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Trends of diagnostic adverse events in hospital deaths: longitudinal analyses of four retrospective record review studies

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Abstract

Objectives: To investigate longitudinal trends in the incidence, preventability, and causes of DAEs (diagnostic adverse events) between 2008 and 2019 and compare DAEs to other AE (adverse event) types.

Methods: This study investigated longitudinal trends of DAEs using combined data from four large Dutch AE record review studies. The original four AE studies included 100–150 randomly selected records of deceased patients from around 20 hospitals in each study, resulting in a total of 10,943 patient records. Nurse reviewers indicated cases with potential AEs using a list of triggers. Subsequently, experienced physician reviewers systematically judged the occurrence of AEs, the clinical process in which these AEs occurred, and the preventability and causes.

Results: The incidences of DAEs, potentially preventable DAEs and potentially preventable DAE-related deaths initially declined between 2008 and 2012 (2.3 vs. 1.2; OR=0.52, 95 % CI: 0.32 to 0.83), after which they stabilized up to 2019. These trends were largely the same for other AE types, although compared to DAEs, the incidence of other AE types increased between 2016 (DAE: 1.0, other AE types: 8.5) and 2019 (DAE: 0.8, other AE types: 13.0; rate ratio=1.88, 95 % CI: 1.12 to 2.13). Furthermore, DAEs were more preventable (p<0.001) and were associated with more potentially preventable deaths (p=0.016) than other AE types. In addition, DAEs had more and different underlying causes than other AE types (p<0.001). The DAE causes remained stable over time, except for patient-related factors, which increased between 2016 and 2019 (29.5 and 58.6 % respectively, OR=3.40, 95 % CI: 1.20 to 9.66).

Conclusions: After initial improvements of DAE incidences in 2012, no further improvement was observed in Dutch hospitals in the last decade. Similar trends were observed for other AEs. The high rate of preventability of DAEs suggest a high potential for improvement, that should be further investigated.

Keywords: diagnostic adverse event; diagnostic safety; longitudinal research; patient safety; diagnostic error; epidemiology

Introduction

Diagnostic safety is an important topic within the domain of patient safety. Although different methods result in different estimates, it is estimated that around 10–15 % of diagnoses result in error [1]. Furthermore, diagnostic errors are found to have a higher level of patient harm than other types of medical errors [2]. Despite this, research into diagnostic error and diagnostic safety has only gained increased attention over the last decade and diagnostic safety focused improvement measures have not yet been widely implemented.

Moreover, it remains unclear whether incidences, causes and consequences of diagnostic error have changed over time. A few studies to address patient safety trends in general have been conducted [3, 4] showing conflicting adverse event trends. These studies did also not specifically investigate diagnostic safety trends. Furthermore, most studies that

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report incidences use a variety of methods (e.g. record review, autopsy reports), in a variety of countries and populations, making these incidences incomparable over time.

In the Netherlands, adverse events (AEs) have been monitored every four years since 2004 using representative random samples of patient records [5–9]. An AE was defined as 'an unintended outcome which resulted in temporary or permanent disability, death or prolonged care, caused by healthcare management rather than the disease'. The studies investigated the incidence, causes, and consequences of AEs in patients who either were discharged from the hospital or died during a hospital stay. AEs were categorised into various clinical processes, including the diagnostic process. These diagnostic adverse events (DAEs) were defined as 'AEs that are predominantly related to the diagnostic process'. Importantly, each of these studies had the same methodology, except for the first study in 2004. This availability of data on both DAEs as other AE types across multiple years, creates the opportunity to investigate and compare longitudinal trends.

For the current study, we combined data of deceased patients from four of these Dutch AE studies to create a longitudinal dataset with data from 2008 to 2019. The research aim was to investigate how DAE incidence rates and causes changed over time and how they compare to other AE types.

Materials and methods

Data from four national Dutch patient record review studies (2008, 2011/2012, 2015/2016 and 2019; hereafter referred to as 2008, 2012, 2016, 2019) were combined to create a longitudinal dataset. Data from the first AE study in 2004 were available but not included due to substantial design differences. The datasets from 2016 to 2019 comprised only deceased patients because it was found that AEs were more common in this group, and therefore resulted in a higher power and more accurate incidence estimate. For these reasons, we decided to exclude the discharged patients from the 2008 and 2012 studies for analyses in the current study. This is in accordance with a previous longitudinal study using data on acutely admitted older adults from the same AE studies [10].

