

A Message from the President

I can hardly believe that I'm already two-thirds through my tenure as president. It has been very rewarding for me to work with this talented board to provide this newsletter and our educational conferences to our members.

You may have noticed a shift in our conference venues this year. We have been very cognizant of the national economic crisis and the potential impact on this organization. By using venues such as Beth Israel Medical Center, Mt. Sinai Medical Center and St. Vincent's Manhattan Center we have been able to offer our members high quality conferences at convenient and comfortable Manhattan locations at a minimum cost to the organization.

Our first three conferences this year were well attended and the feedback from our attendees very positive. On February 10th, a half-day conference was dedicated to mental health and the law. We were fortunate to have r-L Solutions sponsor the breakfast that was provided at the conference.

This spring we are offering two full-day conferences. Our April 7th conference on "Crucial Conversations in Healthcare: Advancing Patient Safety and Avoiding Adverse Events" is co-sponsored by AIG Healthcare and the National Patient Safety Foundation. We are very excited about this partnership, and the ability to offer this conference to our members free of charge.

Grace R. Langan, R.N.

President

In This Issue

2	Defense of Record Keeping Issues for Mental Health Care Professionals in New York: "The Ugly, The Bad and The Good"	16	Risky Business: "When Common Sense is Uncommon"
6	Stemming The Tide of Waterborne Healthcare-Associated Infection Risk	20	Best Practices: Risk Management for Assisted Living Facilities
11	Update on Education – Highlights from Fall 2008 Conference	23	Editor's Corner
12	Malpractice? Says Who? Setting the Standard of Care in an Era of Practice Guidelines	24	AHRMNY Officer and Directors
15	Save-The-Date ▪ Announcements		

DEFENSE OF RECORD KEEPING ISSUES FOR MENTAL HEALTH CARE PROFESSIONALS IN NEW YORK: "THE UGLY, THE BAD AND THE GOOD"

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The defense of professional malpractice claims against mental health care professionals becomes infinitely more difficult when there is little or no documentation reflecting the treatment rendered. While several statutes require documentation of treatment of mental health care patients in New York, they do not set forth specific requirements for what must be contained in patient charts.

Serious consequences exist for failure to maintain records including civil lawsuits and/or license impairment proceedings. The difficult task of balancing a comprehensive but efficient and compensable clinical practice often conflicts with good record keeping practices for many practitioners. Mental health care professionals including psychiatrists, psychologists and social workers are well advised to be aware of the statutes concerning record keeping as well as the cases that interpret them along with the national guidelines concerning ethical codes of conduct to guide them in their practice. Our experience in defending these matters tells us that the defense of even the most well intentioned and planned treatment may be doomed without support of records sufficiently documenting the care rendered. Further the State licensing boards also are very unforgiving in regard to the failure to keep records. The failure to do so will inevitably lead to some type of license sanction.

The Statutes:

The practice of psychiatry in New York State is governed by Education Law Article 131 (Sec. 6520, et seq.) which regulates all areas of medical practice and provides general provisions for conduct of certain licensed medical professionals. More specifically, Sec. 6530 (32) indicates that a finding of professional misconduct for physicians can be supported for: "Failing to maintain a record for each patient which accurately reflects the evaluation and treatment of the patient, ..." ¹ This same section requires that the records must be retained for at least six years and for minor patients six years, and until one year after the minor patient reaches the age of eighteen years.

Psychologists are licensed and governed by Education Law Article 153 which simply indicates that only a person licensed under the provisions of the statute can use the title "psychologist". ² The subsequent sections set up the State Board for Psychology and Requirements for a Professional License. ³ These sections of the statute, however, are

conspicuously silent as to any specific requirements concerning the type or content of records to be generated for patient care. The New York Compilation of Codes, Rules and Regulations (NYCRR) applies the same language found in the Education Law, as referenced above, that applies to psychiatrists and applies it to other health care professionals including those engaged in the professions of psychoanalysis and psychology. ⁴

While these statutes require that records be kept, there is no reference as to what information must be contained. Likewise, a sampling of cases involving disciplinary matters highlights the pitfalls of poor record keeping practices but does not provide much insight as to what treatment records should contain. Oftentimes, the context of the treatment and type of intervention being rendered will dictate the content of the record to be generated that accurately reflects the care. Insurance information, billing information and telephone records are by no means adequate to convey information regarding care and treatment rendered but, surprisingly, are very often relied upon as the only measure of patient records.

The Ugly: No records

Findings of professional misconduct and the revocation or suspension of a professional license are most common in instances where practitioners have kept no records at all for treatment rendered. The following matter details the worst case scenario for a practitioner who did not maintain any records.

For example, in Camperlengo v. Barell, 78 N.Y.2d 674, 578 N.Y.S.2d 504 (1991), New York's highest Court held that the prior determination of the Department of Social Services (DSS) that a psychiatrist had failed to maintain proper records for his Medicaid patients in violation of DSS regulations was proper predicate for the Commissioner of Education to suspend the psychiatrist's license to practice medicine pursuant to an expedited proceeding.

In Camperlengo, the petitioner, a psychiatrist licensed to practice medicine, was found guilty of professional misconduct and his license was suspended for five years, four of which was suspended while he was on probation, and ordered to perform 100 hours of community service. ⁵ The Respondent, Commissioner of Education, made the above determination following an expedited hearing before the Regents Review

¹ See Education Law Article 130 Sec. 6530(32)

² See Education Law Article 153 Sec. 7600, et seq.

³ See Education Law Article 153 Secs. 7602 and 7603

⁴ See 8 NYCRR 29.2[a]

⁵ Camperlengo v. Barell, 578 N.Y.S.2d 505 (1991).

Committee (RRC) limited to evidence relevant to the penalty to be imposed based on the prior finding by the DSS in an unrelated proceeding that found petitioner was guilty of failing to maintain proper records for his Medicaid patients in violation of DSS regulations.⁶ Petitioner commenced an Article 78 proceeding claiming that under the Education Law Sec. 6509(9), respondents could not suspend his license in an expedited procedure based on the DSS determination but had to afford him a full hearing based on the regulations of the Department of Education.⁷

The Court of Appeals in Camperlengo held that the Education Law Sec. 6509(9), incorporated into the statutory provision “unprofessional conduct” as defined by the Board of Regents Rules and included the failure to “maintain a record for each patient which accurately reflects the evaluation and treatment of the patient”.⁸ The Court of Appeals also upheld the RRC’s finding that petitioner violated its rules on record keeping as petitioner had failed to keep records for at least 14 of his patients and that these failures constituted a violation of the DSS record keeping regulation that required him to maintain a record for each patient which “fully disclosed the extent of the care, services or supplies furnished”.⁹ The Court of Appeals held that the RRC correctly concluded that if petitioner failed to keep any record as required by the DSS’s regulations then he necessarily failed to keep any records which “accurately reflect the evaluation and treatment of the patients” per the Department of Education’s record keeping provision.¹⁰

The Bad: Insufficient records

Simply put, the successful defense of professional malpractice matters for mental health care professionals is directly related both to the quantity and, oftentimes more importantly, the quality of patient records. Indeed, as the next group of cases demonstrates, the fact that some records are kept does not at all guarantee a good defense in the litigation of these matters.

In Matter of Sulsoovich v. New York Education Department, 174 A.D.2d 802, 571 N.Y.S.2d 123 (3rd Dept 1991) the petitioner psychologist agreed to provide one of his patients, JBW, with ten psychotherapy sessions. After attending the first five sessions JBW notified the petitioner that he would be unable to attend the remainder.¹¹ The petitioner submitted claims to JBW’s insurer for all ten sessions and then the insurer notified the Office of Professional Discipline of the Respondent Department of Education, that petitioner had filed a claim for services not rendered and charges were then lodged against petitioner for his treatment of JBW.¹² Petitioner was found guilty

of two counts of the statement of charges for unprofessional conduct for failing to maintain records and practicing the profession negligently on more than one occasion.¹³ The petitioner commenced the proceeding urging his records were adequate, that he did not bill excessively and that the sanction was excessive.¹⁴

The Appellate Court in Sulsoovich found that the only records petitioner had were “kept in his head” and a copy of the insurance form submitted with the bill.¹⁵ The form indicated a “Personality Disorder—Depression and Anxiety” diagnosis, “Psychotherapy” treatment, and the dates of the scheduled sessions; no other information was provided.¹⁶ The Appellate Court found that there was “ample evidence that petitioner failed to maintain adequate medical records with respect to JBW.”¹⁷ It further held that the purpose behind the requirement that a proper record be kept for each patient is in part to ensure that meaningful information is recorded in case the patient should transfer to another professional or the treating practitioner should become unavailable.¹⁸ The Court in Sulsoovich upheld the Board of Regents finding indicating that “(e)ven assuming that the petitioner intended the form to serve as the patient’s medical record—which is highly doubtful, the sparse data contained therein does not meet the meaningful information standard”.¹⁹

In Matter of Gross v. New York State Department of Health, 277 A.D.2d 825, 716 N.Y.S.2d 780 (3rd Dept 2000), the petitioner, a psychiatrist, appealed the revocation of her license by the State Board of Professional Medical Conduct (BPMC). The BPMC served petitioner with a notice of hearing and statement of charges detailing six specifications including failure to maintain records. The charges stemmed from the petitioner’s treatment of six patients for whom she had failed to conduct adequate diagnostic assessments and formulate treatment plans.²⁰

During the hearing, the BPMC presented testimony of an expert who opined that the records reviewed for each an every patient failed to detail a formulated treatment plan as well as a diagnosis and later justification for the over-prescription of medication.²¹ The expert also opined that the pharmacologic aspects of these patients’ management posed a serious risk, without proper justification, since petitioner repeatedly failed to integrate their previous histories.²² Also during the hearing, petitioner acknowledged her repeated deficiencies in recordkeeping and testified that she failed to recognize that their

⁶ Id.

⁷ Id.

⁸ Id., citing 8 NYCRR 29.2[a][3].

⁹ Id., at 506 citing 18 NYCRR former 515 [b][11].

¹⁰ Id.

¹¹ Matter of Sulsoovich v. New York Education Department, 174 A.D.2d 802, (3rd Dept 1991).

¹² Id.

¹³ Id., at 503

¹⁴ Id.

¹⁵ Id.

¹⁶ Id.

