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THE SCOPE

DENTAL EDITION

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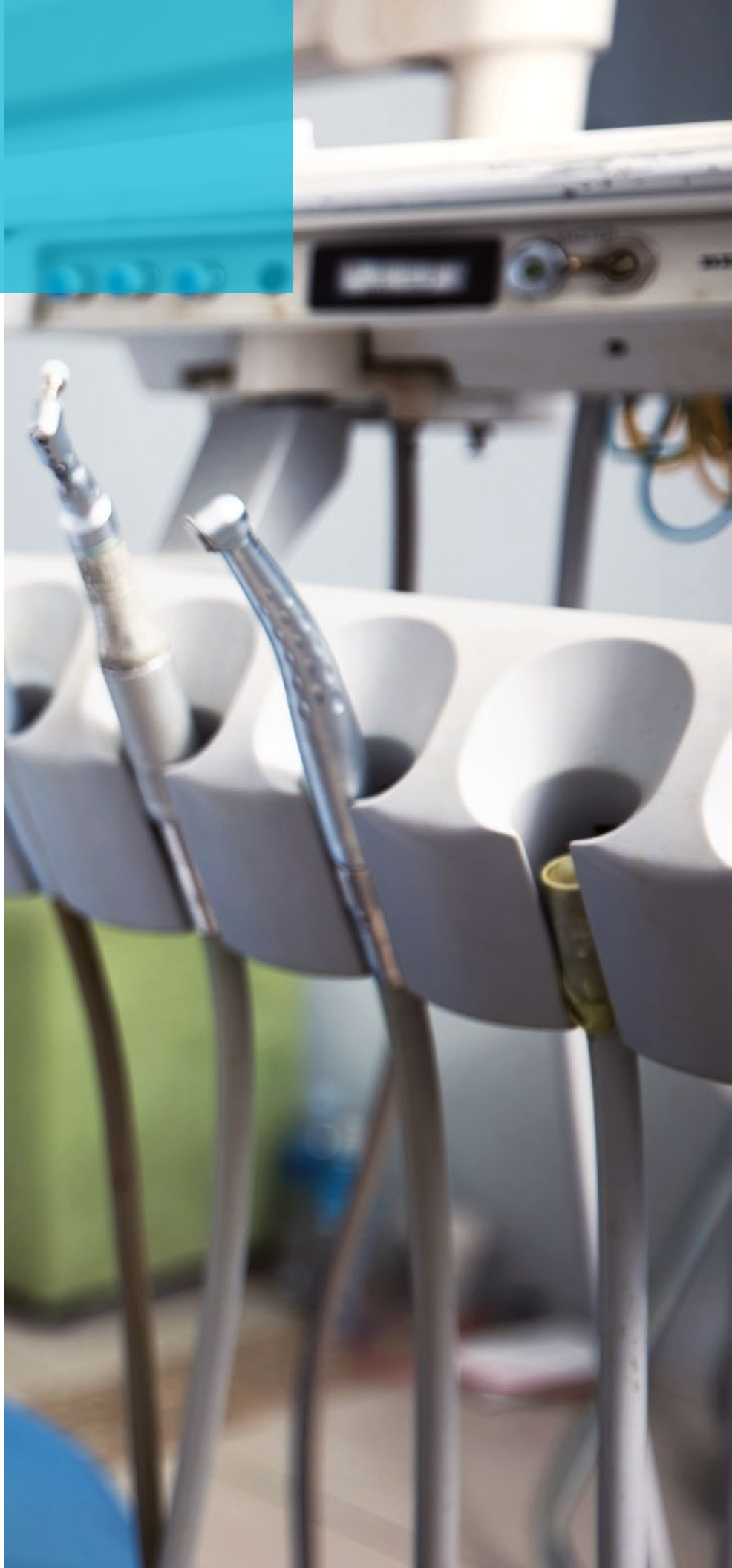
INSIDE



EXECUTIVE MESSAGE

Dear Colleagues,

The current issue of *The Scope* has something for everyone. Elizabeth Ollinick, Esq., has written a very thoughtful and comprehensive piece about a subject that has been front and center these days, namely, artificial intelligence, or AI. This subject has created great excitement, and much anxiety, among us all, and it's fair to say that there are many more questions than answers. Still, I think that there are certain statements that can be made with certainty:

1. AI is here to stay, like it or not.
2. AI has the potential to be a great help in the diagnosis and treatment of certain conditions.
3. AI recommendations will, rightly or not, have the potential to have a ring of certainty in dental professional liability suits.
4. AI will never replace, as a factor in treatment, the importance of a dentist knowing their patient well, including performing and documenting regular, thorough examinations.
5. AI is best seen as another tool at the dentist's disposal in their treatment of the patient.

