by most institutions, and air sampling not introduced or later abandoned by the majority.

With these observations from the literature, it seems that preventive measures to reduce the chance of NTM intake into a HCUs water system are of utmost importance (especially at the manufacturers site), but NTM water contamination is not completely preventable and can only be mitigated once contamination of a HCU has occurred. It therefore seems reasonable to continue microbiological monitoring of water samples, but the frequency can be safely reduced to 3–6 months when results are negative. Air samples are only indicated if NTM are found in the water samples and can then be used to determine whether a HCU needs replacement.

Positioning of the HCUs vent exhaust away from the surgical field is mandatory, when HCUs are positioned within the operating room, according to the recommendation of the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute [10].

Limitation

The small sample size is the major limitation of this study.

Notes

Author's ORCID

- Schulz-Stübner S:
<https://orcid.org/0000-0001-5210-9364>

Ethical approval

Participants agreed to participate in the voluntary anonymous survey by activating the online survey tool.

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Competing interests

The authors declare that they have no competing interests.

AI usage statement

DEEPL was used for assistance with the English language.

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Corresponding author:

Prof. Dr. med. Sebastian Schulz-Stübner
German Consulting Center for Infection Prevention and Control (BZH GmbH), Schnewlinstr. 4, 79098 Freiburg im Breisgau, Germany; phone: +49 761-2026780
schulz-stuebner@bzh-freiburg.de

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