¹⁷ Id.

¹⁸ Id. citing 8 NYCRR 29.2[a][3], Matter of Schwartz v Board of Regents, 89 A.D.2d 711, 712 *lv denied* 57 N.Y.2d 604; See Matter of Revici v Commissioner of Educ. Of State of N.Y., 154 A.D.2d 797, 799-800

¹⁹ Id.

²⁰ Matter of Gross v. New York State Department of Health, 716 N.Y.S.2d 781 (3rd Dept 2000)

²¹ Id.

²² Id.

purpose was to inform other professionals of the nature of the condition or care provided.²³ She testified that she believed that they were solely for her professional use. Petitioner detailed her thought process therapeutic approaches, and efforts to seek opinions of other physicians but that she repeatedly failed to document this information.

The BPMC found that the petitioner maintained inadequate records “that lacked patient diagnoses and treatment plans justifying the medications prescribed”.²⁴ The Appellate Court agreed that the expert’s undisputed testimony concerning the inadequacy of petitioner’s records did not merit further review of the BPMC’s finding.²⁵ The Appellate court also found, however, that license revocation was too drastic under the circumstances given petitioner’s long history of successful treatment of difficult patients, voluntary surrender of her license, modification of her record keeping practices and attendance at courses to address other deficiencies.²⁶

The Good: Professional Guidelines

Whereas the statutes and case law concerning the worst case scenarios are informative, guidelines promulgated by national professional organizations offer perhaps the best insight as to good record keeping practices which would likely serve to protect against poor outcomes during civil litigation and licensing proceedings.

For example, the American Psychological Association’s “Record Keeping Guidelines” provide psychologists “with a general framework for considering appropriate courses of action or practice in relation to record keeping.”²⁷ The APA’s Board of Professional Affairs set up its Committee on Professional Practice and Standards (COPPS) to “examine the possible usefulness of guidelines on record keeping for psychologists.”²⁸ Interviews of psychologists were done to determine the best means of addressing the “vague” and “varied” state regulations of several state jurisdictions which purportedly governed record keeping for psychologists.²⁹ According to the APA, the “Record Keeping Guidelines” are just that, guidelines “intended to facilitate the continued systematic development of the profession and to help facilitate the high level of practice by psychologists”.³⁰

The Guidelines include all aspects of record keeping from the method of their retention to the substantive content contained therein. More specifically, the Guidelines contain information for the practitioner concerning the “rationale” and “application” for each specific aspect of record keeping. The

APA included “rationale” and “application” information for each of the following thirteen specific areas concerning record keeping: Responsibility for Records, Content of Records, Confidentiality of Records, Disclosure of Record Keeping Procedures, Maintenance of Records, Security, Retention, Preserving the Context, Electronic Records, Record Keeping in Organizational settings, Multiple Client Records, Financial Records, and Disposition of Records.³¹

The American Medical Association publishes a reference guide concerning documentation for Psychiatrists: Current Procedural Terminology (CPT) Handbook for Psychiatrists.³² This Handbook was first created in 1966 to provide a “uniform language for describing medical and surgical procedures and diagnostic services that would facilitate more effective communication between clinicians, insurers and patients.”³³ According to the CPT Handbook, the rationale for accurate understandable patient documentation is to provide continuing care.³⁴ According to the Handbook, other important considerations include that “documentation is good medicine.”³⁵ The Handbook points out that recording the when, what and why of services provided is “an intrinsic component of good care”.³⁶ Other benefits of good documentation include that it serves as the basis for selecting accurate procedural codes, protects against audits and protects against malpractice suits.³⁷

The *CPT Handbook* also sets forth the AMA’s documentation principles.³⁸ These principles contain specific information concerning what patient records should contain. According to the AMA’s documentation principles, the records should be complete and legible and contain documentation for each patient encounter including the date, reason for the encounter, history and results of physical, review of labs, x-ray data, if appropriate assessment, plan of care and discharge plan if appropriate.³⁹ The AMA’s documentation principles also indicate that the records should also contain other information including but not limited to past and present diagnoses, reasons for diagnostic studies, relevant risk factors, the patients progress etc.⁴⁰

The CPT Handbook points out very valid and oftentimes competing considerations for clinicians concerning documentation:

The reality is that clinicians must meet community standards of documentation for the clinical needs of their patients and at the same time must meet the administrative documentation requirements of insurers in order to be appropriately reimbursed and remain in compliance with regulatory and institutional requirements.⁴¹

³¹ Id., at 995-1002.

³² Schmidt, C.W., Yowell, R.K., Jaffe, E. CPT Handbook for Psychiatrists, American Psychiatric Publishing, Inc., 2004

³³ Id., at 1

³⁴ Id., at 5

³⁵ Id.

³⁶ Id.

³⁷ Id.

³⁸ The AMA first established documentation principles in 1992.

³⁹ Id at 6

⁴⁰ Id

⁴¹ Id at 7

²³ Id.

²⁴ Id., at 782.

²⁵ Id.

²⁶ Id., at 783.

²⁷ American Psychological Association, (2007) Record Keeping Guidelines, *American Psychologist* 62(9) 993-1004 December 2007.

²⁸ Id at 994.

²⁹ Id. The process of revision and editing the Guidelines was completed and approved on February 16, 2007.

³⁰ Id., at 993.

The CPT Handbook also points out hard fact that militates against good record keeping which is that physicians are reimbursed very little for the “non-face-to-face work of medical record creation and maintenance.”⁴²

Conclusions and Recommendations

While it may appear patently obvious that the failure to maintain patient records will likely guarantee failure in defending civil claims and professional misconduct actions, it has been our experience that many psychiatrists and psychologists engaging in particular forms of treatment are quite averse to note taking. This includes documentation for everything from medication prescriptions and billing to clinical encounters.

With regard to note taking concerning substantive patient encounters we have been advised by some of our clients that certain forms of therapy are not easily or accurately recorded. For example, practitioners engaged in Freudian or similar regression type psychoanalysis have argued to us that any note taking during regression therapy prevents the analyst from following the particular patient’s thought process closely. We have observed that even those practitioners with extensive training, experience and expertise are very hesitant to begin taking notes even after a particular psychoanalysis session has been completed.

We also understand from our clients that effective time management, reimbursement rates and economic considerations of their practice often compete with time available for appropriate record keeping. Our clients frequently argue that they have difficulty allotting time to document more than a few lines before their next patient appointment is scheduled to commence.

However, all the above complaints and excuses are not valid or sufficient arguments to counter the clear dictate that good records must be kept and maintained. Not only do good records with sufficient detail make the defense of these cases that much easier and possible, but good record keeping is important and necessary for practitioners for the benefit of their patients and themselves. Often our clients will complain to us about why record keeping is difficult for them but the critical issue is that detailed and personal facts and experiences are related by patients over weeks, months and even years need to be recorded in some fashion in professional notes. Sometimes patients have months or years of gaps in treatment and records are thus even more important when given patients resume treatment after a hiatus. Record keeping is essential for the continuity of a given patient’s care but also is important for patients that may need or seek care from other providers who would like to then gain access to these records to better treat the patient. Many patients who seek therapy over several years will for various reasons switch therapists. It can be very

helpful to subsequent providers to review and see prior records to help them in evaluating a patient. This also holds true for patients who may have to be hospitalized. The hospital may want to see records to assist them in trying to best treat a patient. The reasons are thus myriad why chronological records are necessary. Although we have been impressed by the recall abilities of our clients who can frequently remember in detail given patients and their histories over time, it boggles the mind to think that a busy mental health provider over the course of many years can keep all the key facts of many patients in their heads at once. Also in the event of the death or disability of the provider this information could be lost forever. This is a disservice to the patient.

Moreover, although it can be argued that mental health records frequently contain very personal information that patients want kept confidential, this does not relieve the provider of the duty to keep records. We have had providers tell us that paranoid patients have asked them not to take notes in case those notes fall into the wrong hands. The failure to take notes based on this request, although well intentioned, again is something that the provider cannot do. A provider must tell his new patients that they are required to take notes and do so. We have been before the licensing board on many occasions where the above excuse was offered in preparatory sessions in an effort to explain why notes were not taken. We have counseled providers to not make too much of this an excuse as it will not receive a good reception before the state boards. The licensing boards do not have much sympathy for these arguments and will still proceed to sanction a provider for failure to keep records.

Unfortunately, our experience in the defense of these matters tells us that even the best trained, well intentioned practitioners often fall victim to documentation issues. Practitioners are well advised to review the state regulations and their particular professional guidelines concerning record keeping to construct record keeping practices that better serve their clients and also protect them against license impairment and civil litigation.

Brief Bio Sketches

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⁴² Id

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In the wake of what has been described as one of the deadliest outbreaks of Legionnaires' Disease (LD) ever reported, one of the 127 recognized victims, which included patients, employees, and visitors initiated a \$600 million class-action lawsuit against the nursing facility at the center of the storm.¹ A 2006 LD outbreak at an acute care facility, which also killed and injured both patients and visitors alike, resulted in a \$5.2 million settlement.² Yet another institution, a renowned university teaching hospital, has for years been plagued by repeated lawsuits related to LD contracted from its water system.^{3,4} However, according to experts, healthcare-associated LD nationwide is simply not that unusual.⁵

According to the U.S. Centers for Disease Control and Prevention (CDC), an estimated 8,000-18,000 cases of LD occur each year in the United States. This is particularly striking as the agency also notes that only a fraction of LD cases are reported. Although LD is a reportable condition in most states, because of under-diagnosis and under-reporting only 2%-10% of estimated cases are actually reported. Most LD cases are sporadic; 23% are healthcare-associated (nosocomial) and 10%-20% can be linked to outbreaks. Death occurs in 10%-15% of LD cases, and a substantially higher proportion of fatal cases occur during nosocomial outbreaks. Disease is often attributed to inhalation of contaminated aerosols from showers and faucets, as well as aspiration of contaminated water. Nevertheless, in normal hosts, bacterial exposures from such water sources are typically cleared by innate defenses, such as the respiratory tract's mucociliary escalator for elimination of inhaled organisms.⁶ However, immunocompromised individuals such as recipients of bone marrow and solid organ transplants, persons with congenital or acquired immunodeficiency syndromes, oncology and burn patients, critically ill patients in intensive care units, smokers, individuals with chronic cardiac and respiratory disorders, and residents of skilled nursing facilities are likely to be at higher risk from LD and infections with other waterborne pathogens (WBP). It is precisely for such patients that appropriate infection control measures are most important.