All initial AE studies were approved by the Medical Ethical Review Committee of the Amsterdam University Medical Center, the Netherlands. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013).

Initial record review studies

Sampling process

The initial studies were performed in 19 (in 2016) to 20 (in 2008, 2012, and 2019) hospitals, representing different hospital types (i.e. university, teaching, and general hospitals) and all regions in the Netherlands. Records of 100 (in 2008 and 2012) and 150 (in 2016 and 2019) deceased patients were randomly selected in each hospital. Patients admitted in a psychiatric or obstetric department, and patients younger than one year old were excluded from the sampling process. The study samples were judged to be representative of the Dutch population of admitted patients with an in-hospital death in their respective years. The sample size for the studies was calculated based on power analyses for a power of 0.8 with an alpha-level of 0.05 to include a sufficient number of cases with potentially preventable harm with all types of AEs.

Record review

The method for the record reviews was similar to the Harvard Medical Practice study [11] and the Canadian Adverse Event study [12]. Trained and experienced nurses and physicians (specialties in surgery, internal medicine, and neurology) reviewed patient records in two phases. First, nurse reviewers screened all records using a list of triggers for indicating potential AEs (e.g. patient had an unplanned admission before index admission) (Supplementary Material, Appendix 1). The list of triggers was based on other AE studies [11, 12]. Second, physician reviewers determined whether an AE was present in cases with at least one trigger. For every identified AE, they evaluated preventability, related clinical process, and underlying cause(s).

An event was considered an AE if all of the following criteria were met: the event comprises (1) an unintended injury, (2) which resulted in prolonged hospital stay, disability, or death, and (3) was caused by healthcare management (or lack of), rather than the disease. Preventability of the AE was defined as care falling below the current level of expected performance of healthcare professionals and/or systems (taking the contemporary clinical guidelines into account). It was scored on a scale from 1 (no indication of preventability) to 6 (certain indication of preventability). Scores of four or higher were deemed preventable AEs. The contribution of an AE to the death of a patient was rated on a four-point scale (1=death was unrelated to the AE, 2=AE has

somewhat contributed to death, 3=AE has substantially contributed to death, 4=death was partially or entirely caused by the AE) of which 3 and 4 were deemed preventable deaths. Reviewers also judged the AEs underlying clinical processes: diagnostic, surgery, nonsurgical medical procedure, medication, other clinical management, discharge, and other. They allocated primary and secondary clinical processes. To keep the DAEs and other AE types separated, only AEs that were judged to have the diagnostic process as the primary clinical process were investigated in the current study. Lastly, physician reviewers classified AE causes based on an adaption of the Eindhoven Classification Model [13]. This model specifies causes on main categories and subcategories. Because of the relatively small numbers in each subcategory when focusing on DAEs, only the main categories of the Eindhoven Classification Model were used in the current study: technical causes, human causes, organizational causes, patient related factors (e.g. comorbidities, therapy adherence), and (protocol) violations (e.g. errors caused by not adhering to existing protocols, routines or guidelines, often due to efficiency-thoroughness trade-off). More than one cause per AE was allowed.

Reviewers were experienced nurses (minimum of 5 years experience) and physicians (minimum of 10 years experience) and were extensively trained during a training day on the consistent use of the correct definitions and ratings of all scales [10]. They had access to handbooks with information and examples throughout the record review. Several meetings and peer-coaching sessions were organized and reviewers could request a discussion meeting with external experts whenever they were unsure about a case.

In each hospital, around 10 % of reports were reviewed by two reviewer. Interrater-reliability of the physician reviewers was based on the positive and negative agreement for classifying an event as an adverse event. The positive agreement (i.e. the chance that both reviewers judged that an AE was present) in the four studies was 54.3–63.3 %. The negative agreement (i.e. the chance that both reviewers judged that no AE was present) in the four studies was 77.7–86.9 % [6–9]. Cohen's Kappa was between 0.35 and 0.50 in the four AE studies, indicating a fair to moderate agreement according to the Landis and Koch classification [14].

