A H R M N Y

RISK MANAGEMENT JOURNAL



JOURNAL OF THE NEW YORK RISK MANAGEMENT CHAPTER OF ASHRM

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The Association for Healthcare Risk Management of New York, Inc.

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Editor's Corner

AHRMNY's Risk Management Journal (RMJ) is the official journal of The Association for Healthcare Risk Management of New York, Inc. (AHRMNY) and is published several times a year.

RMJ's Mission Statement: To enhance the quality of healthcare delivery through education, research, professional practice, and analysis specific to risk management issues.

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

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Article Requirements: Maximum article length 3,500 words. Photos should be high-resolution JPEGs (at least 300 dpi); AHRMNY will not publish articles promoting products or services.

The information presented in AHRMNY RISK MANAGEMENT JOURNAL is for educational purposes only.

Questions or comments to editors may be sent to ahrmny@gmail.com

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PRESIDENT'S MESSAGE
from Rob Marshall



Welcome to The Association of Healthcare Risk Management of New York, Inc.!

Certainly, what the last 16 months has shown us is that the world is changing in fundamental ways which has led to dramatic shifts in the landscape of risk faced by organizations throughout the globe. Global pandemic, digital revolution, climate change, stakeholder expectations, and geopolitical risks will play a significant role moving forward.

As risk professionals supporting healthcare organizations, this will require expanding our competencies and sharing institutional knowledge and experiences. Our association will continue to provide programs and networking opportunities that will allow our members to continue to grow and expand their relationships and industry knowledge.

Under the leadership of our immediate past President, Mike Brendel, the association was able to continue to operate effectively in a virtual environment; increase membership and, offer a multitude of educational webinars. Working with Mike and the rest of the association board during this past year was incredibly rewarding, and we thank Mike for his work and leadership.

We will continue to provide opportunities for our members to learn, grow and network with peers through both in-person and virtual meetings. We will be coming out after the summer with our fall educational and social event meetings for the remainder of 2021 so please keep a lookout for the announcements!

Finally, members should get involved! If you are interested in joining a committee, please reach out to me or President-Elect, Dr. Victor Klein. Also, if you have any suggestions on how to make our association more valuable please don't hesitate to send me a note.

Best Regards,

Rob

On behalf of myself and the entire AHRMNY Board, we thank the following sponsors for their generous support of our 2021 Educational Programs

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Achieving Health Equity: Addressing Root Causes and Eliminating Risks

By Dr. Ronald Wyatt

"I was crushed," she said in a video posted to Facebook. "He made me feel like I was a drug addict."

Dr. Susan Moore, a Black woman and medical doctor was in the ICU under treatment for COVID-19. Dr. Moore pleaded to be believed. She begged that her pain be treated. Her dignity had been taken. "This is how Black people get killed, when you send them home and they don't know how to fight for themselves," Dr. Moore said. Dr. Moore died two weeks later. Dr. Moore was being cared for in an accredited academic medical center. She did not have a problem with access, or language. Dr. Moore was fully aware of the seriousness of her condition and despite her attempts, she was not successful. In response to her preventable death, the hospital CEO, responded by saying the "I do not believe that we failed the technical aspects of the delivery of Dr. Moore's care, I am concerned, however, that we may not have shown the level of compassion and respect we strive for in understanding what matters most to patients. I am worried that our care team did not have the time due to the burden of this pandemic to hear and understand patient concerns and questions. He went on to say, that the nurses and medical staff might have been intimidated". [1] This tragic event illuminates the root causes of the system failures that contributed the preventable death of Dr. Moore. Moreover, it underscores the extensive body of research that has demonstrated the unequal treatment of Black, Indigenous, and other People of Color populations in the US healthcare system. [2]