Since the causative bacterium, *Legionella pneumophila* will not grow in routinely utilized laboratory culture media, LD has been remarkably under-diagnosed. Nevertheless, urinary antigen, direct fluorescent antibody, and culture-based testing for LD have been available to and utilized by clinicians for many years, and enhanced detection methods such as rapid duplex

polymerase chain reaction (PCR) testing have been more recently developed. Despite the likelihood of under-diagnosis, Medicare data presented in the Federal Register indicate that for fiscal year 2007, 351 cases of LD were diagnosed in beneficiaries at a cost of \$86,014 per hospital stay. Thus, the savings for prevention of LD in Medicare beneficiaries alone would be estimated to be over \$30 million per year, substantially higher than for other health care-associated conditions (e.g. air embolism, blood incompatibility, and surgical site infection after coronary artery bypass grafting) recently selected by the Centers for Medicare and Medicaid Services (CMS) in its 2008 Final Rule for exclusion from additional hospital reimbursement. Acknowledging these data, CMS is continuing to consider healthcare-associated LD and infections attributable to other waterborne pathogens in its subsequent rulemaking.⁷

Indeed, while LD outbreaks in healthcare facilities often command headlines, clinicians struggle with other bacterial WBP, such as *Pseudomonas aeruginosa*, *Stenotrophomonas maltophilia*, *Acinetobacter spp.*, and fungal WBP such as *Aspergillus spp.*, among many others on a daily basis in their hospitalized patients. In fact, some of the most frequently isolated Gram-negative bacteria have been found to persist in hospital water for extended periods and have been responsible for nosocomial outbreaks.⁸ A recent review of prospective studies published between 1998 and 2005 indicated that between 9.7% and 68.1% of random intensive care unit water samples were positive for *P. aeruginosa*, and between 14.2% and 50% of patient infections with this organism were due to genotypes found in intensive care unit water.⁹

According to the CDC, the overall incidence of *P. aeruginosa* infections alone in U.S. hospitals averages about 0.4 percent (4 per 1000 discharges), and the bacterium is the fourth most commonly-isolated nosocomial pathogen, accounting for 10.1 % of all hospital-associated infections.¹⁰ In fact, up to 42% of *P. aeruginosa* infections in hospitalized patients have been linked to water;^{11,12} and one investigation has estimated that 1,400 deaths occur each year as a result of waterborne nosocomial pneumonias attributable to *P. aeruginosa* alone.⁸

All of these infections result in huge costs to our healthcare system, as well as a tremendous human toll in excess morbidity and mortality. Moreover, numerous clinical studies published in peer-reviewed medical

literature demonstrate the clinical efficacy and cost-effectiveness of regular water testing, appropriate systemic water disinfection, and point-of-use (POU) hospital water filtration as strategies for reducing infections with Legionella and other WBP in hospitals.¹³ CDC, the World Health Organization (WHO), the Occupational Safety and Health Administration (OSHA), the Veterans Health Administration (VHA), and other recognized standards organizations have established guidelines for the prevention of LD and other WBP that have been available and widely distributed for years.^{14,15,16,17,18,19,20,21} Yet, tragically, many healthcare facilities remain unaware of these issues, exposing patients and their institutions to unnecessary risk.

Hospital Tap Water: An Under-Recognized Reservoir of Risk

Although hospital tap water has been justifiably accepted as perhaps our most reliable weapon in the battle to reduce healthcare-associated infection (HAI), it has also gradually become recognized as the source of a number of these infections. Yet, despite concerns regarding the increasing incidence of serious HAI due to multi-drug resistant Gram-negative pathogens, the risk of waterborne transmission of these microbes has received relatively little attention. Dr. Bruce Dixon, Director of the Allegheny County Health Department, has summed up the problem succinctly, "If you don't look for it, you won't find it. If you don't find it, you don't think you have a problem. If you don't think you have a problem, you don't do anything about it."²²

However, even when healthcare facilities do look for WBP, a better understanding of their ecology in the healthcare environment is necessary in order to gain further insight as to why this risk may go largely unrecognized. Waterborne microbes thrive to varying degrees in both hot and cold water. Yet, whereas cold water is delivered directly to the POU (e.g. taps, showers), hot water in large buildings such as hospitals is supplied via a recirculation loop, which contains organic and inorganic nutrients to nourish waterborne microbes, maintains favorable temperatures for microbial growth, and promotes the formation of biofilm on internal surfaces of pipes and fixtures. Waterborne microbes may be shed from biofilm unpredictably and intermittently, complicating efforts at detection. Moreover, WBP, adapted to life in a relatively nutrient-poor environment, may be difficult to culture using nutrient-rich growth media for short incubation periods (e.g. 24-48 hours at 37°C), as is standard practice for the culturing of specimens obtained from patients by clinical microbiology laboratories. Successful culturing of Legionella and other WBP may require special media and extended incubation periods at lower temperatures (e.g. 25°C for 14-28 days).

Biofilm: Giving Hospitals the Slip

Ubiquitous in hospital plumbing as in nature, biofilm may be recognized as the slippery material on the surfaces of stones that one may feel between one's toes when wading barefoot in a body of water. Scientists define biofilm as a microbially-derived sessile community characterized by cells that are irreversibly attached to a substratum or to one other, are embedded in a matrix of extracellular polymeric substances that they have produced, and exhibit altered characteristics with respect to growth rate and gene transcription.²³ Biofilm affords microbial pathogens protection from adverse environmental conditions outside the host;²⁴ and it has been established that biofilm bacteria display a higher level of resistance to antimicrobial agents^{25,26,27,28,29} and environmental controls (e.g. ultraviolet light, metals, and acid pH)^{30,31,32} than do planktonic (free-floating) bacteria. Interestingly, for clinically important organisms such as *P. aeruginosa*, a single genetic locus has been identified to be associated with both the ability to form biofilm and antimicrobial resistance.³³

The ability to form and maintain biofilm communities for protection from adverse environmental conditions has permitted WBP to survive, thrive, and to evolve further mechanisms for resistance to outside threats across millennia. Thus, our difficulties in detecting and eradicating these organisms by means of altering environmental conditions in our water distribution systems should come as no surprise.

Stemming the Tide: Available Technologies for Risk Reduction

Methods used to protect patients and water systems must adequately address biofilm in order to be effective. Eight major preventive strategies have been employed, usually in response to an outbreak. They include: hot water flushing of the plumbing system, chlorination, chlorine dioxide, monochloramine

(used exclusively at the municipal treatment level in the U.S.), copper-silver ionization, ultraviolet light (UV), ozonation, and point-of-use (POU) water filtration. Each method has advantages and disadvantages related to ease of implementation, cost, maintenance issues, and short- and long-term effectiveness. Aside from POU filtration, these methods are often incompletely effective in the long-term for several reasons. Maintenance of systemic disinfection agents at concentration levels that would consistently prevent biofilm establishment and proliferation is difficult. In addition, seasonal variability in water quality, facility construction and renovation activities constantly challenge systemic disinfection methodologies beyond their capabilities. Finally, the innate structure of biofilm effectively protects microbes harbored within its protective matrix against the harsh effects of systemic disinfection strategies.

Of these preventive methods, flushing all parts of the plumbing system at temperatures of greater than 65°C is perhaps the easiest to implement, but precludes the use of water outlets during the procedure, occupies substantial facility management resources, may cost on the order of \$20,000 per episode, and presents a risk of scalding. Recent data corroborate earlier observations that hot water flushing is inadequate in eliminating *Legionella* from plumbing systems over the longer term,³⁴ even though temperatures above 59°C were associated with an inability to culture *Legionella*.^{35,36} One study disclosed that a system flush using hot water at 80°C was incapable of eradicating *Legionella* serogroup 5.³⁷ In fact, one published observation documented the presence of a persistent strain of *Legionella* in a hospital over the course of 15 years.³⁸ Hyperchlorination was added to the hot water flushing, and *Legionella* was still recovered from showers, prompting the disconnection of central water supply lines and the use of electrical hot water heaters for showers. This finally resulted in a substantial reduction in recoverable *Legionella* without clinical incident.³⁹

Chlorination is also relatively simple to establish. However, it can be challenging to maintain adequate levels of chlorine throughout a hospital water system. Electrolytic chlorine generation systems in large scale studies appear to be no better than sodium hypochlorite (also known as bleach).⁴⁰ However, chlorination is not free of potential byproduct-associated genotoxicity, which is an emerging concern.⁴¹ Bench-scale chlorination compared with UV irradiation showed that both methods were effective in reducing the bioburden of indicator organisms. However, pathogens of clinical concern were less affected by chlorination.⁴²

Data continue to be accumulated suggesting that waterborne pathogens are protected against chlorination by biofilm.^{43,44} These findings suggest that chlorination may be less effective than other alternatives, despite its relative cost efficiencies.

Chlorine dioxide effectively reduces, but may not eliminate *Legionella*.^{44,45} Testing of multiple disinfection strategies has indicated that chlorine dioxide may be the most effective systemic disinfection regimen for the control of *Legionella*.⁴⁴ In simulated potable water system testing, chlorine dioxide was shown to be more effective in reducing heterotrophic bacterial counts, with reduced levels of some but not all organic halogenated byproducts.⁴⁶ However, chlorine dioxide systems remain more costly to install than chlorination.