Data analyses

The merge of the four datasets was performed using Stata/SE (StataCorp, 2015; version 14.1) and subsequent analyses were performed using R Statistical Software (R Core Team, 2020) and Rstudio (Rstudio Team, 2020; version 1.3.1093) using the glmmTMB package [15] for the random effects models and ggplot2 [16] for creating graphs. Incidences of DAEs were calculated using weighting, to account for an over-representation of university hospital types in the studies compared to the national distribution of hospital types. DAE incidences were compared over time by calculating odds ratio's using univariable regular logistic regression because random effects regression to account for clustering within hospital types showed no improvement in model fit based on AIC (Akaike Information Criterion). Relative incidence of types of AE (DAE vs. other) was analysed using a random effects poisson regression model to account for correlation within patients. For other comparisons chi-squared tests or t-tests were used as appropriate.

Results

General characteristics

The combined dataset comprised 10,943 patients who died in the hospital. General characteristics of the patients, their hospital stay, and the hospital type are shown in Table 1. In total, 1,396 (12.8 %) patients experienced an AE, of which 138

Table 1: General characteristics of patients, hospital, and hospital stay, for patients with DAEs, other AE types, patients without AEs, and all patients.

Characteristics	DAEs (n=138)	Other AE types (n=1,258)	No AEs (n=9,547)	Total (n=10,943)
Male, %	50.7 %	54.1 %	53.9 %	53.9 %
Age, median (IQR)	78 (70–86)	76 (66–83)	77 (68–85)	77 (68–85)
Length of stay in days, median (IQR)	7 (3–16)	11 (4–21)	5 (2–12)	6 (2–13)
Unplanned admission, yes, %	85.5 %	70.7 %	89.2 %	87.0 %
Hospital type, %				
University	15.9 %	26.6 %	19.8 %	20.6 %
Teaching	32.6 %	30.8 %	34.3 %	33.9 %
General	51.4 %	42.6 %	45.9 %	45.6 %

AE, adverse event; DAE, diagnostic AE; IQR, interquartile range. Percentages are calculated within column. There are two missing values for no-AEs in variables sex, age, and LOS, and one missing in other AE types for age.

(9.9 %) were categorized as a DAE (i.e. predominantly related to the diagnostic clinical process), and the other 90.1 % as other AE types (i.e. predominantly related to one of the other clinical processes). The majority of patients were older adults (median age 77, IQR: 68 to 85) and male (53.9 %). Additionally, there was a small increase in median age from 76 in 2008 to 78 in 2019. Most admissions were unplanned (87 %).

Trends of DAEs and compared to other AE types

Longitudinal analyses indicate that the incidence of DAEs decreased between 2008 (2.3 %) and 2012 (1.2 %, OR=0.52, 95 % CI: 0.32 to 0.83) and remained stable since (2016: 1.0 %, OR=0.87, 95 % CI: 0.51 to 1.53; 2019: 0.8 %, OR=0.81, 95 % CI: 0.46 to 1.43). The same pattern was found for DAEs with potentially preventable harm and potentially preventable death, see Supplementary Material, Appendix 2 and left side of Figure 1.

Furthermore, the trend of DAE incidence between 2016 and 2019 was relatively stable which differed significantly with the increasing trend of other AE types during the same period (rate ratio=1.88, 95 % CI: 1.12 to 2.13, p=0.017; see Figure 1). This difference in trends was not found in other years and was not found for the DAE and AE subtypes with potentially preventable harm and potentially preventable death. In addition, DAEs were more often judged preventable than other types of AE (81.9 vs. 30.1 %; p<0.001) and, within preventable AEs, DAEs were more often the cause of preventable death (80.5 vs. 68.3 %, p=0.016).

Causes of DAEs and other AE types

Across all years, the mean number of cause types per AE was higher for DAEs than other AE types (1.64 vs. 1.28, p<0.001). Figure 2 shows DAEs were more often judged to be caused by human factors (83.1 vs. 28.7 %, p<0.001), organizational factors (29.4 vs. 8.5 %, p<0.001), and (protocol) violations (11.8 vs. 6.4 %, p=0.033), compared to other types of AE. Patient-related factors were less often implicated (32.4 vs. 53.3 %, p<0.001; see Figure 2).

