

RESEARCH ARTICLE

Medical Records Quality as Prevention Tool for Healthcare-Associated Infections (HAIs) Related Litigation: a Case Series

Giuseppe Davide Albano¹, Giuseppe Bertozzi¹, Francesca Maglietta¹, Angelo Montana², Giulio Di Mizio³, Massimiliano Esposito², Pietro Mazzeo⁴, Stefano D'Errico⁵ and Monica Salerno^{1,2*}

¹Department of Forensic Pathology, Clinical and Experimental Medicine Department, University of Foggia, Ospedale Colonnello D'Avanzo, Foggia, Italy; ²Department of Medical, Surgical Sciences and Advanced Technologies "G.F. Ingrassia", University of Catania – A.O.U. "Policlinico V. Emanuele", Catania, Italy; ³Department of Law, University of Catanzaro Magna Graecia, Campus Universitario "S. Venuta" Catanzaro, Italy; ⁴Department of Legal Medicine Azienda ASP Catania, Italy; ⁵Department of Legal Medicine Azienda USL Toscana Nordovest Lucca, Italy

Abstract: Background: Healthcare-associated infections are one of the most serious Public Health concern, as they prolong the length of hospitalization, reduce the quality of life, and increase morbidity and mortality. Despite they are not completely avoidable, the number of healthcare-associated infections related to negligence claims has risen over the last years, contributing to remarkable economic and reputation losses of Healthcare System.

Methods: In this regard, several studies suggested a key role of medical records quality in determining medical care process, risk management and preventing liability. Clinical documentation should be able to demonstrate that clinicians met their duty of care and did not compromise patients safety.

Results: Therefore, it has a key role in assessing healthcare workers liability in malpractice litigation. Our risk management experience has confirmed the role of medical records accuracy in preventing hospital liability and improving the quality of medical care.

Conclusion: In the presented healthcare-associated infections cases, evidence-based and guidelines-based practice, as well as a complete/incomplete medical record, have shown to significantly affect the verdict of the judicial court and inclusion/exclusion of hospital liability in healthcare-associated infections related claims.

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1. INTRODUCTION

Healthcare-associated infections (HAIs) are one of the most serious Public Health concern, as they prolong the length of hospitalization, reduce the quality of life, and increase morbidity and mortality [1, 2].

Despite they are not completely avoidable, the number of HAIs-related negligence claims has risen over the last years, contributing to remarkable economic and reputation losses of Healthcare System (HS) [3-5].

Prevention and surveillance programs showed to be helpful tools for infections control [6], having allowed to increase patients safety and HS quality.

Quality of medical care is defined as the capacity of the healthcare system to achieve several medical and non-medical goals [7]. In this regard, several studies suggested a key role of medical records quality in determining medical care process, risk management and preventing liability [8-11].

The aim of this paper is to present some cases of HAIs claims from our daily risk management activity performed in a southern Italy Hospital and discuss the association between medical records quality and HAIs-related litigation.

*Address correspondence to this author at the Department of Medical, Surgical Sciences and Advanced Technologies "G.F. Ingrassia", University of Catania - A.O.U. "Policlinico V. Emanuele", Via S. Sofia, 87 - Sector 10, Building B-95123 Catania, Italy; Tel: +39095378111; E-mail: monica.salerno@unifg.it

Fig. (1). The day of surgery no mention to antibiotic prophylaxis is present in therapy schedule (red square).

Fig. (2). No mention to antibiotic prophylaxis nor operating room facilities nor instruments sterilization is present in surgical safety checklist.

2. CASE SERIES

Here, we present three significant HAIs-related cases in which documentation accuracy had a crucial role in assess-

ing Hospital liability in our risk management activity in the Regional Oncological Reference Center (CROB) Hospital, of Rionero, in Potenza District, Italy.