MLMIC Insurance Company, of course, is closely monitoring developments in this field, always with an eye for how we can protect and help our insureds. At this early stage, I feel I can safely make the following strong recommendation: If your diagnosis and/or treatment differ from what AI tells you, please document in your record the fact that you are aware of the difference and why you feel your diagnosis and/or treatment is best for the patient. This will document the thought process of a thoughtful and concerned dentist and should help greatly at any trial.

Stay tuned!

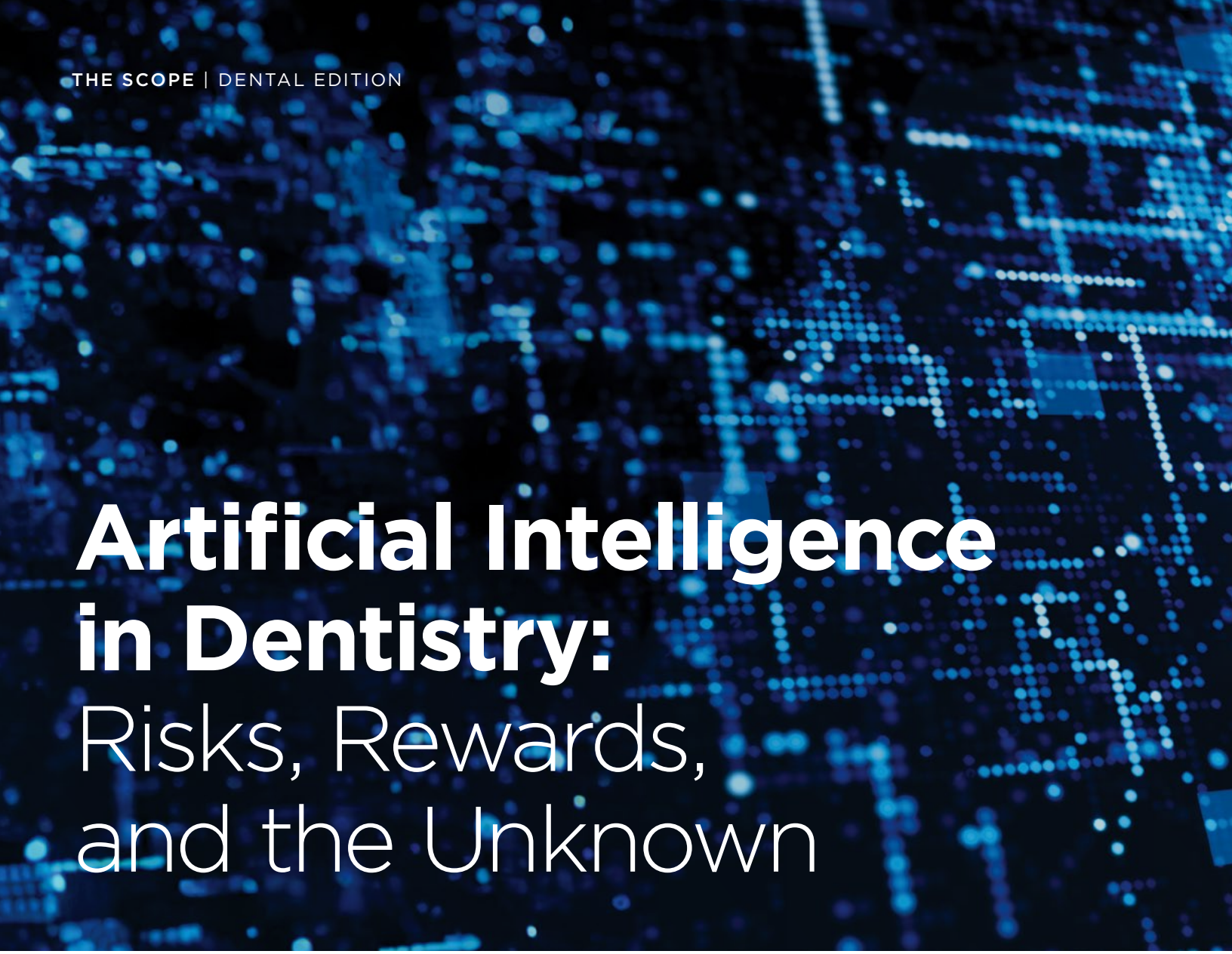
In another vein, the Grieving Families Act is once again threatening us. As you know, it has passed the New York State Assembly and Senate, and it will once again be up to Governor Hochul to either sign, veto, or recommend modifications to the bill. The bill is only slightly different from the bill she vetoed last year. At that time, a host of organizations were successful in their efforts to have this harmful bill vetoed.