In 2010, Don Berwick MD, then President of the Institute for Healthcare Improvement and former CMS Administrator, stated that "race is an independent risk factor for death in the USA".[3] A decade later, the USA and the world is in the throes of the COVID-19 pandemic that has laid bare the unequal healthcare system that exist. A study of selected states and cities with data on COVID-19 deaths by race and ethnicity showed that 34% of deaths were among non-Hispanic Black people, though this group accounts for only 12% of the total U.S. population.[4] The Black maternal mortality rate is 3-4 times what is for white women, regardless of socioeconomic status or level of education attained.[4]

A landmark report from the Institute of Medicine (IOM) in 2003 documented that from the simplest to the most technologically advanced diagnostic and therapeutic interventions, African American (or Black) individuals and those in other under-resourced communities receive fewer procedures and poorer-quality medical care when compared to white communities.[5,6] These differences existed even after statistical adjustment for variations in health insurance, stage and severity of disease, income, or education, comorbid disease, and the type of health care facility. Very limited progress has been made in reducing racial/ethnic disparities in the quality and intensity of care.[7] The IOM report concluded that multiple factors contribute to racial disparities in medical care and that unconscious bias by health care professionals contributes to deficits in the quality of care.

In the 1899 seminal publication, "The Philadelphia Negro", WEB DuBois wrote "The most difficult social problem in the matter of Negro health is the peculiar attitude of the nation toward the well-being of the race. There have... been few other cases in the history of civilized peoples where human suffering has been viewed with such peculiar indifference".[8] To begin the eliminate the peculiar attitude, that has persisted for too long, the leading root causes must be corrected.

These root causes are the major risk factors contributing to the preventable harm, preventable injury and preventable death of the racially marginalized and other under resourced populations in the US and globally. To better understand these root causes, we must first understand the definitions of the root causes and factors that contribute to the higher risk.

The IHI Whitepaper, "Achieving Health Equity: A Guide for Health Care Organizations, defines health disparity, health equity and health inequity.

Health equity as defined by Professor Margaret Whitehead, head of the WHO Collaborating Centre for Policy Research on the Social Determinants of Health, is health differences "which are unnecessary and avoidable but, in addition, are also considered unfair and unjust." Whitehead goes on to state that, when there is equity in health, "ideally everyone should have a fair opportunity to attain their full health potential and, more pragmatically, no one should be disadvantaged from achieving this potential, if it can be avoided."[10] This is the definition can be used as a guide to work on improving health equity.

Additional definitions recommended in the IHI paper are:

- **Health disparity and health inequity**: Health disparity is defined as the difference in health outcomes between groups within a population. While the terms may seem interchangeable, "health disparity" is different from "health inequity."

- **"Health disparity**" denotes differences, whether unjust or not. "Health inequity," on the other hand, denotes differences in health outcomes that are systematic, avoidable, and unjust.
- **Health care disparity**: Defined by the Institute of Medicine as "racial or ethnic differences.

The IHI white paper focuses on disparities in health outcomes rather than the provision of health care; however, the equitable provision of health care is essential to reducing disparities in health outcomes.

Major contributors and root causes that drive health and health care inequities include:

1. Implicit bias
2. Microaggressions
3. Stereotyping
4. Structural and Institutional racism.

Implicit bias refers to how unconscious stereotypes or attitudes, which have arisen from pre-formed mental associations, can affect what we say and do without our knowledge and may even contradict our conscious beliefs. These feelings are so deeply woven into our psyche that it has been shown that implicit attitudes may be better at predicting behavior than self-reported explicit attitudes.[12]

Scientific evidence indicates that conscious and unconscious bias combine to create patterns of racial/ethnic discrimination in employment, bank loans, housing, purchasing a car, and hailing a taxi. Individuals who face discrimination are aware of some of these experiences, which are a source of psychosocial stress. Self-reported measures of discrimination were adversely related to multiple indicators of health (eg, hypertension, all-cause mortality, incident asthma, incident breast cancer, and poor mental health), several early indicators of clinical disease (eg, inflammation, carotid intima-media thickness, visceral fat, obesity, coronary artery calcification, shorter telomeres, and cortisol dysregulation), and health behaviors (eg, poor sleep quantity and quality, cigarette smoking, and substance use).