CHECKLIST PER LA SICUREZZA IN SALA OPERATORIA		
SIGN IN da effettuare prima dell'anestesia	TIME OUT da effettuare prima dell'incisione	SIGN OUT da effettuare prima dell'uscita dalla sala operatoria
<p>Il paziente ha confermato:</p> <ul style="list-style-type: none"> - identità <input checked="" type="checkbox"/> SI <input type="checkbox"/> NO - sede di intervento <input checked="" type="checkbox"/> SI <input type="checkbox"/> NO - procedura <input checked="" type="checkbox"/> SI <input type="checkbox"/> NO <p>Sono stati acquisiti i consensi:</p> <p>anestesiological chirurgico emocomponenti</p> <p><input checked="" type="checkbox"/> SI <input type="checkbox"/> NO <input checked="" type="checkbox"/> SI <input type="checkbox"/> NO <input type="checkbox"/> SI <input checked="" type="checkbox"/> NO</p> <p>Il sito dell'intervento è marcato? <input checked="" type="checkbox"/> SI <input type="checkbox"/> NO</p> <p>Perché</p> <p>Controlli per la sicurezza dell'anestesia completati? <input checked="" type="checkbox"/> SI <input type="checkbox"/> NO</p> <p>Perché</p> <p>Posizionamento del Pulsossimetro sul paziente e verifica del corretto funzionamento? <input checked="" type="checkbox"/> SI <input type="checkbox"/> NO</p> <p>Identificazione dei rischi del paziente:</p> <ul style="list-style-type: none"> - Allergie <input type="checkbox"/> SI <input checked="" type="checkbox"/> NO - Difficoltà di gestione delle vie aeree o rischio di aspirazione? <input type="checkbox"/> SI <input checked="" type="checkbox"/> NO - Rischio di perdita ematica > 500ml <input checked="" type="checkbox"/> SI, l'accesso endovenoso è adeguato e i fluidi sono disponibili <input type="checkbox"/> NO - Conferma messa in atto profilassi antitrombotica <input type="checkbox"/> Calze antitrombosi <input type="checkbox"/> Comprensore 	<p>Tutti i componenti dell'équipe si sono presentati con il proprio nome e funzioni <input checked="" type="checkbox"/> SI <input type="checkbox"/> NO</p> <p>Il chirurgo, l'anestesista e l'infermiere hanno confermato: identità del paziente, sede d'intervento, procedura, il corretto posizionamento <input checked="" type="checkbox"/> SI <input type="checkbox"/> NO</p> <p>Anticipazione di eventuali criticità o preoccupazioni:</p> <p>Chirurgo: durata dell'intervento, rischio di perdita di sangue, altro? <input type="checkbox"/> SI <input checked="" type="checkbox"/> NO Descrizione:</p> <p>Anestesista: specificità riguardanti il paziente, altro? <input checked="" type="checkbox"/> SI <input type="checkbox"/> NO Descrizione: bpco</p> <p>Infermiere: è stata verificata la sterilità (compresi i risultati degli indicatori) <input checked="" type="checkbox"/> SI <input type="checkbox"/> NO Descrizione:</p> <p>ci sono eventuali problemi relativi ai dispositivi e/o altre preoccupazioni? <input type="checkbox"/> SI <input checked="" type="checkbox"/> NO Descrizione:</p> <p>La profilassi antibiotica è stata eseguita negli ultimi 60 minuti? <input checked="" type="checkbox"/> SI <input type="checkbox"/> NO</p> <p>Le immagini diagnostiche sono state visualizzate? <input checked="" type="checkbox"/> SI <input type="checkbox"/> NO</p>	<p>L'infermiere conferma verbalmente insieme ai componenti dell'équipe:</p> <ul style="list-style-type: none"> - nome della procedura registrata <input checked="" type="checkbox"/> SI <input type="checkbox"/> NO - il conteggio finale di garze, bisturi, aghi e altro strumentario chirurgico, è risultato corretto? <input checked="" type="checkbox"/> SI <input type="checkbox"/> NO - il campione chirurgico, con relativo contenitore e richiesta, è stato etichettato (compreso l'identificativo del paziente e descrizione del) <input checked="" type="checkbox"/> SI <input type="checkbox"/> NO - eventualità di problemi relativamente all'uso di dispositivi medici <input type="checkbox"/> SI <input checked="" type="checkbox"/> NO <p>Sono prevedibili elementi critici per la gestione dell'assistenza post operatoria: <input type="checkbox"/> SI <input checked="" type="checkbox"/> NO</p> <p>Quali:</p> <p>Conferma piano per la profilassi del tromboembolismo post-operatorio <input checked="" type="checkbox"/> SI <input type="checkbox"/> NO</p> <p>L'infermiere di sala operatoria Scorzelli Carmine</p> <p>Il coordinatore della checklist _____</p> <p>Data 29/05/2014</p>

Fig. (3). Antibiotic prophylaxis timing administration is documented in surgical safety checklist.