Efficacy studies of chloramines alone or in combination with free chlorine indicate that neither alone is complete as a disinfectant.⁴⁷ In addition, the spectrum of potentially harmful halogenated byproducts left by combination chlorination regimens⁴⁸ will take some time to assess. Chlorine and

chloramines also differ in their spectrum of antimicrobial activity. For example, *Klebsiella pneumoniae* appears to be more sensitive to chloramines than to free chlorine under certain conditions.⁴⁹

Studies of copper-silver ionization used either alone or in combination with other systemic disinfection strategies have been recently reviewed, and these studies have found this technology to be effective to varying degrees.⁵⁰ However, this technology was also demonstrated to be more effective when used in combination with another disinfection technology. More importantly, none of these studies was able to demonstrate sustained eradication of *Legionella*. From a practical perspective, however, an *in vitro* study of copper and silver ions alone and in combination provided evidence of bactericidal activity of greater than 99.999% against the clinically relevant WBP (e.g. *P. aeruginosa*, *A. baumannii*, and *S. maltophilia*, in addition to *Legionella*).^{51,52}

UV irradiation, which is rarely used in the hospital setting in the U.S., has poor penetrating power, is only effective at the source of irradiation, and remains prone to fouling of the quartz sleeves surrounding the UV lamp.⁵³ One notable advance is the use of light emitting diodes to deliver UVA radiation, which has been shown to be effective as a bactericidal treatment. However, this technology awaits further characterization.⁵⁴ Like other combinations of systemic disinfection strategies, it should not be surprising that UV and ozonation used in combination have been shown to be better than either used alone.⁵⁵

While regulations governing the oxidative byproducts of halogenated disinfectants exist, additional byproducts continue to be identified. One obvious consideration is that any systemic disinfection strategy will always bear a level of uncertainty concerning toxic byproducts that accrue from its use. In contrast, POU filtration lacks this drawback and offers the potential benefit of immediate and complete effectiveness against waterborne bacteria, fungi, and protozoa.

Although the implementation of POU water filtration for at-risk patient populations in the healthcare setting is a relatively new phenomenon in the U.S., this technology has been used extensively in Europe for over a decade. POU filtration studies have appeared extensively in the scientific literature and have repeatedly addressed the role of filtration technology in both reducing infections due to WBP and reducing costs for healthcare institutions. These studies have focused primarily upon *Legionella* and *P. aeruginosa*; although, studies in progress are beginning to investigate other common waterborne pathogens such as *Acinetobacter* spp. and *S. maltophilia*.

Sheffer et al⁵⁶ conducted a study during which it was demonstrated that POU filters labeled for a maximum

use life of seven days completely eliminated *L. pneumophila* and *Mycobacterium gordonae* from hot tap water over an eight-day period of use. Vonberg et al⁵⁷ observed that 99.6% of 256 filtered water samples obtained during their study were devoid of *Legionella* spp.

After an observation period of 11 months, during which a high incidence of *P. aeruginosa* bacteremia was observed in a hematology unit with severely neutropenic patients, Vianelli et al⁵⁸ performed extensive sampling in an attempt to trace the environmental source of the isolates that were appearing in patient blood cultures. Upon identifying faucets and showers in the unit as the primary environmental sources of those isolates, POU filters were installed on all hematology unit water outlets. Highly statistically significant reductions in bloodstream infections were subsequently observed over the course of the next two years.

In a study spanning a period of two years, Trautmann et al⁵⁹ documented a decrease in the monthly rate of *P. aeruginosa* infections in a surgical intensive care unit (SICU) from 2.5 per month prior to POU filter installation to 0.8 per month after POU filter installation. Van der Mee-Marquet et al⁶⁰ surveyed pseudomonad infections of blood, urological, and pulmonary origin over 23,611 patient days in an intensive care unit over a period of 7.5 years (90 months). During a timeframe of 2.5 years (30 months) prior to the use of POU filtration, 8.7 infections per 1,000 patient days were observed, while in the five years (60 months) after installation of POU filters, only 3.2 infections per 1,000 patient days were recorded.

In a neonatal intensive care unit, La Ferriere⁶¹ employed a variety of infection control interventions, including POU filtration, in order to effect a dramatic decline in HAIs attributable to *P. aeruginosa*.

Though extremely reliable, a potential limitation of a POU water filtration strategy includes the risk of possible retrograde contamination of incoming tap water.⁶²

The added cost incurred for HAI in U.S. hospitals has been conservatively estimated at \$15,275-\$38,656 per infection.^{63,64} While scientific studies have supported the use of POU water filters to reduce at-risk patient exposure to WBP, economic benefits can also be realized by healthcare institutions that adopt this technology. Hall et al⁶⁵ demonstrated that costs associated with filtered drinking water supplied to immunocompromised patients were drastically lower than those for both bottled sterile water and commercially available bottled water. In addition, Trautmann et al⁶⁶ recounted savings realized on the cost of antibiotics used to treat *P. aeruginosa* infections in a SICU during implementation of POU water filters on faucets.

Going with the Flow or Stemming the Tide?

Despite the often highly publicized evidence of risk posed by WBP such as *Legionella* and the well-documented efficacy of measures to reduce this risk, the control of WBP in U.S. healthcare institutions remains a fragmented work in progress. As has been previously stated, the U.S. lags far behind Europe in recognition of tap water as an important source of HAI. Currently, the approaches taken by many U.S. healthcare institutions to control WBP vary greatly, and generally fall into one of four categories: nonexistent, sporadic, incomplete, and enlightened.

The *nonexistent* approach is self-explanatory. These institutions either lack awareness, or actively choose not to address the problem at all. The *sporadic* approach is characterized by responding to an outbreak by culturing water, and temporarily installing some preventive measure such as POU filters. When the outbreak ends, POU filters are removed, leaving the facility unprotected as the clock ticks toward the inevitable next outbreak.

The *incomplete* approach involves an undisciplined and haphazard approach to water culturing, installation of a systemic disinfection technology, and failure to implement complementary POU filtration. This approach leaves the facility continually vulnerable to biofilm in the plumbing system, changes in water pressure, and seasonal variations in water quality. It also ignores studies conducted indicating that electronic (non-touch) faucets can harbor and promote the proliferation of WBP due to the fact that their electrical solenoid valves remain warm at all times, providing an incubated environment for planktonic and biofilm-based bacteria, fungi, and protozoa.^{67,68,69}

Finally, *enlightened*, thought-leading facilities have recognized the importance and cost-effectiveness of performing routine microbial analyses of tap water in at-risk patient areas, installing an appropriate systemic disinfection technology, and continually utilizing POU filtration to protect their most vulnerable patients.

Finding a Safe Harbor

It has been suggested that hospital water distribution systems are among "the most overlooked, important, and controllable sources of HAI."⁸ Available evidence in the peer-reviewed literature has demonstrated that hospital tap water contains microbial pathogens, and that biofilms in water delivery systems resist disinfection and deliver pathogenic organisms to the healthcare environment. At-risk patients are susceptible to infection through direct contact, ingestion, and inhalation of WBP, as numerous clinical reports attest. Systemic water treatment technologies reduce levels of recognized WBP; however, they vary in initial and long-term

maintenance costs, efficacy against specific organisms, and compatibility with facility plumbing system materials. Moreover, they do not permanently and completely eradicate biofilms within healthcare facility plumbing. Finally, existing POU filtration technologies have been reported to interrupt clinical outbreaks of infection due to recognized WBP in the healthcare environment, and may offer a cost-effective complementary infection control strategy, particularly when targeted for patients at high risk.

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UPDATE ON EDUCATION

The AHRMNY Autumn 2008 Half-Day Educational conference was held on November 14, 2008 at the Stern Auditorium at Mount Sinai Medical Center.

The topics “Managing the Risk of Healthcare Acquired Infection, Patient Safety Organization (PSO) Regulations, and The “New” CPLR Article 50-A were covered by experts in their various fields.

Emily Rhinehart, RN MPH CIC CPHQ, Vice President AIG Consultants discussed the increasing public focus and scrutiny of Healthcare acquired infections, CMS denials and the increasing Risk and Liability issues, stressing infection prevention over infection control. Amy Goldberg-Alberts, MBA FASHRM, Senior Risk management Analyst ECRI Institute was well versed in the Patient Safety and Quality Improvement Act advising on what healthcare providers need to know about Patient Safety Organization formation. Kenneth Mauro, Partner Mauro Goldberg and Lilling LLP presented valuable practical applications of the CPLR Article 50-A that can be used in medical malpractice defense cases and settlement structures.

The conference was well attended by clinicians, attorneys, and risk management, claims, utilization & quality improvement professionals. The conference evaluations advised that 82% of the attendees gave a very good to excellent score to the conference.

The 65 attendees received 3.0 contact hours of Continuing Education Credit granted by the ASHRM.

By: Barbara Finger, Esq.

As the United States shifts increasingly to the development of evidence-based practice guidelines, there is a real question on how those guidelines will affect medical malpractice litigation. Is practice outside of the guidelines malpractice *per se*? Does- and should- compliance with guidelines immunize a practitioner from allegations of malpractice? The law in this area is uncertain – both in the United States and abroad. And there are significant policy implications which warrant careful thought before advocating one position or another.

By way of background, the law defines medical malpractice as a departure from accepted standards of care which causes injury to a patient. While the definition is easy to state, articulating what constitutes accepted standards of care is much more difficult. For example, it is a cardinal principal of law that the exercise of judgment is not malpractice. However, who is to say whether that judgment was properly exercised? Were the right questions asked? The right tests performed? Who is qualified to tell us so? Does the expert have to work in the same geographic area as the practitioner? Is the expert required to have the same level of qualifications as the defendant physician?

The increasing role of evidence based medicine in clinical care, and the promulgation of clinical practice guidelines derived from evidence based medicine raises new and interesting questions as to the applications of such guidelines in medical malpractice litigation. Clinical practice guidelines are being promulgated with increasing frequency across many, many areas of medicine. The American College of Physicians alone has guidelines pertaining to treatment of Type 1 Diabetes, dementia, end of life decision making, management of chronic obstructive pulmonary disease, diagnosis and treatment of low back pain, management of chronic, stable angina, and many, many more. The American College of Pediatrics has guidelines covering issues from treatment of otitis media to discharge from the neonatal intensive care unit. The American College of Obstetrics and Gynecology has guidelines covering all aspects of obstetrics. In Great Britain, the National Institute for Health and Clinical Excellence was created, in part, to monitor the implementation of guidelines.

The move to develop guidelines stems from a number of different goals. One goal is to improve the quality of care provided by practitioners across the board. Another is to control costs. And yet a third is to try to get a handle on malpractice issues. Guidelines are derived from careful

review of evidence based medicine. Evidence based medicine represents medical practice derived from examination of the scientific literature and clinical studies to determine what constitutes the best care and treatment under specific circumstances. Evidence-based medicine represents a movement away from empiric treatment, and towards integrating the best available scientific research and practices with proven effectiveness in daily medical decision-making. Utilizing evidence based medicine, professional societies have increasingly developed clinical practice guidelines which incorporate these findings in an attempt to improve the quality of medical care provided across the board.