Since that time, I sense a certain lethargy has set in among us, and I urge you to call the governor's office to express your opposition to this bill. I did this, both last year and again this year. The call was warmly received by her office, and I urge you to make your own call. The number is (518) 474-8390. Press Option 1 to leave a voicemail or Option 2 to speak with a person. It won't take long. Do it today.

Please continue to forward me your feedback on *The Scope* so that we may provide information you consider most valuable.

Sincerely, your colleague,

John W. Lombardo, M.D., FACS
Chief Medical Officer, MLMIC Insurance Company
jlombardo@mlmic.com



Artificial Intelligence in Dentistry: Risks, Rewards, and the Unknown

Adopting emerging artificial intelligence (AI) technologies in the field of dentistry can create benefits such as increased accuracy and safer, more efficient care, but these benefits are naturally accompanied by risk. While dental professionals need to know how AI applications function, as well as how the law will assign liability for injuries that may arise from them, AI systems are still too new to have been challenged in dental professional liability lawsuits. Regulatory bodies like the Food and Drug Administration (FDA) are working to develop cohesive standards and compliance processes, but the advancement of AI technologies is exceeding regulatory bandwidth.

In the absence of legal precedent and regulatory guidance, ongoing review of potential risks and the proactive implementation of an adaptable risk management process can foster a strong defense against legal claims. This article discusses some foreseeable risks of using AI technologies in dentistry and suggests corresponding risk management strategies based on current information.

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Applications of AI in Dentistry

AI can be challenging to define with precision. In nontechnical terms, we can define AI as programs or machines performing tasks that once required human intelligence, such as problem-solving, reasoning, perceiving, learning, and exercising creativity.

From a dental perspective, applications of AI can be classified into diagnosis, decision making, treatment planning, and prediction of treatment outcomes. Applications are expected to improve the accuracy of dental diagnosis, provide visualization of anatomical guidelines during treatment, and, through the analysis of large amounts of data, predict the occurrence and prognosis of oral diseases. At present, the most popular application is diagnosis through the use of dental imaging, but AI applications can also enable dentists to easily access medical and dental history information necessary for personalized approaches to patients.

Unresolved Risks

With the prolific use of AI in dental imaging, we can no longer credibly question whether AI has a place in dentistry. But there are still many unresolved risks that dentists should consider when planning risk management strategies.

Blind Judgment — The Black Box Conundrum

Transparent and interpretable AI models that offer decisional rationales to a dental professional who proceeds to follow them should reduce the rate of malpractice actions. However, in many cases, AI clinical support technologies are "black box" AI models. This means the clinician can give the system input, such as an image, and the system can provide an output, such as a diagnosis, but the provider cannot see the rationale for the decision.

Black box AI creates a number of risks. Defending a provider's decision to follow or not follow an AI recommendation is difficult when the system offers no rationale to compare against the provider's judgment. The argument may be that the clinician's decisions were based on blind judgment. The absence of rationale can also complicate the informed consent process if the recommended treatment is informed by inexplicable AI output.

Regulators and thought leaders are attempting to correct this issue by requiring AI developers to incorporate transparency into the AI decision-making process, but until those regulations are established, the risk of patient injury due to incorrect AI recommendations remains.