2.1. Case No. 1

A 43-year-old man with a history of lumbar disc herniation was admitted to the emergency department for lumbar pain radiating along the right lower limb. He underwent magnetic resonance examination, and an L4-L5 disc herniation with roots nerve compression has been diagnosed. He was admitted to the Neurosurgery department and after all routine exams, he underwent arthroscopic microdiscectomy. Seven days after surgery, he was discharged. Three weeks after surgery, he came back to the emergency department with pain in the surgical site and loss of function. A methicillin-resistant *Staphylococcus Aureus* (MRSA) spondylodiscitis was diagnosed. Medical records analysis showed no mentioning of perioperative antibiotics prophylaxis, as well as operating room facilities sterilization (Figs. 1-2). A malpractice lawsuit was brought and the court established Hospital legal liability.

2.2. Case No. 2

A 78-year-old man with a history of senile osteoporosis, spondyloarthropathy, spondylolisthesis, atrial fibrillation, chronic renal failure and chronic obstructive pulmonary disease, was admitted to orthopedics department to undergo spine stabilization surgery of T5-T6 and T10-T12 vertebrae

and L2 vertebroplasty in arthrodesis. Ten days after hospital discharge, he was admitted to the geriatric department due to thoracic pain, coughing and fever. After a thorax X-ray and laboratory tests, pneumonia was diagnosed. Tracheobronchial mucus analysis was positive for MRSA. Due to MRSA pneumonia, length of Hospitalization was prolonged for 30 days. Patient Medical records review showed a correct and well-documented antibiotic prophylaxis therapy, a complete and accurate description of surgery and complete documentation of sterilization of both operating room facilities and surgical instruments (Figs. 3-5). The malpractice claim was settled and wasn't brought to trial.

2.3. Case No. 3

A 40-year-old woman with multifactorial anemia, atrial fibrillation and mitral valve prolapse, was admitted to Cardiology ward in December 2011 for heart failure. In 22nd of May 2012, she went to the emergency department for dyspnea and lower limb edema; then, she was admitted to cardiology ward with right heart failure diagnosis. After seven days, she underwent a blood cultural exam that was positive for MRSA. After Echocardiography examination, mitral valve endocarditis was diagnosed. She underwent mitral valve replacement surgery due to moderate-severe mitral insufficiency. The HAIs-related malpractice claim against

Fig. (4). Operating room facilities and instruments sterilization (red arrows).

the Hospital was brought to trial. Medical record and clinical documentation were accurate and complete in all aspects of medical care (Fig. 6). Further, MRSA endocarditis is more frequently acquired in a community, and heart failure (admittance diagnosis) is a frequent endocarditis consequence characterized by low body temperature levels. Infection presence was assessed after admission, and a nosocomial origin was excluded. Thus, the court verdict excluded any hospital liability.

3. DISCUSSION

HAIs issue has been widely debated in recent years. Surgical site infections (SSIs) are frequent complications that occur in 2-5% of patients who undergo surgery. More than 60% of SSIs have been estimated to be preventable by using evidence-based guidelines [12,13]. However, despite several measures could be taken, such as improvement of operating

room facilities, administration of antibiotics as prophylaxis against infection and improvement of surgical technique, it is impossible to completely prevent SSIs, as well as SSIs related litigation [14]. Moreover, as shown in two of the reported cases and as it was reported by several studies, community-acquired MRSA is frequently observed in elderly patients who have comorbidities [15, 16]. However, complete and accurate documentation of SSIs surveillance and prevention may be a helpful tool in SSIs-related litigation, by suggesting an evidence-based practice for infection control.