The increasing role of evidence – based medicine in clinical practice, and the concomitant development of clinical guidelines by professional societies puts setting the standard of care in a new light. Now there are formal written documents that both sides can point to in support of their positions. Doctors want to argue that compliance with professional guidelines immunizes them against suit. Plaintiffs want to argue that deviations from practice guidelines constitute proof of malpractice *per se*.

The issue, in terms of medical malpractice litigation, is what is the proper role for these guidelines. Are they a sword to be used by plaintiffs to challenge any care which does not comport with the guidelines? Are they a shield, behind which doctors can hide, so long as their care is in line with the guidelines? In terms of medical malpractice litigation, these questions are unsettled, and there are very real impediments to their use in medical malpractice litigation.

There are two primary difficulties with using guidelines as proof of the standard of care in malpractice litigation. First of these is the hearsay rule.

Hearsay is defined as “an out of court statement offered to prove the truth of the statement contained within.” Courts exclude hearsay evidence because it lacks reliability. As with malpractice itself, hearsay is notoriously easy to say and difficult to apply. Hearsay is problematic in the court room, because the author of the statement or the opinion is not available to be cross examined as to the basis of that opinion, or any potential flaws in it. A statement contains putative facts, yet the person who authored those facts cannot be questioned as to the accuracy of those facts, or the basis for the statements. The side hurt by the testimony has no way to challenge the basis for the conclusions, the evidence upon which the conclusion are based, or the

process by which the conclusions were reached. In malpractice litigation, where the offered testimony is often offered in support or opposition to a given scientific principle, the absence of the author limits the ability of the parties to challenge its accuracy. In short, hearsay is problematic in the court room, because the author of the statement or the opinion is not available to be cross examined as to the basis of that opinion, or any potential flaws in it.

Applying these concerns to the use of clinical practice guidelines to prove departure from, or compliance with, a standard of care, the problem of hearsay is as follows.

Guidelines contain within them the considered opinions of professionals in the field as to what they believe the standard of care in a given situation is. Their opinion is derived from their review of the work of others. In the courtroom, neither the author of the guideline, nor the authors of the works upon which the guidelines are based, are available for cross-examination. Nonetheless, guidelines have reached a level of acceptability within the professional community such that to exclude them in total from the court room would give proof to Dicken's adage that "the law is a ass". The compromise position taken by some courts is to allow guidelines into evidence based on the testimony of a physician that the guidelines are the sort of professional standard which doctors in a given specialty commonly rely on. The expert, through whose testimony the guidelines are admitted, is then open to cross examination about the scope of the guidelines, the applicability to the clinical situation at issue, the process through which the guidelines were developed, and any other matter which the opposing side believes is appropriate to challenge the authority of the guideline.

The second problem has to do with restricting the traditional role of jurors as finders of fact. To give dispositive weight to guidelines would effectively take away all discretion from the jury. Yet allowing a jury to decide whether or not an individual physician committed malpractice is probably the single issue which most enrages doctors. "Why should I be answerable to someone who has no formal medical training?" "How can someone who has not been in a science classroom since high school tell me whether or not I provided good care?" Nonetheless, the jury is the cornerstone of the common law of medical malpractice. The standard of care is set by those who receive the care – not those who provide it. And the courts have been very leary of substituting anyone's judgment for that of jurors.

This is exactly what giving dispositive weight to guidelines does. It tells jurors that they may not reach a decision contrary to that of the professional body that developed the

guidelines. It removes their discretion in any situation where a doctor has done what the guidelines tell him should be done. Yet by the same token, from the point of view of the practioner, he is between a rock and a hard place. "What more can I do, other than provide care the way my professional societies tell me I should?"

The New York Court of Appeals spoke to this question recently in Hinlicky v. Dreyfuss 6 N.Y.3d 636, 648, 848 N.E.2d 1285, 1291, 815 N.Y.S.2d 908, 915 (N.Y., 2006). In that decision, the Court struck a balance between these competing interests, allowing the guidelines into evidence as proof of the defendant physician's thought processes, but staying shy of giving them dispositive weight.

The case involved a claim of malpractice in not having a 71 year old woman undergo cardiac prescreening before undergoing an endarterectomy. She suffered a heart attack after the surgery and died 25 days later.

The defendant anesthesiologist testified that in making the decision to forego a preoperative cardiac evaluation, he relied on guidelines promulgated by the American Heart Association in conjunction with the American College of Cardiology. He explained to the jury what the guidelines were, how they were developed and how he used them in deciding that Mrs. Hinlicky did not need a cardiac workup before the endarterectomy. The guidelines themselves were admitted as demonstrative evidence of the anesthesiologist's thought processes.

At the conclusion of the trail, the Court charged the jury as follows:

"The plaintiff's position and contention is that [a cardiac evaluation] referral was required by the standards of care prevailing in 1996, given Marie Hinlicky's physical condition and history. The defendants contend that the 1996 guidelines adopted by the American Heart Association and the College of Cardiology were the standards of care in 1996 and were followed by the defendants in their care and treatment of Marie Hinlicky. And that, in accordance with the guidelines and their findings, a judgment was reached that no such referral was warranted."

Plaintiff's counsel argued that the Court erred in so charging and that Court should not have admitted the guidelines into evidence, even merely for demonstrative purposes.¹ The Court of Appeals rejected this contention. It held that in this case, all the experts who testified – both for

¹New York law recognizes a distinction between materials admitted into evidence at trial as direct proof of an issue in the trial, and those which are merely demonstrative. Demonstrative evidence is offered as illustration of an issue at trial, not as direct proof of that issue.

the plaintiff and for the defendants – discussed the role of guidelines in setting the standard of care. It further held the trial court acted properly in allowing the anesthesiologist to testify about the guidelines because that testimony was directly tied to his decision-making process about this patient. In a footnote, the Court of Appeals discussed limitations on use of clinical practice guidelines in other settings. They noted that in *Diaz v. New York Downtown Hosp.*, 99 N.Y.2d 542, 545, 754 N.Y.S.2d 195, 784 N.E.2d 68 [2002], the Court refused to allow plaintiff's expert to use clinical practice guidelines "to prove an accepted practice where the authoring body explicitly stated the guidelines were "not rules" and the expert failed to set forth a factual basis for her reliance on them."

However, in *Hinlicky*, the evidence of the guidelines was admissible because the defendant anesthesiologist testified that he relied on them in his decision-making as to this patient. Had the defendant not specifically utilized them in caring for this patient, it is far from clear that the Court would have admitted them into evidence. Indeed the Court specifically declined to decide whether guidelines would be admissible as direct proof of compliance with, or departure from, accepted standards of care, holding that question open for another case.

We recently successfully defended a case at trial to a defense verdict, where the plaintiff's theory was at odds with practice guidelines promulgated by the relevant professional society. The case involved treatment of varicocele-related male subfertility. The plaintiff and his wife had approached an expert in male infertility because they had been unable to conceive. The husband has bilateral testicular varicoceles. The physician proposed – and performed – bilateral varicocelectomies, having fully discussed risk, benefits and alternatives with both the patient and his wife. Following the surgery, the husband had sustained some nerve damage. At trial, plaintiff's expert testified that instead of performing the varicocelectomy, the patient should have been offered non surgical medical treatment with Clomid. This was in contradiction to the position of the guidelines promulgated by the American Society for Reproductive Medicine.

Defense counsel objected to the testimony, arguing that the Court should not allow in testimony which was in opposition to carefully developed policies of the responsible medical societies in the field. The Court overruled defense counsel's objections, and allowed the testimony in, holding that it was a legitimate expression of opinion.

While the jury ultimately rejected the plaintiff's position, the fact that the Court allowed expert testimony which was

contrary to carefully developed positions of the professional society in this area was troublesome, to say the least. The Court was of the opinion that allowing defense counsel to vigorously cross examine the plaintiff's expert was sufficient protection against "made up" medicine.

One issue of concern is whether the development of guidelines will infringe on a physician's discretion to vary care from that prescribed by guidelines. In *Lowry v. Henry Mayo Newhall Memorial Hospital*, 185 Cal.App.3d 188, 195, 229 Cal.Rptr. 620, 624 (Cal.App. 2 Dist.,1986) plaintiff attempted to use American Heart Association guidelines offensively as proof of a departure from accepted standards of practice. The case involved resuscitation following cardiac arrest. The defendant doctor argued she was entitled to the benefit of California's Good Samaritan law and asked the Court to dismiss the case. The plaintiff argued that the defendant was not entitled to the statutory protection because she had deviated from American Heart Association guidelines for advanced cardiac life support by administering the drug Atropine rather than Epinephrine. The defendant disagreed with this, and offered an affidavit explaining her exercise of judgment in electing to use Atropine. The Court accepted the explanation and dismissed the suit.

Levine v. Rosen 532 Pa. 512, 516, 616 A.2d 623, 625 (Pa.,1992) was a medical malpractice case involving an alleged failure to diagnose breast cancer. The case involved contentions of "dueling" guidelines. The plaintiff's expert relied on guidelines of the American Cancer Society, and testified that the defendant was negligent for not ordering a mammogram every year after the plaintiff reached her 50th birthday.

The defendant's expert, in contradiction to the plaintiff's expert, relied on the guidelines of the American College of Obstetrics and Gynecology. These guidelines, he explained, recommended only "regular," as opposed to yearly, mammograms. He defined regular to mean within the physician's discretion.

In Pennsylvania, a defendant is entitled to a complete defense against claims of malpractice when he can establish that there are two schools of thought with regard to a given practice, and he exercised his judgment in following one in lieu of the other. The charge to the jury should be as follows: "Where competent medical authority is divided, a physician will not be held responsible if in the exercise of his judgment he followed a course of treatment advocated by a considerable number of recognized and respected professionals in his given area of expertise." In *Levine*, the Court held that the defendant was entitled to that charge, and the defendant prevailed at trial.