Cybersecurity Risks

HIPAA and HITECH are part of the common vernacular in the healthcare space, but those laws contemplate data breach caused by human intelligence, not AI. In this age of advanced healthcare technology, most patient information is no longer stored and accessed in provider-controlled environments. AI-systems can create a complex flow of data that increases multiple-party use, storage, and access to electronic patient information. Multi-party access increases infrastructure vulnerability and opens dental practices to the risk of imputed liability for downstream breaches. Dentists should identify all parties with downstream access and use appropriate contractual provisions to minimize the risk of imputed liability for third-party breach.

Bias

Bias presents another risk of using AI technology in dentistry. There are several ways bias can be introduced by AI, including relying on under-representative data or nonrepresentative data. AI systems learn from the data on which they are trained and can incorporate biases from that data. For instance, if the data available for an AI application is primarily gathered from expensive wearables, the resulting AI systems will know less about patients from populations that cannot typically afford wearables. Treatment of those patients may be less effective or even harmful.

Litigation Risk

What AI means for dental malpractice risk still largely remains to be seen and will evolve as acceptance of AI grows. The standard of care and allocation of responsibility are not yet clear.

Dental Malpractice

To establish a *prima facie* case of liability in a malpractice action, a plaintiff must prove that the provider deviated from accepted standards of dental practice and that such deviation proximately caused injuries. Presently, there are no established standards directing when and how a provider's judgment should be based on the "intelligence" of a machine, or at what point dentists can or should "delegate" or defer to an AI recommendation.

> **In fact, the number of FDA-approved, AI-enabled medical devices has been growing over the past few years.[1]**

There are several diagnostic modalities where studies have shown that the AI system appears to outperform experienced physicians. In fact, the number of FDA-approved, AI-enabled medical devices has been growing over the past few years.[1] There are also an increasing number of AI clinical decision support technologies that make treatment recommendations. Some providers will utilize these AI technologies, while others will not. The question will be which decision meets the standard of care. At what point do positive results in preliminary studies or FDA approval make those technologies the standard of care? Will failure to use them constitute a breach of duty?

Vicarious Liability

Vicarious liability is a theory of imputed responsibility based on control and supervision. Professional entities can be held vicariously liable for the acts of their employees and affiliates. AI will introduce new complexity to the question of when a practice offering dental care can be vicariously liable for an injury caused by an individual provider's use or failure to use an AI technology. In many cases, the entity, rather than the dental clinician, will select, install, and provide training for the AI technology. As a result, the entity may be directly or vicariously liable for any faults, including a decision not to make the latest AI capabilities available, deficiencies in the installation, and failure to properly train staff on the AI system. The institutional owner of the AI system may also face liability for issues related to the proper care and maintenance of the AI equipment.

Regulatory Determinants of Malpractice

In addition to case law, the regulatory status of AI in dentistry will be an important determinant of malpractice risks. However, at present, providers have no cohesive regulatory framework to set parameters for the standard of care. The lack of regulatory oversight poses legal uncertainty for dentists when using AI applications.

The FDA is actively regulating AI technologies that fit into the definition of medical device, including imaging technologies used in dentistry, but those regulations provide no guidance on the use of AI technology defined as Clinical Decision Support (CDS). The FDA considers an AI technology as a medical device if it is intended to treat, diagnose, mitigate, or prevent disease or other conditions. CDS is software that supports or provides recommendations to a healthcare professional who independently reviews and makes the decision.

Efforts are underway to address this regulatory gap at the macro level. This includes the blueprint for an AI Bill of Rights published by the Biden administration in October 2022, and the white paper published by the American Dental Association Standards Committee on Dental Informatics in February 2023.[2] Providers can also look to emerging guidance from industry thought leaders, including the Coalition for Health AI (CHAI), which published

[1] A list of AI/ML-enabled medical devices legally marketed in the United States as of October 2022 is available on the FDA website at **https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices.**

[2] ADA SCDI White Paper No. 1106 for Dentistry — Overview of Artificial and Augmented Intelligence Uses in Dentistry

its first version of the Blueprint for Trustworthy AI Implementation Guidance and Assurance for Health Care in April 2023. The blueprint recognizes that uncritical acceptance of an automated clinical recommendation is a known safety risk. This recognition may support an injured patient's argument that failure to question an AI clinical recommendation is a departure from the standard of care. But that argument may flip in the future.