HAIs area has seen a rising number of clinical negligence claims [17,18]. HAIs are associated with significant costs to society, related to the increased length of hospitalization, laboratory tests, imaging studies and human resources [19-22]. In this regard, according to Eber et al. [23], in the United States, there were 2.3 million patient hospitalization days, \$8.1 billion in-hospital costs, and 48 000 deaths as a consequence of healthcare-associated sepsis and pneumonia

INTERVENTO CHIRURGICO ESEGUITO
 Stabilizzazione vertebrale percutanea D5-7 , D10-12, Vertebroplastica L2

ORA INIZIO INTERV. ORA FINE INTERV.
 10.30 11.30

DESCRIZIONE INTERVENTO

Si pone il paziente in posizione prona. Con l'ausilio della fluoroscopia si identifica in AP la frattura vertebrale a livello di L2. Previa incisione cutanea si posiziona per via transpeduncolare ago 12G con cannula di lavoro in ciascuno dei peduncoli, verificando mediante fluoroscopia continua in AP e LL la giustaposizione. Si esegue biopsia del corpo vertebrale. Iniezione di cemento Kyphon Expede attraverso le cannule di lavoro mediante bone filler ed iniettore idraulico (circa 3 ml per livello) con visualizzazione continua in fluoroscopia LL. Riempimento adeguato del corpo vertebrale. Rimozione bone filler e cannule. Con l'ausilio della fluoroscopia si identifica in AP la frattura vertebrale a livello di D6 e la vertebra sopra e sottostante. Previa incisione cutanea si posiziona per via extrapeduncolare a livello di D5 e D7 ago 12G in ciascuno dei quattro peduncoli, verificando mediante fluoroscopia continua in AP e LL la giustaposizione. (SISTEMA LONGITUDE) Sempre mediante fluoroscopia LL, attraverso l'ago si introducono fili di Kirschner , quindi si rimuovono gli aghi e si posizionano, previa dilatazione progressiva della cute quattro viti cannulate fenestrate transpeduncolari (5.5 x 40 D5 e 5.5 x 45 a D7). Si procede alla loro allocazione all'interno delle vertebre. Iniezione di cemento Kyphon attraverso la vite mediante bone filler (circa 3 ml per livello) con visualizzazione continua in fluoroscopia LL per garantire un fissaggio adeguato. Previa incisione cutanea in sede caudale rispetto alle viti, si posizionano due barre precurve (80 mm) e si verifica il loro ingresso all'interno degli occhielli delle viti. Serraggio delle viti e delle barre. Verifica della corretta posizione in AP e LL. Con l'ausilio della fluoroscopia si identifica in AP la frattura vertebrale a livello di D11 e la vertebra sopra e sottostante. Previa incisione cutanea si posiziona per via extrapeduncolare a livello di D10 e D12 ago 12G in ciascuno dei quattro peduncoli, verificando mediante fluoroscopia continua in AP e LL la giustaposizione. (SISTEMA LONGITUDE) Sempre mediante fluoroscopia LL, attraverso l'ago si introducono fili di Kirschner , quindi si rimuovono gli aghi e si posizionano, previa dilatazione progressiva della cute quattro viti cannulate fenestrate transpeduncolari (5.5 x 45 D10 e 5.5 x 45 a D12). Si procede alla loro allocazione all'interno delle vertebre. Iniezione di cemento Kyphon attraverso la vite mediante bone filler (circa 3 ml per livello) con visualizzazione continua in fluoroscopia LL per garantire un fissaggio adeguato. Previa incisione cutanea in sede caudale rispetto alle viti, si posizionano due barre precurve (90 mm) e si verifica il loro ingresso all'interno degli occhielli delle viti. Serraggio delle viti e delle barre. Verifica della corretta posizione in AP e LL.
 Sutura delle incisioni a strati.

Fig. (5). Detailed and complete surgery description.