Great Britain approaches these issues differently. The law in England has been, for many years, that “a doctor is not negligent if what he has done would be endorsed by a responsible body of medical opinion in the relevant specialty at the material time.” This doctrine was articulated in a decision entitled Bolam v. Friern Hospital Management Committee, 1 WLR 583 (1957) and became known as the *Bolam* doctrine. Commentators have suggested that this doctrine gives too much authority to the medical profession, and allows for too little review by the courts. A 1997 decision, Bolitho v. City and Hackney Health Authority 4 All ER 771, gives more responsibility to the Courts in actively critiquing expert positions and setting the standard of care.² With the increased move in the UK to the use and development of clinical guidelines through NICE (National Institutes of Clinical Healthcare Excellence) as part of Great Britain’s overall move towards efforts to standardize and improve the quality of care, the courts are beginning to look for some evidence of what has been accepted as, and put forward as, the standard of care by professional societies.

In conclusion, it is clear that guidelines will increasingly play a role both in the provision of medical care, and in the ways that courts – and juries – assess the quality of care provided. Guidelines offer doctors the potential of a “safe haven”. Yet by the same token, they may impose constraints on the exercise of a physician’s best judgment. Before clinicians argue too strenuously that guidelines should be relied on by the Courts to establish the standard of care in a given situation, thought should be given to the effect such use will have on the discretion available to physicians to utilize their best judgment in caring for patients. It may be that guidelines are too fixed and rigid to be applied as a dispositive rule. Perhaps the better course is that currently struck by the Courts in New York, which is allow their admissibility as some evidence of the standard of care, subject to cross examination and argument by opposing parties. In any event, it is a safe bet that the issue will continue to evolve as guidelines are given ever greater roles in the provision of medical care.

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² See, for a further discussion, *The Role of Clinical Guidelines in Medical Negligence Litigation: A Shift From the Bolam Standard?*, 14 Medical Law Review 321 (Autumn, 2006), Samanta et al.



SAVE THE DATE

AHRMNY Upcoming Education Programs

Tuesday, April 7th, 2009

AHRMNY jointly with AIG and the National Patient Safety Foundation will host a full-day conference entitled: “Crucial Conversations in Healthcare: Advancing Patient Safety & Avoiding Adverse Events”

The program will explore the importance of clear and concise communication between physicians, nurses, patients, families and other healthcare team members. Failures in communication among staff have a major impact on patient safety and continue to be a major cause of sentinel events and errors in healthcare. Likewise, poor communication between providers and patient/family members fosters mistrust and diminishes the important role of the patient/family in reducing errors. To avoid these consequences, healthcare providers should understand & utilize effective communication strategies at crucial moments with each other and with patients and families. Breakfast and Lunch will be provided. ASHRM CEU’s will be granted.

Friday, June 12th, 2009

AHRMNY’s Annual Conference will focus on the financial health of the New York healthcare industry. The program will analyze how local healthcare institutions are weathering the storm and advice on best practices to survive the current economic environment.

Both conferences will be held in the Swiss Re Conference Center at St. Vincent Catholic Medical Centers.

Detailed registration information will be available soon!

CALL FOR NOMINATIONS

The Nominating Committee of AHRMNY sent out a call for nominations on February 8th, 2009 in preparation of the upcoming election of Officers for the year 2009-2010 and Directors for the years 2009-2011.

Current members of AHRMNY are eligible to nominate themselves or other members for officer and director positions within the organization. There is still time to nominate a potential candidate. Nominations will be collected through 2/28/09.

If you are in need of the nomination documents, please request them at AHRM@optimum.net.

CPHRM EXAM WINNER

Marianne Ambookan, RN-Assistant Vice President of Regional Risk Management Services for North Shore-LIJ Health System was selected as the recipient of the **COMPLIMENTARY CPHRM EXAM** waiver. The drawing was held on December 3, 2008 and she is now eligible to register and take the examination without a charge. On behalf of the Officers and Board of Directors of AHRMNY we congratulate Marianne and wish her good luck on the exam.

RISKY BUSINESS “When Common Sense is Uncommon”

Pamela Monastero, MBA, CASHRM

Dear Risk Manager:

This column, which will appear regularly in the AHRMNY Newsletter, is designed to assist both the novice and seasoned risk manager by presenting brief *pearls of wisdom* based on the experiences of our colleagues. The column is anonymous and we encourage our members to submit their experiences which may be e-mailed to Pamela.monastero@nychhc.org or mailed to AHRMNY, P.O. Box on the RISKY BUSINESS form which can be found on our website at AHRMNY.org. The form permits confidentiality.

COMMON SENSE TIPS FOR STAFF:

This quarter's column is devoted to risk avoidance in obstetrics.

Reason: Recent media reports in New York City cite the woes of hospitals maintaining obstetrical services given the high associated malpractice costs. Indeed, it was recently reported that one Brooklyn-based hospital had considered closing its obstetrical service as a cost saving measure, raising the issue of whether other local hospitals can (and are willing to) absorb the overflow. The Department of Health decided that the hospital should keep the obstetrical service intact for the time being. Given escalating malpractice costs and the reported decline in the number of obstetricians, we wonder what the future holds in terms of hospitals seeking to limit their exposures vis-à-vis obstetrics. A brief overview of obstetrical statistics follows:

- An obstetrician can expect to be sued 2.64 times during his or her career and can face possible multimillion dollar judgments¹
- Due to escalating malpractice costs, many obstetricians are curtailing their obstetrical practices to practice gynecology, are avoiding high risk patients or high risk interventions or are retiring early.¹ Earlier surveys from 1998 to 2002 indicated that the number of practicing OB/GYN's in New York State decreased by more than 4%* while the rest of the nation was relatively stable. An unpublished survey by the New York Office of the American College of Obstetrics & Gynecology (ACOG) reported that about 67% of OB/GYNs in New York State reduced their services in some way in response to the rising costs of malpractice premiums.²
- Hospitals nationwide are closing their obstetrical services¹
- Increasingly, nurse midwives are filling the gap left by obstetricians¹
- In New York State, staggering multimillion-dollar verdicts have been sustained. This sometimes results in early, pre-trial or mid-trial settlement of obstetrical cases for high dollar amounts to avoid runaway jury verdicts. For those facilities with excess commercial insurance coverage and, indeed, for self-insured facilities and captives, these are real financial challenges—especially in today's economy of decreasing or negative investment returns.
- As reported in Modern Healthcare on October 8, 2007, an 18 month national study conducted by Marsh & McLennan of 25,000 claims from the period of 1991 to 1995 collected data from 357 healthcare facilities in 41 states represented \$3.4 billion in incurred malpractice claims and expenses. While obstetrics accounted for 14% of the claims, it represented 32% of the dollars paid in claims with an average claim payout of \$365,477 for an obstetrical claim, which is significantly higher than other clinical disciplines.³ While not broken down by clinical discipline, it was reported that, in 2002, of the top ten malpractice verdicts in the country, New York courts were responsible for seven.⁴

Most of what is outlined below is written with a view to improve patient safety and outcomes by prevention of adverse outcomes. However, as we know, not all adverse outcomes are preventable. Therefore, we have included several comments for risk managers that are intended to assist in defending those occasional adverse outcomes that do occur. These comments are not meant to foster the practice of defensive medicine but are written in the spirit of reducing liability exposures by making alleged malpractice cases more defensible.

- **Tips & Tools:** ECRI’s new Healthcare Risk Control report (Volume 4 January 2009) entitled “Obstetrics and Neonatal Safety” is a must read for all risk managers. The publication includes proactive measures to help reduce risk exposure and promote patient safety in obstetrics. It also includes a comprehensive list of references. The article cites various studies—one of closed claims against certified nurse midwives attributing negligence as to fetal assessment/tracing interpretation (34%) and shoulder dystocia (28%). Another study outlines top risk management concerns from malpractice claims and lists mismanagement of labor, misinterpretation of diagnostic studies, miscommunication among providers, mismanagement of pregnancy, failure to order diagnostic tests, failure to appropriately monitor the patient, documentation and consent issues, etc.¹ In New York State, Greater New York Hospital Association and the United Hospital Fund have developed the “Perinatal Safety Collaborative” in an effort to improve and standardize patient-centered care in the perinatal setting.⁵

Outlined below are some of the issues addressed in the aforementioned as well as additional risk reduction suggestions. Overall, the drive should be to focus on a culture of safety that improves communication and hand-offs among caregivers, focuses on multidisciplinary approaches to patient medicine, continued education (e.g. reading of fetal monitoring strips, etc.), development of “rapid response teams” for obstetrical emergencies, using outcome measures to gauge effectiveness of practices and progress towards reducing adverse outcomes and improving quality.

- **Teamwork and Communication:** Outlined in Joint Commission’s 2004 Sentinel Event Alert (SEA) #30 “Preventing Infant Death and Injury During Delivery,” are the identified root causes in 47 case studies. It should not be a surprise that 72% of the root causes were attributed to communication issues and 55% cite organizational culture as a barrier to effective communication and teamwork (including hierarchy, intimidation, failure to function as a team, failure to follow chain-of-communication, etc.).⁶ We all recognize the importance of using findings from Root Cause Analyses and Failure Mode and Effects Analysis (FMEA) to identify issues and put measures in place to avoid recurrences. However, how many risk managers feel that there has been significant improvement since this SEA was issued and after countless RCAs and FMEA’s? If recurrences are happening at your facility, a lack of teamwork and communication issues may be the cause. **Tip:** Consider implementing programs like TeamSTEPPS or Crew Resource Management to improve communication among caregivers and foster teamwork to produce better patient outcomes and promote patient safety. It is important to focus on all staff relationships—including superior, peer and subordinate relationships—special attention should be paid to more subtle relationships, e.g. the relationship between the anesthesiologists assigned to OB/GYN and the obstetricians/OB residents. Do all staff treat each other with professional courtesy and respect? Does the organizational culture and labor and delivery department culture reward, punish or ignore disruptive and unprofessional behavior? Using TeamSTEPPS, Crew Resource Management and other similar tools to create a climate conducive to teamwork, open communication and professionalism is one basic building block to improving patient safety and quality outcomes.
- **Fetal monitoring strips/equipment:** Ensure there is continuous staff education/certification on reading (and responding to changes in) fetal monitor strips. Inadequate fetal monitoring was cited as a root cause in 40% of the cases reviewed in JCAHO’s SEA #30.⁶ Provide continuous education to ensure that staff are familiar with equipment (especially new equipment) and can demonstrate competency in equipment use (e.g. vacuum extractions and the number of pop offs allowed by the manufacturer). Manufacturers can assist in staff education as necessary.
- **Drills:** Conduct monthly or quarterly obstetrical emergency drills for shoulder dystocia, blood loss, “off-unit” labor and delivery patients (e.g. obstetrical patients in the ER, in ICUs, medical-surgical units, etc.), pre-eclampsia, placenta abruption, maternal illness (seizures, respiratory, etc.), multiparty deliveries (can your pediatric staff handle the simultaneous resuscitation of premature twins or triplets?), availability of pediatric/neonatal code carts in “off-unit” areas such as the ICUs, ER, etc. If your facility frequently receives obstetrical emergencies from outpatient centers (e.g. birthing centers), take the necessary steps to make sure that those centers and ambulances call the emergency department in advance to mobilize the team for the obstetrical emergency.
- **Hand-offs:** Are handoffs limited as much as possible? Are nursing staff encouraged to work beyond their hours in the operating rooms to avoid shift change issues (as we know, frequent hand-offs in the operating rooms can cause problems in maintaining proper surgical counts which can be a contributing factor in retained foreign bodies)?