Implicit biases are pervasive. Everyone possesses them, even people with avowed commitments to impartiality. Implicit and explicit biases are related but distinct mental constructs. They are not mutually exclusive and may even reinforce each other. The implicit associations we hold do not necessarily align with our declared beliefs or even reflect stances we would explicitly endorse. We generally tend to hold implicit biases that favor our own in-group, though research has shown that we can still hold implicit biases against our in-group. These biases serve as a survival mechanism. This is especially true during a crisis, like a pandemic, when care teams are fatigued, burned out, anxious and depressed.[13] The result of these human factors include thinking fast, taking cognitive shortcuts, increased use of microaggressions and stereotyping, all of which likely contributed to the failures in the care of Dr. Susan Moore.

Implicit biases are malleable. The implicit associations that we have formed can be gradually unlearned through a variety of debiasing techniques."[15]

Debiasing techniques to consider are awareness of implicit bias, increasing workforce diversity, counter-stereotype training, stereotype replacement and imaging, individuation, perspective taking, intergroup contact and mindfulness.

Stereotyping is an ending point of a generalization, standard mental picture that represents an oversimplified opinion, a prejudiced attitude, and/or an uncritical judgment and it does not consider whether the statement fits the individual. The temptation to group people by perceived common traits is known in any other sphere of life as stereotyping. In healthcare there is also a dangerous habit of racial stereotyping. This tendency to treat people in the same social group as similar, to enter biological essentialism, unfairly simplifies the complexities and breadth of individual differences. Stereotyping has been shown to result in Black and Hispanic and Asian people receiving inadequate pain treatment, lower levels of antibiotic usage, and fewer Asian people with dementia being prescribed anti-dementia drugs than white people.[17]

Racial microaggressions are brief and commonplace daily verbal, behavioral, and environmental indignities, whether intentional or unintentional, that communicate hostile, derogatory, or negative racial slights and insults to the target person or group. They are not limited to human encounters alone but may also be environmental in nature, as when a person of color is exposed to an office setting that unintentionally assails his or her racial identity. For example, one's racial identity can be minimized or made insignificant through the sheer exclusion of decorations or literature that represents various racial groups.[16]

Structural racism is the leading root of inequities. Racism, as defined by Camara Jones MD MPH, is a system that structures opportunity and assigns value based on the social interpretation of how one looks, which unfairly disadvantages some individuals and communities, unfairly advantages other individuals and communities; and saps the strength of the whole society through the waste of human resources.

Undoing the system of racism requires dismantling structures, policies, values, practices, and norms that have resulted in the disparate clinical outcomes that currently exist in health and

healthcare. This goes beyond the clinical encounter and must include entire communities.[17] In a 2017 report, Dr. Zinzi Bailey describes these structures of racism as a key determinant of population health including medicine, public health, housing, and human resources.[18]

For over 400 years, the USA has operated on the principle of racial capitalism that has resulted in non-white populations as the quintessential essential work force. Racial capitalism is the fundamental cause of racial and socioeconomic inequities that is seen in disease disparity and outcomes. Pirtle delineated additional areas of racial capitalism including residential segregation, the shaping access to flexible resources such as money, power, prestige, and beneficial social connections all which impact health outcomes, what is referred to as the social determinants of health. Racist capitalism has contributed to pandemics in the past as well as the current COVID-19 pandemic.[19]

Structural racism must be dismantled. A "Roadmap for Promoting Health Equity and Eliminating Disparity" published by the National Quality Forum advocates for identifying and prioritizing disparity, implementing evidence-based practices to reduce disparity, developing, and using health equity performance measures and providing incentives to reduce disparity and achieving health equity. The roadmap provides guidance for addressing a wide spectrum of disparities based on age, gender, income, race, ethnicity, nativity, language, sexual orientation, gender identity, disability, geographic location, and other social risk factors. It emphasizes the importance of cultural competence, community engagement, and cross-sector partnerships to reduce disparities. In particular, the roadmap includes measurement beyond clinical settings, structures, and processes of care. For example, it includes the assessment of collaboration between healthcare and other sectors (e.g., schools, social services, transportation, housing, etc.) to reduce the impact of social risk factors.[20]

Emerging interventions to address inequity include structural competency, structural humility, and cultural safety. These interventions must be implemented to encourage a lifelong commitment to self-reflection and mutual exchange in engaging power imbalances along the lines of cultural differences.

