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

Giuseppe D. Albano ${ }^{1}$, Giuseppe Bertozzi ${ }^{1}$, Francesca Maglietta ${ }^{1}$, Angelo Montana ${ }^{2}$, Giulio Di Mizio ${ }^{3}$, Massimiliano Esposito ${ }^{2}$, Pietro Mazzeo ${ }^{4}$, Stefano D'Errico ${ }^{5}$ and Monica Salerno ${ }^{1,2^{*}}$<br>${ }^{I}$ Department of Forensic Pathology, Clinical and Experimental Medicine Department, University of Foggia, Ospedale Colonnello D'Avanzo, Foggia, Italy; ${ }^{2}$ Department of Medical, Surgical Sciences and Advanced Technologies "G.F. Ingrassia", University of Catania - A.O.U. "Policlinico V. Emanuele", Catania, Italy; ${ }^{3}$ Department of Law, University of Catanzaro Magna Graecia, Campus Universitario "S. Venuta", Catanzaro, Italy; ${ }^{4}$ Department of Legal Medicine Azienda ASP, Catania, Italy; ${ }^{5}$ Department of Legal Medicine Azienda USL Toscana Nordovest, Lucca, Italy

Accepted December 16, 2018


#### 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 patient's 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 guidelinesbased 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.


Keywords: Healthcare-associated infections (HAIs), litigation, malpractice, claims, medical records, quality, prevention, clinical documentation.

## 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].

[^0]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 nonmedical 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.

## 2. CASE SERIES

Here, we present three significant HAIs-related cases in which documentation accuracy had a crucial role in assessing Hospital liability in our risk management activity in the Regional Oncological Reference Center (CROB) Hospital, of Rionero, in Potenza District, Italy.

### 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 methicil-lin-resistant Staphylococcus Aureus (MRSA) spondylodiscitis was diagnosed. Medical records analysis showed no mentioning of perioperative antibiotics prophylaxis, as well as operating room facilities sterilization. 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. 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 $22^{\text {nd }}$ 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 the Hospital was brought to trial. Medical record and clinical documentation were accurate and complete in all aspects of medical care. Further, MRSA endocarditis is more frequently acquired in a community, and heart failure (admittance diag-
nosis) 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, communityacquired 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 [1922]. 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 48000 deaths as a consequence of healthcare-associated sepsis and pneumonia 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]. WellDocumented 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

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

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

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, comprehensive 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 HAIsrelated 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 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. Evi-dence-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 healtheare quality.

## LIST OF ABBREVIATIONS

HAIs $=$ Healthcare-Associated Infections
HS $\quad=$ Healthcare System
HCWs = healthcare workers
MRSA $=$ Meticillin-Resistant Staphylococcus aureus

## ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

## HUMAN AND ANIMAL RIGHTS

The authors followed the CARE Guidelines of Equator Network.

## CONSENT FOR PUBLICATION

Not applicable.

## AVAILABILITY OF DATA AND MATERIALS

The source of our data cannot be disclosed because they are not yet closed cases of litigation, therefore the right to privacy applies in these cases.

## FUNDING

None.

## CONFLICT OF INTEREST

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

## ACKNOWLEDGEMENTS

Declared none.

## REFERENCES

Arias, C.A.; Murray, B.E. Antibiotic-resistant bugs in the 21 st century-a clinical super-challenge. N. Engl. J. Med., 2009, 360(5), 439-443.
[2] Donaldson, L.I.; Appleby, L.; Boyce, J. An organisation with a memory: report of an expert group on learning from adverse events in the NHS. Norwich, United Kingdom: Stationery Office, 2000.
[3] Goldenberg, S.D.; Volpé, H.; French, G.L. Clinical negligence, litigation and healthcare-associated infections. J. Hosp. Infect., 2012, 81 (3), 156-162.
[4] Mulcahy, L.; Tritter, J. Pyramids, pathways, and icebergsunderstanding the relationship between dissatisfaction, complaints and disputes. Social. Health Illn., 1998, 20(6), 825-847.
[5] Dancer, S.I. Pants, Policies and paranoia. J. Hosp. Infect., 2010, 74(1), 10-15.
[6] Pittet, D. Infection control and quality healthcare in the new millennium. Am. J. Infect. Control, 2005, 33(5), 258-267.
[7] Steffen, G.E. Quality medical care: a definition. JAMA, 1988, 260(1), 56-61.
[8] Gutheil, T.G. Fundamentals of medical record documentation. Psychiatry (Edgmont), 2004, l(3), 26.
[9] Dunlay, S.M.; Alexander, K.P.; Melloni, C.; Kraschnewski, J.L.; Liang, L.; Gibler, W.B.; Peterson, E.D. Medical records and quality of care in acute coronary syndromes: results from CRUSADE. Arch. Intern. Med., 2008, 168(15), 1692-1698.
[10] Garcia, A.; Revere, L.; Sharath, S.; Kougias, P. Implications of Clinical Documentation (ln) Accuracy: A Pilot Study Among General Surgery Residents. Hosp. Top., 2017, 95(2), 27-31.