Are hand-off documentation tools comprehensive? Are hand-offs being done appropriately (e.g. are they also done for “bedside” procedures so that appropriate staff are involved/notified of significant patient issues)?

- **Enforcement of work hours:** staff fatigue is known to contribute to poor patient outcomes. Make sure resident work hour restrictions are consistently enforced. Conduct annual in-services on the effect of fatigue on staff to highlight awareness.
- **Policies & Procedures:** Ensure L&D suites follow the same policies/procedures as the main operating rooms (e.g. re surgical counts, time out, etc.). Review OB/GYN policies for issues such as: consistency (internal and with other departments), congruity with ACOG guidelines (American College of Gynecology)—e.g. does your OB policy state that stat c-sections must be done within ACOG timeframes or is it more stringently written (which can damage claims defense)? Remember, policies are useless if staff are unaware of their existence and do not understand or follow them.
- **Staffing:** If your facility uses per diems, float staff, agency staff, etc. it is important to remember that they are your most vulnerable staff, especially in specialty areas such as L&D, newborn nursery, neonatal ICUs, etc. This is especially true if your facility engages in any non-standard practices, e.g. “workarounds.” This is a set up for a medical error as they are unfamiliar with your facilities policies and workarounds only make sense to seasoned staff.
- **Close the loop:** Ensure that corrective measures put in place to avoid recurrences of events (e.g. RCAs, FMEAs, quality monitors, etc.) are working properly and are being enforced. With frequent staff turnover and the rotation of residents, memories become short and new staff are unaware of events that may have occurred and “fixes” that were put in place.
- **Documentation/electronic medical record:** If there is a bad outcome, the attending of record must be encouraged to personally complete the chart (operating report, discharge summary, etc.). Ask legal counsel to assist in educating staff regarding proper documentation, honesty in documentation and terms to avoid. Also consider issues revolving around synchronization of wristwatches, wall clocks, computers (electronic medical record) on a daily basis and particularly close to daylight savings time. Regarding the electronic medical record, while it solves some documentation problems, it also creates others. Depending on the software, inattentive staff may be less prone to read the notes of other clinicians and, even worse, may try to cut and paste from the progress notes of other caregivers or document “agree with above” or “agree with Dr. X.” Therefore, when less experienced staff misdocument or use inappropriate descriptors and unfortunate word choices, the entire medical record can become replete with untrue and damaging documentation, rendering a malpractice case difficult, if not impossible, to defend. As with a paper medical record, timing of notes can be problematic if someone is inclined to “creative” documentation. Staff must be continuously educated that electronic footprints and audits exist which demonstrate the exact time a note was written. Encourage staff to document in real time and note “saw patient at e.g. 10:00 am...” instead of back-timing or backdating entries. Research on line references regarding pitfalls of electronic medical record documentation.
- **Cord gases/placenta pathology, etc.:** Because many hospitals do not routinely refer all placentas for pathology review, risk managers should meet with defense counsel, the chairs of OB/GYN and Pathology to review circumstances in which it is important to obtain pathology review (e.g. low apgar births, difficult deliveries, unexpected or adverse outcomes, etc.). The importance of continuous staff education on ordering appropriate tests during difficult deliveries/unexpected outcomes is essential. This is especially true in teaching hospitals wherein new residents enter the facility each year and in institutions with high staff turnover. Staff must be reminded to order cord gases, pathology on placenta, etc. Work with hospital administration to determine the cost-benefit of analyzing placenta on all cases and be specific as to what pathology should comment on in their report which tends to be generic. If your hospital participates in saving cord blood, ensure that the proper policies/procedures are in place and are being followed to avoid mislabeling of specimens, lost specimens, proper handling and storage of specimens, etc.
- **Neonatology/Neonatal Intensive Care Unit/Newborn Nursery:** Encourage frequent staff training regarding medication errors, which can have much more severe results in neonates than in adults. Again, be aware that agency, floating, part time and per diem staff are your most vulnerable staff in terms of patient safety. Reinforce

the use of two patient identifiers—we have seen countless cases of staff returning infants to the wrong bassinette, bringing the incorrect infant to a mother for breastfeeding (imagine the consequences of having an infant fed by different mother—or a patient with a communicable disease or is HIV+).

- **Risk Management presence:** Risk Managers should be accessible to the OB/GYN department. Attend weekly grand rounds and QA meetings and bond with the Chair of OB/GYN. Become an integral part of their discussions. OB/GYN staff should feel comfortable contacting the risk manager for advice and guidance.
- **Education:** Risk Managers should conduct frequent in-services to continually educate staff and raise the level of awareness. Dissect settled obstetrical cases and highlight the defensible and indefensible aspects and utilize additional resources to drive home the message (e.g. your professional liability carrier may conduct risk assessment surveys or policy/procedure reviews, defense counsel can conduct in-services to highlight cases from legal literature or from their experiences, hire consultants (albeit expensive) to help identify and outline high risk issues and suggest improvements/corrective action, etc.). Ensure that all staff are intimately familiar with important hospital and department policies.

ENDNOTES

¹ ECRI Institute, Healthcare Risk Control, "Obstetrics and Neonatal Care," Vol. 4, Jan 2009.

² ACOG "Medical Liability Survey Reaffirms More OB-GYNs are Quitting Obstetrics" July 16, 2004, "In 1998 there were 13.9 OB/GYNs per 100,000 population in the US and in 2002 there were 13.6. In New York State, the comparable numbers declined from 19.5 per 100,000 in 1998 to 18.7 in 2002, American Medical Association, "Physician Characteristics and Distribution in the United States", Washington DC 2000 and 2004.

³ Modern Healthcare, "Malpractice Claims Drop: Report" by J. DerGurahian, October 8, 2007.

⁴ National Law Journal, "100 Largest Verdicts of 2002".

⁵ GNYHA/UHF, "Perinatal Safety Collaborative," Revised December 2008.

⁶ Joint Commission, Sentinel Event Alert No. 30 "Preventing Infant Death and Injury During Delivery," July 21, 2004.

Tools, Resources and Literature:

- American College of Obstetricians and Gynecology (www.ACOG.org)
- ECRI Institute (www.ecri.org)
- Joint Commission (www.jcaho.org)
- Institute for Healthcare Risk Improvement (www.ihl.org),
www.ihl.org/IHI/Topics/PerinatalCareGeneral/EmergingContent/PerinatalTriggerTool.htm).
- Greater New York Hospital Association (www.gnyha.org)
- Greater New York Hospital Association, "Medical Malpractice Insurance Costs and Coverage" January 2005
- Perinatal Patient Safety, "Horizontal Hostility" by K. Simpson, Vol. 33, Number 5 Sept/Oct 2008
- Joint Commission Journal on Quality and Patient Safety, "Impact of CRM-Based Team Training on Obstetric Outcomes and Clinicians' Patient Safety Attitudes" by S.D. Pratt, S. Mann, M. Salisbury, P. Greenberg, R. Marcus, B. Stabile, P. McNamee, P. Nielsen, B. Sachs, Vol. 33, Number 12, Dec 2007
- Joint Commission Journal on Quality and Patient Safety, "Eliminating Birth Trauma at Ascension Health" by F. Mazza, J. Kitchens, S. Kerr, A. Markovich, M. Best, L. Sparkman, Vol. 33, Number 1, Jan 2007
- Joint Commission Journal on Quality and Patient Safety, "The Road to Zero Preventable Birth Injuries" by F. Mazza, J. Kitchens, M. Akin, B. Elliott, D. Fowler, E. Henry, S. Landers, M. Nix, S. Ourston, C. Sheppard, D. Stallings, D. Weihs, Vol. 34, Number 4, Apr 2008
- Obstetrics & Gynecology, "Getting to Havarti" by L. Veltman, Vol. 110, No. 5, Nov 2007
- Obstetrics & Gynecology, "Effects of Teamwork Training on Adverse Outcomes and Process of Care in Labor and Delivery" by P. Nielsen, M. Goldman, S. Mann, D. Shapiro, R. Marcus, S. Pratt, P. Greenberg, P. McNamee, M. Salisbury, D. Bimbach, P. Gluck, M. Pearlman, H. King, D. Tomberg, B. Sachs, Vol. 109, No. 1, Jan 2007
- JAMA, "A 38 Year Old Woman with Fetal Loss and Hysterectomy" by B. Sachs, Vol. 294, No. 7, August 17, 2005
- Joint Commission, Sentinel Event Alert No. 30 "Preventing Infant Death and Injury During Delivery," July 21, 2004
- National Perinatal Information Center, www.npic.org
- Agency for Healthcare Research and Quality, contains comparative State by State data of maternal and child health care quality measures and metrics, www.ahrq.gov
- www.teamstepps.ahrq.gov

BEST PRACTICES: RISK MANAGEMENT FOR ASSISTED LIVING FACILITIES

By Brian T. Valery¹

Margaret Thatcher, Britain's former Prime Minister put it best, "The unexpected will happen. You had better be prepared for it." With the nation's population getting older, Assisted Living Facilities ("ALF") are one of the best alternatives for dignified living for the aging adult population. However, growing regulation and liability faced by ALFs cause concern for the operation of ALFs, both for the residents and their owners. ALFs must employ proper risk management and loss prevention to protect their assets, residents and reputation from the expected as well as the unexpected. This includes placing resident safety at the forefront of risk management.