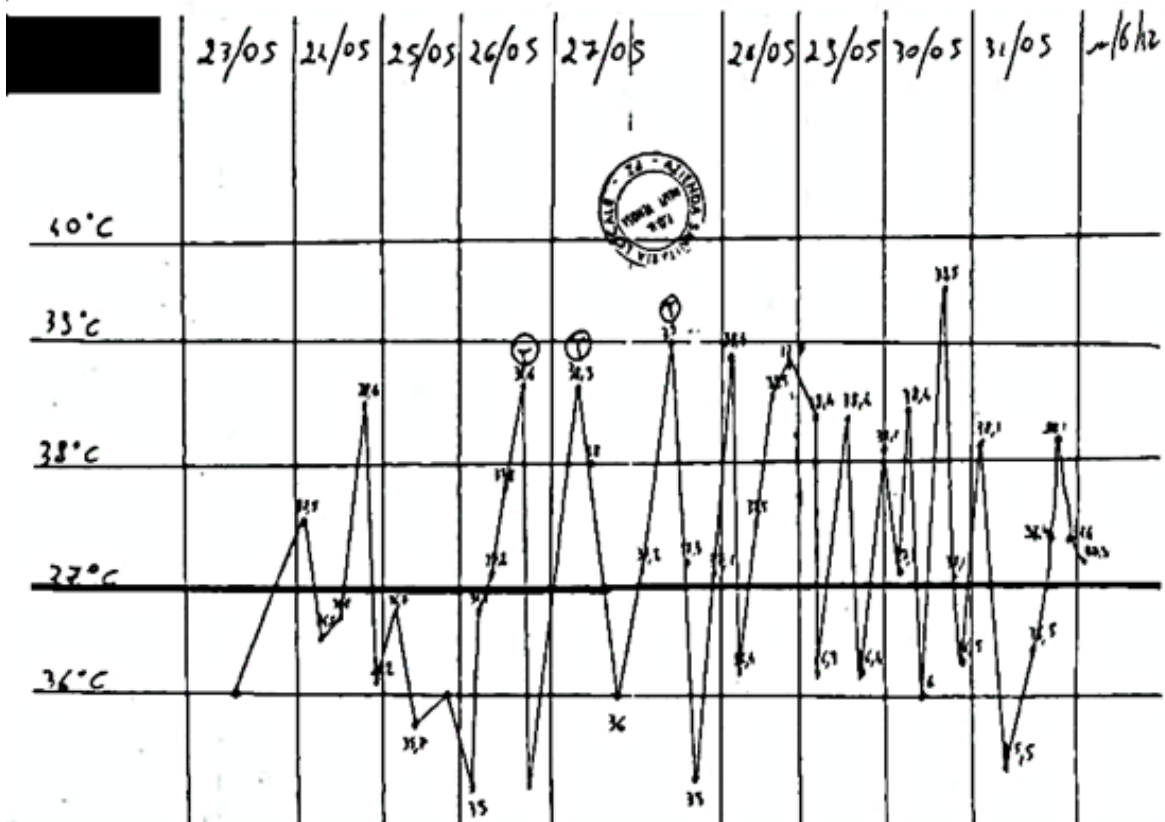


Fig. (6). Basal body temperature chart.

in 2006. Moreover, litigation is a remarkable HAIs-related cost, accounting for considerable litigation payments that include additional costs due to staff time involved in the investigation and management of claims [24]: in England, between 1996 and 2010, *Clostridium Difficile* or MRSA related claims led to total litigation payments of £35.2 million [3]. A recent study suggested how insufficient and/or lack of documentation is a frequent contributing factor in hospital malpractice cases [25], thereby leading to hypothesize a crucial role of medical records quality in assessing HAIs hospital liability.

Medical records documentation is crucial in patient medical care. It was demonstrated that medical records quality and evidence-based medicine are strictly connected with patients outcomes [9]. Indeed, the quality of clinical documentation reflects a more organized HS [26]. Well-Documented written guidance on patient movement and accurate bed management is associated with a lower rate of nosocomial infections [27]. Conversely, inaccurate clinical documentation may contribute to patient safety impairment and higher malpractice risk exposure [28]. Moreover, Healthcare workers (HCWs) need to warn patients regarding medical procedure risks, including HAIs, and such information needs to be documented [29]. According to the Westlaw United States, a legal database in 32.7% of medical malpractice claims a lack of informed consent, is present [30]. Moreover, several studies have established communication defects as a crucial factor linked to malpractice claims [31-34]. Indeed, patient participation in medical decisions was demonstrated to reduce the number of HAIs malpractice claims [35].