Dang, V.M.; Francois, P.; Batailler, P.; Seigneurin, A.; Vittoz, J.P.; Sellier, E.; Labarère, J. Medical record-keeping and patient perception of hospital care quality. Int. J. Health Care Qual. Assur., 2014, 27(6), 531-543.
[12] Anderson, D.J.; Podgorny, K.; Berrios-Torres, S.I.; Bratzler, D.W.; Dellinger, E.P.; Greene, L.; Kaye, K.S. Strategies to prevent surgical site infections in acute care hospitals: 2014 update. Infect. Control Hosp. Epidemiol., 2014, 35(S2), S66-S88.
[13] Hawn, M.T.; Vick, C.C.; Richman, J.; Holman, W.; Deierhoi, R.J.; Graham, L.A.; Itani, K.M. Surgical site infection prevention: Time to move beyond the surgical care improvement program. Ann. Surg., 2011, 254(3), 494-501.
[14] Park, B.Y.; Kwon, J.W.; Kang, S.R.; Hong, S.E. Analysis of malpractice claims associated with surgical site infection in the field of plastic surgery. J. Korean Med. Sci., 2016, 31(12), 1963-1968.
[15] Defres, S.; Marwick, C.; Nathwani, D. MRSA as a cause of lung infection including airway infection, community-acquired pneumonia and hospital-acquired pneumonia. Eur. Respir. J., 2009, 34(6), 1470-1476.
[16] Zetola, N.; Francis, J.S.; Nuermberger, E.L.; Bishai, W.R. Com-munity-acquired meticillin-resistant Staphylococcus aureus: An emerging threat. Lancet Infect. Dis., 2005, 5(5), 275-286.
[17] Guinan, J.L.; McGuckin, M.; Shubin, A.; Tighe, J. A descriptive review of malpractice claims for healthcare-acquired infections in Philadelphia. Am. J. Infect. Control, 2005, 33(5), 310-312.
[18] Bailey, T.M.; Ries, N.M. Legal issues in patient safety: the example of nosocomial infection. Healthc. Q., 2005, 8, 140-145.
[19] Plowman, R.; Graves, N.; Griffin, M.; Roberts, J.A.; Swan, A.V.; Cookson, B.; Taylor, L. Socio-economic burden of hospital acquired infection. Health Protection Agency, 1999.
[20] Wilcox, M.H.; Dave, J. The cost of hospital-acquired infection and the value of infection control. J. Hosp. Infect., 2000, 45(2), 81-84.
[21] Gould, I.M.; Reilly, J.; Bunyan, D.; Walker, A. Costs of healthcareassociated methicillin-resistant Staphylococcus caureus and its control. Clin. Microbiol. Infect., 2010, 16(12), 1721-1728.
[22] Ghantoji, S.S.; Sail, K.; Lairson, D.R.; DuPont, H.L.; Garey, K.W. Economic healthcare costs of Clostridium difficile infection: A systematic review. J. Hosp. Infect., 2010, 74(4), 309-318.
[23] Eber, M.R.; Laxminarayan, R.; Perencevich, E.N.; Malani, A. Clinical and economic outcomes attributable to health careassociated sepsis and pneumonia. Arch. Int. Med., 2010, 170(4), 347-353.
[24] Authority, N.L. Factsheet 3: Information on claims. National Health Service Litigation Authority, 2011.
[25] Schaffer, A.C.; Puopolo, A.L.; Raman, S.; Kachalia, A. Liability impact of the hospitalist model of care. J. Hosp. Med., 2014, 9(12), 750-755.
[26] Cox, J. L.; Zitner, D.; Courtney, K.D.; MacDonald, D.L.; Paterson, G.; Cochrane, B.; Johnstone, D.E.; Undocumented patient information: an impediment to quality of care. Am. J. Med., 2003, 114(3), 211-216.
[27] Mears, A.; White, A.; Cookson, B.; Devine, M.; Sedgwick, J.; Phillips, E.; Bardsley, M. Healthcare-associated infection in acute hospitals: Which interventions are effective? J. Hosp. Infect., 2009, 71(4), 307-313.
[28] Wilbanks, B.A.; Geisz-Everson, M; Boust, R.R. The role of documentation quality in anesthesia-related closed claims: A descriptive qualitative study. CIN: Computers, informatics. Nursing, 2016, 34(9), 406-412.
[29] Turillazzi, E.; Neri, M. Informed consent and Italian physicians: change course or abandonship - From formal authorization to a culture of sharing. Med. Health Care Philos., 2015, 18(3), 449-453.
[30] Paik, A.M.; Mady, L.J.; Sood, A.; Lee, E.S. Beyond the operating room: A look at legal liability in body contouring procedures. Aesthet. Surg. J., 2014, 34(1), 106-113.
[31] Hickson, G.B.; Federspiel, C.F.; Pichert, J.W.; Miller, C.S.; GauldJaeger, J.; Bost, P. Patient complaints and malpractice risk. JAMA, 2002, 287(22), 2951-2957.
[32] Levinson, W.; Roter, D.L.; Mullooly, J.P.; Dull, V.T.; Frankel, R.M. Physician-patient communication: The relationship with malpractice claims among primary care physicians and surgeons. $J A$ MA, 1997, 277(7), 553-559.
[33] Bhattacharyya, T.; Yeon, H.; Harris, M.B. The medical-legal aspects of informed consent in orthopaedic surgery. JBJS, 2005, 87(11), 2395-2400.