> **This recognition may support an injured patient's argument that failure to question an AI clinical recommendation is a departure from the standard of care.**

CHAI reported that its stakeholders are working to establish standards of AI output reliability. Once established, those reliability standards may flip the standard of care from critical review to unquestioned acceptance. Faced with this uncertainty, dentists should critically evaluate an AI recommendation and document their rationale for any rejection of an AI clinical recommendation. If a rejected recommendation may have injurious consequences for a broader patient population, reporting the issue to an appropriate in-house oversight committee will also be an important risk management strategy.

Risk Management Strategies

In the absence of a clear standard of care and with minimal regulatory oversight of emerging AI technologies in dentistry, dental professionals must consider potential outcomes and proactively implement adaptable AI technology risk management strategies.

Start Early

Risk management related to AI technologies should start at the procurement phase with a proactive team approach. The team should include a representative end user and the IT professionals who will scope the cybersecurity risk, analyze compatibility with existing infrastructure, and own responsibility for updates and maintenance.

The team should be clear about the end user's objectives for the AI technology and ensure the vendor discloses any use limitations and potential for data bias. Siloing information is a foreseeable risk of patient injury. Any vendor-disclosed limitations

should be communicated to end users. To address concerns regarding the ongoing accuracy of data, the team should also ensure that the technology is designed to maintain clinically relevant data acquired in a consistent manner.

Use the Contract to Allocate Risk

With the uncertainty over who will be liable for any patient injuries caused by the design and use of an AI application, use contractual warranties, indemnities, and liability limitations to allocate risk. Where applicable, the contract should require vendors to secure appropriate cybersecurity insurance to cover any indemnity obligations arising out of third-party access to the organization's IT infrastructure.

Given the risks and uncertainties, AI technology purchase agreements are often complex and usually one-sided. Professionals should not shy away from contract negotiation and may want to employ experienced legal counsel to, at least, review the agreement and provide guidance for negotiation. For example, the contract may or may not require the provider to notify the manufacturer before disclosing metadata in response to discovery demands in a legal malpractice action. It will be important to know whether this obligation exists and limit the obligation to the extent possible and ensure compliance.

Training and Use

Inadequate end-user training is a foreseeable risk and can result in vicarious liability. It will be important to require all dental professionals, including new hires, to engage in training activities and demonstrate competency before engaging in clinical use and to require ongoing educational programs at appropriate intervals.

Oversight and Monitoring

Evidence of a comprehensive oversight and monitoring process can be used in defense to show a good faith effort to ensure responsible use. To effectuate this process:

- Establish clear lines of operational control and unambiguous ownership of responsibility.
- Assign oversight responsibility to individuals who demonstrate appropriate expertise and experience.
- Develop comprehensive policies and procedures, including protocols for training and competencies, use of each application, updating and maintaining the technology, and communicating and addressing errors and unanticipated outcomes.
- Perform assessments to evaluate outputs on an ongoing basis.
- Remain alert for potential biases, peer review errors and unexpected outcomes. Continuously evaluate security vulnerabilities, and monitor timeliness of system maintenance and technology updates.
- Include AI-related issues in event reporting procedures.

Conclusion

The use of AI in dentistry is outpacing the law. There is no clear legal precedent or cohesive regulatory framework to guide a defensible approach to the use and implementation of these emerging technologies. In the absence of legal guidance, dental professionals should take a proactive approach to risk management, monitor the law on a consistent basis, and update policies and procedures as new legal precedent and regulations require.

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PATIENT SAFETY CHECKLIST #1

MANAGEMENT OF EQUIPMENT FOR PATIENT CARE

Many procedures are performed in the office setting using dentist-owned or leased equipment. Failure or malfunction of this equipment may lead to patient, staff, or dentist injury. The appropriate maintenance of equipment is essential to patient safety.