In 2007, the World Health Organization (WHO) promoted guidelines for medical record and clinical documentation [36]. Such recommendations highlight its role in improving HS quality. According to WHO guidelines, medical records need necessarily to be clear, concise, correct, com-

prehensive and contemporary. Indeed, clinical documentation should be able to demonstrate that clinicians met their duty of care and did not compromise patients' safety. Medical records and clinical documentation should include all aspects of patient care and his function is to record all direct HCWs knowledge, observations, actions, decision and outcomes in order to implement a tailored approach [37-39]. Therefore, it has a key role in assessing HCWs liability in malpractice litigation. Indeed, in a judicial trial, appropriateness of a healthcare practice must be compared to accepted standards. Courts often consider guidelines or best clinical practice to determine legal standards of care, and Italian law (recent law n. 24 of March 2017 "Gelli-Bianco") encourages such orientation. All HCWs in their daily practice need to be encouraged in performing evidence-based practice, including accurate and guidelines-based medical records recording, both for patient safety and liability prevention. In this regard, in HAIs and suspected HAIs cases, in all elements of patient care, accurate and complete documentation of infection control and surveillance is mandatory in order to avoid HAIs-related litigation. Table 1 shows the medical records key points [36, 40] to follow in order to prevent HAIs-related liability.

Our risk management experience has confirmed the role of medical records accuracy in preventing hospital liability and improving the quality of medical care [41]. In the presented HAIs cases, evidence-based and guidelines-based practice, as well as a complete/incomplete medical record, has shown to significantly affect the verdict of the judicial court and inclusion/exclusion of hospital liability in HAIs-related claims.

According to the World Health Organization, HAIs "are infections acquired during hospital care which are not present or incubating at admission. Infections occurring more than 48 hours after admission are usually considered nosocomial" [42]. For common infections (surgical site infection, urinary infection, respiratory infection, vascular catheter

Table 1. Key points that medical records should include in order to reduce HAIs-related litigation.

<i>History</i>	All relevant information regarding infectious diseases.
<i>Physical examination</i>	A complete examination need to be performed and documented at patient admission and discharge in order to exclude infection-related findings presence.
<i>Diagnosis</i>	In clear, readily understood terms. It should be clear how you got to this conclusion.
<i>Information and Communication</i>	Patient should be carefully informed about HAIs risk and such information need to be documented. All patient communications need to be demonstrated.
<i>Admission/Discharge laboratory tests and imaging studies</i>	Infection control surveillance analysis after admission and before discharge in high-risk patients.
<i>Therapy</i>	An accurate account of antimicrobial treatment (dosage, timing), intervention and care planning.
<i>Progress</i>	Clear and complete antibiotic prophylaxis. Surgery room facilities and instruments sterilization. Detailed and complete surgery description.
<i>Follow-up</i>	Clear and complete recommendations regarding discharge therapy
<i>Prevention and Surveillance</i>	Access to HAIs surveillance and prevention hospital program should be provided.
<i>HAIs-related litigation data</i>	Access to HAIs-related malpractice claims data should be provided.

infection, septicemia), simplified surveillance criteria for infection presence have been established [38]. In this regard, by performing a surveillance criteria analysis after admission and before discharge, it is possible to exclude the nosocomial origin of the infection with significant resiliencies on hospital liability in HAIs-related malpractice claims.

As we mentioned before, despite not all HAIs are preventable, their incidence may be largely reduced by prevention activities [43]. HAIs prevention and surveillance contribute to an improvement in patient safety and Healthcare quality, as well as costs reduction. Moreover, accurate and guidelines-based medical records filling was demonstrated to reduce HAIs-related litigation, improve patient medical care appraisal, therefore HS quality. The most frequent type of infections, SSIs and isolate MRSA, is more likely to be seen as preventable, and, in a judicial trial, medical records are the only elements able to demonstrate standard care adhesion for infection control.

CONCLUSION

HAIs prevention and surveillance are helpful tools to improve HS quality and reduce HAIs-related litigation. Evidence-based clinical practice enhanced physician-patient communication, and documentation accuracy may have a relevant role in reducing hospital liability in HAIs malpractice claims, leading to costs reduction and advances in standard of patient care. Medical records accuracy need to be encouraged and promoted to obtain better healthcare quality.

LIST OF ABBREVIATIONS

HAIs	=	Healthcare-Associated Infections;
HS	=	Healthcare System;
HCWs	=	healthcare workers;
MRSA	=	Meticillin-Resistant <i>Staphylococcus aureus</i>

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

HUMAN AND ANIMAL RIGHTS

No Animals/Humans were used for studies that are base of this research.

CONSENT FOR PUBLICATION

Not applicable.

AVAILABILITY OF DATA AND MATERIALS

Not applicable.

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CONFLICT OF INTEREST

The authors declare no conflict of interest, financial or otherwise.

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Declared none.

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