ALFs are unique in terms of risk management in that the failure to address risks can have detrimental effects on the ALFs residents and the longevity of the ALF's business. ALFs are in a business where two facts are accepted: (i) life is terminal; and (ii) accidents do happen. It is that later fact that can be addressed by proper risk management. Proper risk management will limit exposure to accidents or even eliminate the risks associated with accidents. Inherent in this effort are the identification of risks and the management of those risks by use of traditional and nontraditional risk transfer or risk retention mechanisms. The goal is to protect residents and the ALF's operation from actual and potential risks.

There is more to proper risk management than the purchase of an insurance policy. Three areas of risk management, discussed in more detail below, are:

- (i) Identification of risks;
- (ii) Evaluation of those risks and the selection of a method of offsetting the risk or reducing the exposure; and
- (iii) The management and implementation of the selected risk management tool(s).

ALFs cannot necessarily eliminate risk, but can take action to reduce risk and the facilities risk exposure. Equal emphasis on the three areas of risk management

identified above is necessary in properly addressing risk exposure. In terms of risk management, knowledge is clearly the key to success.

RISK EXPOSURES FOR ALFS

Risk identification is likely the most important step an ALF can take in its quest for proper risk management. Some of the most prevalent types of risks that ALFs face include:

1. Wandering and Elopement²;
2. Resident falls;
3. Medication errors;
4. Residents' rights violations; and
5. Negligent care of residents or failure to monitor.

Of these risks, the most common claim faced by ALFs is resident falls and the most costly claim is one involving negligent or improper care of residents.³ As with any operation in the health care arena, human resource plays an important role in the management of risks. In fact, the risks identified above can often effectively be dealt with by the implementation of good human resource policies, including: (i) continued education of staff – be sure that the facilities management is taking steps to educate staff of recent trends in the industry and methods of identifying issues that may lead to risk; and (ii) hiring and retention of trained employees – facilities must pay close attention to its hiring practices as well as its ability to retain employees

For example, one ALF with more than 100 residents did not address its risk management issues and it developed a problem with its staff not adequately servicing its residents. Specifically, during certain hours, it was suspected that the staff was not properly attending to their duties, but rather "sleeping on the job". Of course, this, in and of itself, creates certain risks for residents as well as the ALF. After a thorough review of the risk, a monitoring system was implemented and the issue was resolved by identification of the culpable staff member(s) and

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²Marie Boltz, "Wandering and Elopement: A Comprehensive Approach," (Assisted Living Consult Sept./Oct. 2006)

³See, "Transforming Aging Services, CNA Healthpro Long Term Care Claims Study 2001-06," CNA Healthpro (10/2007).

the deterrence factor that the monitoring system instilled. In addition, a security guard was retained for the night hours (between 10:00 p.m. and 6:00 a.m.) which served both as deterrence and as a vital part of the night staff.

This discovery by the ALF, however, pointed to a much larger issue. The ALF did not focus enough on hiring and employee retention, both areas amounting to a fertile group for risk incubation. After implementing the risk evaluation methods discussed herein, the ALF was able to create a plan that included increased scrutiny with regard to hiring practices and addressing the turnover rates with employee training. This also had a positive affected on issues related to staff being more attentive in servicing the residents. In addressing the hiring practices issues, the ALF instituted a more detailed application process, background research on applicant, and drug testing for applicants.⁴ Addressing the issue related to employee turnover can be more challenging.

The employee turnover problem within ALFs creates risk in and of itself. As noted above, frequent turnover of employees can lead to a lack of "connection" between residents and staff. In addition, with frequent employee turnover there is an increased chance that there are now former employees that have gained specific knowledge about the ALF's operation that could be used to negatively impact the ALF. Items like theft, break-ins, vandalism and other similar risks can often be traced back to former employees. To reduce turnover, the ALF implemented policies and programs that reduced this risk. The ALF began frequent employee reviews, created an anonymous call line to report problems, and began regular employee training programs. This caused a decrease in employee turnover and an overall positive effect on the ALF and its residents. The frequent reviews were accompanied by merit bonuses and staff promotions creating an achievement structure within the ALF. This also contributed to the downturn in employee turnover.

Employee management may be the most fertile ground for risk management in the ALF field. Often times a lack of communication causes liability and increases risks for ALFs. ALFs can increase communication by implementation of a few policies that instill communication between staff, management, and even its residents. An ALF can create schedules for group meetings, compliance sessions and

training. It has been show that even this small operational change can decrease risk exposure substantially by increasing communication and creditability among residents, staff and management.

The majority of claims that ALFs face can be managed by diligent and effect planning and operational management. Too often, ALFs look to the more costly method, insurance, as the way of dealing with risk exposure; however, insurance is only part of the equation and is not the panacea for the management of risks that ALFs may face. Successful risk management must begin with the basics.

GENERAL APPROACH TO RISK MANAGEMENT

The most effective approach to risk management can best be described in the following phases. If an ALF is looking to implement or update its risk management policies and procedures⁵ the use of a phase approach will assure the most comprehensive results in alleviating actual and potential risks.

Phase One – Risk Reduction

This phase includes review of the ALFs operations and identification of risks that may affect its patients and overall operation. Phase one should be a thorough review and inspection of the ALF operation, including areas such as: (1) the facilities "bricks and mortar" to identify potential risks related to the building and the facilities operational environment. Issues as simple as items that cause hazards related to falls or ease of elopement to more complex matters of security and inventory shrinkage; (2) review of current policies and procedures as to the handling and intake of residents to identify possible issues that are lacking in attention; (3) employee interviews that may result in the identification of concerns the employees have about the operation and its resident management; (4) assessment of staff training and monitoring; and (5) review of incident reports to identify patterns related to certain incidents to rectify or limit exposures related thereto. Phase one in the risk management process is likely the most important in that ALFs must conduct a full review of the facility and its operations to identify risks that it may face. Although this industry may have similarities between facilities, each ALF must do its own due diligence to determine its risk exposure and address it accordingly. In this regard, industry check lists are helpful, but facilities' management must give independent thought to risk as each facility's residents vary, as do many factors

⁴Many States mandate health care facilities to conduct background research, including criminal history, and drug testing on employees prior to their employment.

⁵It is recommended that ALFs review its risk management policies and procedures yearly. Regulation, risk exposure and general patient population change and all can have an impact on risk exposure.

that relate to risk exposure. The importance of identifying risk exposure and properly addressing it was made clear to companies affected by the events of September 11, 2001. Many companies discovered that failing to identify risk was devastating as liability and property losses mounted after September 11th. Companies failed to completely identify the risks that they may face, including business interruption and other business related risks that often go overlooked by management. Because of this precautionary failure, many of the companies affected by the events of September 11, 2001 were fully exposed to risks that could have been properly managed pre loss.

Risk identification is an ongoing process that can be instilled in employees and management of any ALF and should be part of any policy and procedure that the ALF maintains, including employee handbooks.

Phase Two – Plan and Design of Risk Solutions

This phase uses the knowledge gained from phase one about the risks that an ALF may face and allows the ALF to begin designing solutions. To protect their assets and reputation, ALFs must place resident safety and concerns at the forefront of their solution considerations. Indeed, solutions can be designed to best protect the residents of the ALF and, at the same time, protect the ALF operation. The design and structuring of risk exposure solutions may include the drafting of programs and policies, implementation of training programs, the installation of security hardware, adaptation of current policies and procedures and the structuring of insurance programs or other risk transfer mechanisms. Many risks can be managed by the implementation of corporate policies or minor operational change.

When determining the best solution to manage a particular risk, ALFs should consider issues such as the overall impact of the suggested solution on other potentially impacted areas; the cost related to the solution of a particular risk versus the exposure to the ALF, and, most importantly, the impact on the ALF's residents and their families.

Phase Three – Implementation

It is this phase that brings the entire process together resulting in comprehensive risk management. Phase three includes the implementation of the remedy(ies) that address the risks the ALF has identified. This may include the drafting or updating of policies and procedures or training manuals, the implementation of training course(s) for employees and management, the installation of security and monitoring technology, and other risk solutions determined as

part of the phase two process. Proper implementation of the solution is imperative. So often, facilities have policies and procedures that are well written and thought out, but not put to use because of a lack of understanding regarding their importance. Many times, risk management solutions are left on the shelves and not reviewed and discussed as part of daily operations. As part of the facilities culture, management needs to understand that risk management is part of the daily operation and exists for the protection of the residents and the overall operation of the facility.

It is important to note that all potential risks can never be identified, and all risks can never be completely absolved. This is why insurance plays an important role in the risk management equation. Insurance should be looked at as an element of the solution rather than the ultimate solution. ALFs should be proactive in risk management to limit exposure and lessen their reliance on insurance. Proper structuring of insurance programs should take into account the other risk management efforts the ALF conducts. Indeed, an ALF with no risk management policies and procedures should retain higher limits of insurance resulting in equally higher premiums. However, ALFs that apply proper risk management techniques can be rewarded with lower insurance premiums and less claims history which directly effects the insurance premium equation.

ONGOING RISK REVIEW

As stated above, ongoing risk review is a necessary component to proper risk management. This review should include items such as semi regular review of industry news and related issues, frequent review and assessment of regulatory issues and the ALFs compliance with old and new regulations, regular staff reviews and group staff meetings and weekly or monthly review of incident reports to identify patterns related to specific incidents. This ongoing monitoring is sure to have a positive impact on the operation of any ALF and provide and its residents.

CONCLUSION

Proper risk management is something that should become part of the regular business operations of any ALF. ALFs should not wait until something occurs to address risk exposure. This waiting will surely cost more in the long run in terms of liability, public perception and direct cost to the ALF.

Aside from the cost reduction that can result from proper risk management, the facility will appreciate better overall operation, employee retention, and resident safety. These improvements will undoubtedly result in increase of occupancy for the ALF. Discuss your facilities risk exposure with a risk professional and determine the best approach for management of risk for your facility. It is important to address your risk exposures today and not wait for the potential risk to become reality.

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This newsletter will contain articles on a wide variety of subjects related to risk management, patient safety, insurance, quality improvement, medicine, healthcare law, government regulations, as well as notices of improvement and other relevant information of interest to risk managers. The articles are usually written by *AHRMNY* members, so the newsletter serves as an opportunity for members to showcase their writing talents.

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