	YES	NO
1. A process is in place for the maintenance of equipment. The manufacturers' directions for use and the recommended preventative maintenance schedule are followed.	☐	☐
2. All patient care equipment is inspected on an annual basis at a minimum, or more often if recommended by the manufacturer.	☐	☐
3. A designated staff member confirms that all required inspections and preventative maintenance of equipment are performed at appropriate intervals.	☐	☐
4. A record of all maintenance activities is generated and retained.	☐	☐
5. Equipment is labeled with the inspection date, the initials of the inspector, and the date that the next inspection is due.	☐	☐
6. Relevant staff are properly trained in the use of equipment. Documentation of training and education is maintained in their personnel files.	☐	☐
7. The scope of practice of personnel/licensed staff is considered when they perform or assist in a procedure and/or use equipment.	☐	☐
8. A process is in place that requires the immediate removal of malfunctioning equipment from use in the practice. This process includes a provision to sequester any piece of equipment that may be directly involved in injury to a patient, staff, or dentist. MLMIC is promptly notified when an equipment-related patient injury occurs.	☐	☐

The attorneys at MLMIC Insurance Company's Legal Department are available to assist you in the proper management of equipment. Contact them in Syracuse at **(315) 428-1380**, Colonie at **(518) 786-2880**, and Long Island at **(516) 794-7340**, or call **(877) 426-9555** toll-free.

CASE STUDY:

The Unfortunate Results of **"Textbook Malpractice"**

Initial Treatment

A 56-year-old male presented to the dentist's office to address his smile. He completed his medical and dental history forms during the initial visit. He also signed consent forms for intended dental procedures, including films and bridgework. Although it is not documented, the dentist stated that he explained the risks, benefits, and alternatives to the proposed treatment to the patient. The examination revealed that the patient required extraction of seven teeth as well as crowns on his remaining 20 teeth. Impressions were made for temporary upper and lower bridges.

Over the next few months, the seven teeth were extracted. At each visit, a Z-pak was prescribed for the patient. Shortly thereafter, the dentist prepared for crowns on the remaining lower teeth (#20–#22, #24, and #26–#29). A temporary bridge was then cemented with acrylic, temporary cement, and permanent cement. Two weeks later, the bridge was re-cemented with permanent cement and temporary cement.

The upper arch was started four months after the patient's initial visit, with crown preparation and a temporary bridge for teeth #2–#6, which was cemented with acrylic and temporary cement. The

temporary bridge for teeth #7–#13 was cemented a month later with acrylic and temporary cement. One month later, this temporary bridge had to be re-cemented. The dentist then took impressions for the permanent upper and lower bridges.

Later Treatment

Permanent bridgework was cemented. However, over the following eight months, the patient was seen multiple times for the try-ins and re-cementing of the upper and lower bridges. Over the next three years, the patient sporadically returned to the dentist for annual cleanings. During the following two years, the patient saw the dentist for inflamed gums, re-cementation of the bridge, and various adjustments. The patient also received several prescriptions for a Z-pak.

> During this hospitalization, the insured was advised that the source of his endocarditis was likely the patient's dental work.

Ultimately, the patient had extractions of two more teeth (#7 & #13), and he underwent RCT to teeth #6, #10, and #11. This occurred over five visits spanning two months. Ten days after posts were inserted, the dentist was advised that the patient missed his appointment due to hospitalization for a heart infection. During this hospitalization, the insured was advised that the source of his endocarditis was likely the patient's dental work. He was also simultaneously diagnosed with diabetes mellitus. This was the last contact the dentist had with the patient.

New Dentists Seen and Lawsuit Filed

After the patient was discharged from the hospital, he went to a new general dentist who observed decay throughout his mouth, noting that nothing was salvageable in the maxilla. The patient was referred to an oral surgeon but could not afford to get the recommended treatment, which consisted of removal of his remaining teeth with bone surgery.

The patient sought a second opinion from another dentist, who agreed that his teeth were infected, rotten, and decayed down to black and yellow nubs. He documented this with photographs. This dentist ultimately extracted 14 teeth in total and inserted eight implants in the upper arch and six in the lower to support the dentures.

As a result, the patient filed a lawsuit against the original dentist. He alleged that the defendant dentist did not perform sufficient examinations of his teeth nor take films over an eight-year period. This resulted in rampant decay, RCTs, infection, and endocarditis, which necessitated his hospitalization and treatment with IV antibiotics.