Gogos, A.I.; Clark, R.B.; Bismark, M.M.; Gruen, R.L.; Studdert, D.M. When informed consent goes poorly: A descriptive study of medical negligence claims and patient complaints. Med. J. Aust., 2011, 195(6), 340-344.
[35] Merle, V.; Tavolacci, M.P.; Moreau, A.; Dubreuil, N.; Dollois, B.; Gray, C.; Czernichow, P. What factors influence healthcare professionals' opinion and attitude regarding information for patients about hospital infection? J. Hosp. Infect., 2007, 66(3), 269-274. World Health Organization. Guidelines for medical record and clinical documentation. In: WHO-SEARO coding workshop, 2007.
[37] Di Sanzo, M.; Cipolloni, L.; Borro, M.; La Russa, R.; Santurro, A.; Scopetti, M.; Simmaco, M.; Frati, P. Clinical applications of personalized medicine: A new paradigm and challenge. Curr. Pharm. Biotechnol., 2017, 18(3), 194-203.
[38] La Russa, R.; Fineschi, V.; Di Sanzo, M.; Gatto, V.; Santurro, A.; Martini, G.; Scopetti, M.; Frati, P. Personalized Medicine and Adverse Drug Reactions: The experience of an Italian Teaching Hospital. Curr. Pharm. Biotechnol., 2017, 18(3), 274-281.

Borro, M.; Gentile, G.; Cipolloni, L.; Foldes-Papp, Z.; Frati, P.; Santurro, A.; Lionetto, L.; Simmaco, M. Personalised healthcare: The DiMA Clinical Model. Curr. Pharm. Biotechnol., 2017, 18(3), 242-252.
[40] Panting, G. How to avoid being sued in clinical practice. Postgrad. Med. J., 2004, 80(941), 165-168.
[41] Pomara, C.; D’Errico, S.; Neri, M.; Riezzo, I.; Telesforo, F.; Martelloni, M. Quality of the medical record as a medical - legal indicator of appropriateness and instrument for clinical risk management. First Pugliese experience in private healthcare - verification and analysis of the results of a study on 2000 medical records. Profession - Culture Prac. Doctor D'Oggi, 2009, 8, 24-30.
[42] Ducel, G.; Fabry, J.; Nicolle, L. World Health Organization. Prevention of hospital-acquired infections: A practical guide, 2002.
[43] Umscheid, C.A.; Mitchell, M.D.; Doshi, J.A.; Agarwal, R.; Williams, K.; Brennan, P.J. Estimating the proportion of healthcareassociated infections that are reasonably preventable and the related mortality and costs. Infect. Control Hosp. Epidemiol., 2011, 32(2), 101-114.


[^0]:    *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