Results of analyses of DAE causes over time show only a significant change in the percentage of DAEs caused by patient-related factors between 2016 and 2019 (29.5 and 58.6 % respectively, OR=3.40, 95 % CI: 1.20 to 9.66; see Figure 3).

Discussion

This study analysed longitudinal data from four large Dutch adverse event (AE) studies with 19–20 hospitals each, focusing on diagnostic adverse event (DAE) incidence. Results show an initial decline between 2008 and 2012 after which the rate stabilized. Similar patterns were found for the subtypes potentially preventable DAEs and potentially preventable DAE-related deaths. Trends of DAEs and other AE types over time were similar except for the period between 2016 and 2019 were DAE incidence remained stable while incidence of other AE types increased. DAEs were more often preventable and had different causes compared to other AE types.

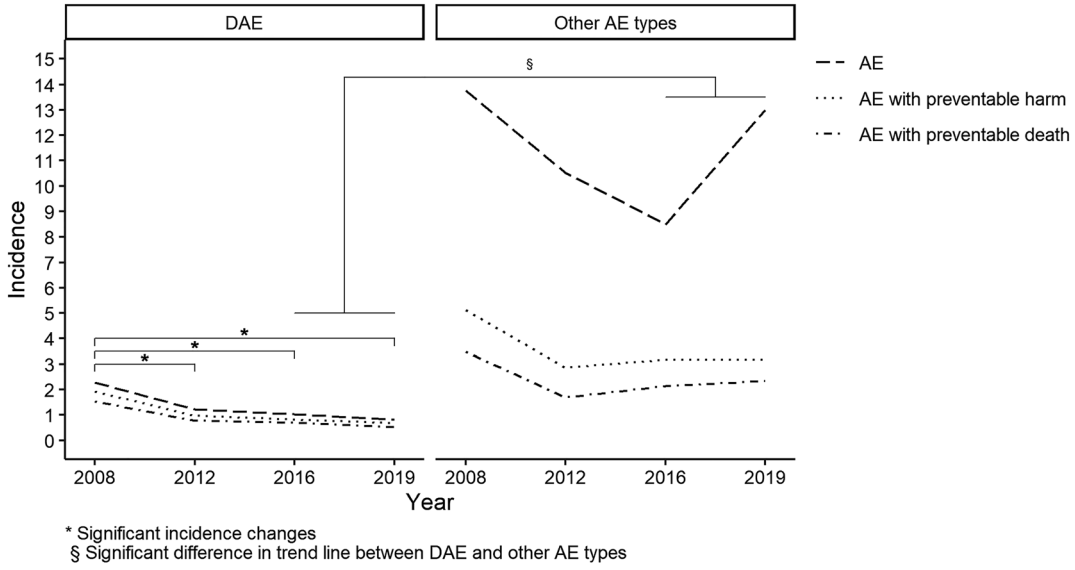

Figure 1: Incidences of AE, AE with preventable harm, and AE with preventable death, separately for DAEs and other AE types, including indications of significant longitudinal differences for DAEs and indications of significant trend differences between DAE and other AE types.