Expert Review

Our expert reviewed the original dentist's care and noted that his treatment was "textbook malpractice in every possible way". The records contained sparse documentation and insufficient films, and there was absence of periodontal charting. Extractions were performed with insufficient films, and there was no documentation of recommendations for frequent cleanings or home care.

> The records contained sparse documentation and insufficient films, and there was absence of periodontal charting.

Documentation did not include informed consent for the RCTs or any other treatment after the initial consent form was signed during the patient's first visit. A rubber dam was not utilized during the RCTs, nor were measurement films taken. It did not matter that the RCTs appeared to look clinically acceptable since the teeth were decayed to, or below, the gum line. Additionally, the bridges never fit properly as evidenced by the repeated need to re-cement them.

Settlement

This case was reviewed by the District Claim Committee. It focused on the dentist's lack of informed consent documents and the very poor documentation in general of the care he rendered. The Committee concurred with many of the issues outlined by the expert. There was criticism of the films and the dentist's failure to obtain a full mouth series. Had the films shown that the bridges fit well and the dental record contained better documentation and an updated medical history, the dentist would have been able to point to, and back up, an alternative explanation for the breakdown.

Unfortunately, this dentist never personally documented the chart, it was done solely by his assistant. All the chart entries were handwritten and difficult to read. The dentist did not perform well at his deposition since he was unable to fill in the blanks of his very sparse dental record. As a result, the Committee felt that the case should be settled.

The demand from the plaintiff was $650,000, and the case was ultimately settled for $290,000.

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MLMIC Introduces **New Dental Premium Pricing Plan**

Effective December 1, 2023, MLMIC Insurance Company will offer dentists and oral surgeons a unique premium pricing plan that enables them to have their policy reflect their individual practice characteristics.

"With this new premium modification plan, MLMIC is in a great position to offer dentists affordable coverage, specifically tailored to their particular, unique practice," said Nicole Lombardo, MLMIC Insurance Company senior underwriting manager.

The new rating plan for dentists includes a 5% discount for NYSDA members and combines MLMIC's current discount offerings, including Risk Management course completion and waiver of consent. This new plan does not apply to new graduates or new to practice insureds.

MLMIC policies renewing on or after December 1, 2023, will be eligible for the new rating plan. New policies with an effective date on or after December 1, 2023, will be eligible as well. Contact MLMIC via the email or phone number below if you have not received the application update email 60 days prior to your renewal date.

You can email dental@mlmic.com or call (800) 416-1241 with any questions.

FROM THE BLOG

Disposing of Paper Dental Records and Imaging: Best Practices for Dentists

While many dentists have already completely embraced the electronic dental record, some practices still need to dispose of paper records and imaging. The following is some general information to consider when destroying paper dental records and imaging.

Regulatory Requirements for Retaining Dental Records

The **New York State Department of Health** requires that dental professionals **retain dental records and imaging** ("records") of adult patients for six years. Records for minor patients must be maintained for at least six years and for one year after the minor patient reaches the age of 21, whichever is longer. It is, however, recommended that dental records be retained for 10 years from the date of receipt of the last claim for payment.

READ MORE >

Evidence-Based Clinical Guidelines for Acute Dental Pain in Children

A panel assembled by the **American Dental Association Council on Scientific Affairs**, the **American Dental Association Science and Research Institute**, the **University of Pittsburgh School of Dental Medicine**, and the **Center for Integrative Global Oral Health at the University of Pennsylvania** developed seven recommendations and five good practice statements after a review to determine the effect of pain medication on managing acute dental pain in children. The systemic review and guidelines were published in the **Journal of the American Dental Association** for dentists to follow. Dentists should take some time to review these guidelines and modify their prescription of pain medication to children as needed.

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Check out the 2023–2024 NYSDA Member Benefits Guide for a comprehensive list of all the benefits and resources available exclusively to NYSDA members!

NYSDA offers many services specifically tailored for dentists in New York, such as:

- Legal Protection Plan
- Continuing Education
- Peer Review
- Substance Abuse Support Services
- Practice Resources
- Contract Analysis
- Our Scientific Research Journal... and more

View NYSDA's Member Benefits Guide today.

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