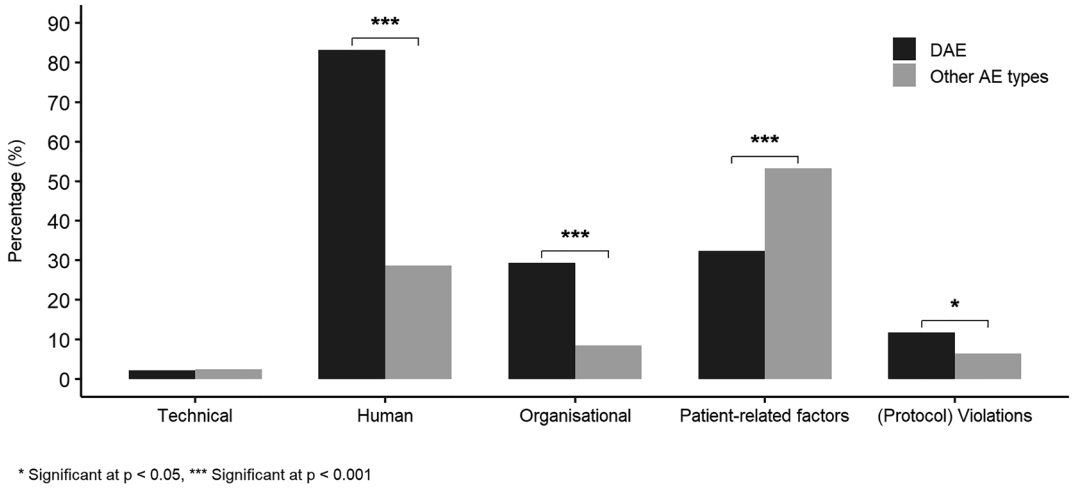

Figure 2: Causes of DAEs and other AE types as percentages within their own group.

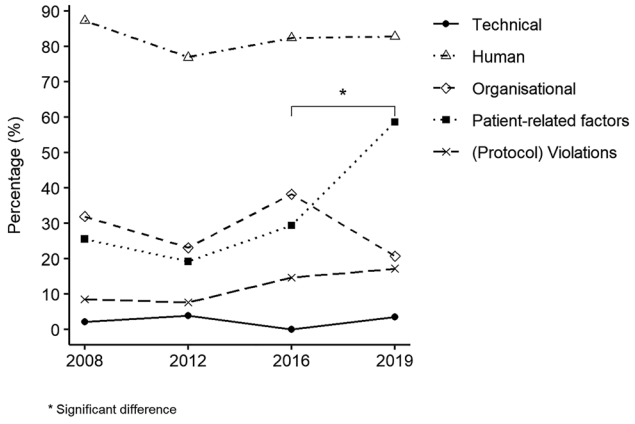

Figure 3: Causes of DAEs over time.

Several factors may have contributed to the observed trends in DAE incidence. The initial decrease coincided with activities of the National Dutch Patient Safety Programme (2008–2012), in which all Dutch hospitals participated [17]. The safety program was an initiative of various healthcare organisations (e.g. sector organisations for hospitals, medical specialists, nurses, and patients) and funded by the government [17, 18]. It comprised guidelines, education, and training on 10 themes which were chosen to reduce preventable harm in hospitals. Although the safety program did not include themes or implementations that were specifically focused on improving the diagnostic process, some had overlap with diagnostic safety. Most notably, three themes were focused on early recognition and monitoring of patients in certain conditions (i.e. sepsis, risk at vital organ failure, and frailty in older adults). Early identification of such patients could help physicians determine the correct diagnosis timely. Monitoring of these patients can help with recognizing deterioration of the patient's condition, which is considered to be an aspect of diagnostic safety as well. Therefore, the safety program could have had impact on decreasing DAEs. Moreover, the improvements might have improved safety culture in general, extending its reach beyond the initial safety themes.

Furthermore, the current study only investigated AEs that were judged to have the diagnostic process as the primary contributing clinical process and these were compared to AEs with all other clinical processes (e.g. surgery, medication, or other clinical management). It is important to note that is possible that DAEs were related to other clinical processes as well, and vice versa, allowing DAEs to be improved by improving other aspects of health care.

In addition, we cannot rule out that there are other factors why the 2008 incidences of DAEs were higher than those of subsequent years, especially when considering the AE study in 2004. While this study had a slightly different methodology, it is reported that there was a significant increase between 2004 and 2008 for AE incidences [19].

DAEs were highly preventable and showed a different and more diverse cause profile, including more human and organisational cause types, and (protocol) violations compared with other AE types, and relatively few patient-related factors. The high preventability and the different cause profile might be related, as it is likely that more causes, especially human causes, can contribute to the preventability of the AE. Notably, the proportion of patient-related causes showed a sharp rise during the last period, perhaps related to growing patient complexity (e.g. more atypical presentations and comorbidities) [20]. Interestingly, this increase in patient-related factors has not affected the incidence of DAEs overall nor the subtypes of potentially

preventable DAEs and potentially preventable DAE-related deaths. It is difficult to determine why this was observed, as it likely reflects a complex interplay of factors that cannot be fully explored with the data of this study.

The '(protocol) violations' are defined as intended actions that deviate from the hospital's protocols or guidelines. However, it is important to note that these actions generally not malicious, but arise through efficiency-thoroughness trade-offs (i.e. the choice between working thoroughly to help one patient vs. working more efficiently to help multiple patients) and could be linked to the Safety-II framework: While the Safety-I approach argues that healthcare professionals should adhere to protocols and guidelines, Safety-II emphasizes adaptivity and resilience [21]. This perspective allows healthcare professionals to deviate from existing protocols and guidelines if the situation calls for it.

Based on the current data, it is difficult to generate specific improvement strategies because the causes were studied using the main categories of the Eindhoven Classification Model which are quite broad, leaving the possibility for high heterogeneity of causes within each main category. Nevertheless, the current study has shown that the incidences of DAEs, potentially preventable DAEs and potentially preventable DAE-related deaths among patients who died in hospitals in the Netherlands have not further declined after 2012. The high preventability of DAEs, including preventable deaths, suggests there is room for improvement. Since the start of these AE studies in the Netherlands, no national programs have focused on improving diagnostic safety specifically. Results of the current study suggest that DAEs can react to improvements to general patient safety, as shown by the decrease between 2008 and 2012. However, DAEs could possibly benefit more from targeted safety interventions, especially since results suggest that DAEs have more diverse cause types compared to other AE types. Specific directions for such interventions as well as future research to improve diagnostic safety and reduce patient harm have been prioritized by both researchers and patients in two recent research agenda papers [22, 23].

Strengths and limitations

This study combined data from four large national AE studies with representative samples from Dutch hospitals. Each iteration of the study used the same method, making it possible to create a longitudinal dataset comprising a large number of cases and AEs. This is a unique dataset because of the availability of information on DAEs and other AE types, which made it possible to analyse not only the DAE incidences over time, but also compare the trends and characteristics of DAEs and other AE types, giving further insight in how DAEs compare to other clinical processes.

There are some limitations of these data as well. First, using reviewers to retrospectively judge complex clinical situations based solely on patient records, introduces challenges such as subjectivity and possible hindsight bias. However, this is inherently unavoidable in a record review study, and even with its flaws, medical record review is usually the most applied and accepted method to assess AEs [24]. Noteworthy, the reviewers were thoroughly trained. Nonetheless, the inter-rater reliability on whether an AE was present or not was fair to moderate, according to the Landis and Koch classification for Cohen's Kappa, and the positive agreement was on the low end. A low inter-rater reliability is a common limitation record review studies, and it may have introduced some variability and noise to the data in this study as well, which should be taken into account when interpreting the results.

Second, our decision to classify an AE as a DAE only when the primary clinical process was related to the diagnostic process, may have led to an underestimation of the total number of DAEs. The incidence rates in this study may also not be directly comparable to diagnostic error rates, as the latter can include wrong or delayed diagnoses that did not result in patient harm, making our estimates even more conservative. Last, there are signs that patients have become more complex over the years (e.g. slight age increase, more patient-related factors present), which could have added a small layer of noise to these data.

Conclusions

The incidence of DAEs, potentially preventable DAEs, and potentially preventable DAE-related deaths in Dutch hospitals has decreased in 2012 compared to 2008 after the National Dutch Patient Safety Programme, but remained stable thereafter. While DAEs and other AE types were found to largely have the same incidence patterns, the incidence for other AE types increased relative to that of DAEs. DAEs remained highly preventable over the years and showed a different cause profile from other AE types with relatively more human and organisational causes, (protocol) violations and relatively few patient-related causes. These results suggest that DAEs are responsive to general patient safety improvements, but could benefit even more from targeted safety interventions.

Research ethics: All initial AE studies were approved by the Medical Ethical Review Committee of the Amsterdam University Medical Center, the Netherlands. The study was

conducted in accordance with the Declaration of Helsinki (as revised in 2013).

Informed consent: Not applicable.

Author contributions: All authors were involved in the conception of this study. MCdB and CW carried out the initial adverse event studies. JH and BS prepared the data for analyses. JH, JJS, and LZ analysed and interpreted the data. JH, LZ, and JJS drafted the manuscript. LZ, JJS, BS, MCdB and CW gave feedback on the manuscript. All authors have accepted responsibility for the entire content of this manuscript and approved its submission.

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Conflict of interest: The authors state no conflict of interest.

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Data availability: The raw data can be obtained on request from the corresponding author.

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