These approaches emphasize the value of gaining knowledge about structural racism, internalized scripts of racial superiority and inferiority, and the cultural and power contexts of health professionals and their patients or clients.[21] Structural competency is the capacity for health professionals to recognize and respond to health and illness as the downstream effects of broad social, political, and economic structures. Structural humility is the orientation emphasizing collaboration with people receiving care and populations in developing responses to structural vulnerability, rather than assuming the care teams alone have the answers.[22] This includes increased awareness of interpersonal privilege and power hierarchies in the healthcare environment.

Actions to take in the clinical setting might include restructuring clinic within constraints to best meet patient needs, advocate to change the restraints, engage the community by asking what matters not what the matter is, co-design case management with the inclusion of patient and family advocates and community leaders, and integrate behavioral service with mental health services.

Camara Jones MD MPH recommends naming racism, ask how racism operates in your system, understand how racism is embedded in policies, practices, and values. Bailey proposes that steps to dismantle structural racism and non-acceptable risks might include embracing the intellectual project of documenting the health impact of racism, medical and public health communities must reflect and increase recognition of harms arising from the uncritical use of racial categories which reinforces implicit assumptions that racial differences are genetic in origin. Change will require policies that restructure the chances for a healthy life for people of color, and righting the wrongs done by the foundational racial hierarchy that continue to shape everyday life. [23]

Necessary interventions to consider include medical and nursing schools, health care organizations, and credentialing bodies should pay greater attention to disparities in health and health care as a high national priority. These organizations should accelerate efforts to increase awareness of disparities, enhance diversity in the health professions, and work toward eliminating structural and institutional risks that result in harm which harms patients, families, workforce and the organization and its adverse effects on health and health care.

Achieving health equity requires leadership and system wide commitment to codesigning an intentional framework. Marshall Chinn has recommended that this intentional design includes to advance health equity consists of two simultaneous tracks: Create a culture of equity in which the whole organization—senior leadership, mid-level management, front-line staff, and clinicians—truly values and buys in to the mission of advancing health equity. Developing a culture of equity requires an inward personal look for biases as well as examination for systematic structures within the organization that bias against and oppress marginalized groups.[24]

Health care systems should commit to the stratification of clinical quality measures and patient experience by race, ethnicity, language, sexual orientation and gender identity, disability status and socioeconomic status. This will help systems discern potential disparities, safety risks to the system as well as help develop action plans to address disparities found in stratified analyses of quality measures.

Other interventions must include data collection methods and measures to identify participants' proficiency in the majority language and need for language services. Use of qualified medical interpreters throughout the care continuum, and consideration of policies which address the use of minors and family members when qualified interpreters are not immediately available. Establishment of measurable thresholds for use of qualified interpreters—i.e., what percent of encounters qualified interpreters should be used rather than less ideal alternatives—across inpatient and outpatient settings. Improving patient and family experience requires more evidence of input by and engagement of patients in the design, implementation, and evaluation of the language access services and written translated documents. Stratification of performance data by language as well as stratification of patient experience, clinical performance, and safety data by language to detect and address health care disparities should be developed and monitored.

Leadership including governing boards will need to become more competent in the methods of provisions of structural competency, cultural humility, and anti-racism training and/or orientation programs for all administrative and clinical leaders.

Linking health equity measures to accreditation programs would be an intermediate forcing function whose time has come. A national safety goal to ensure structures and processes to eliminate disparity and achieve health and health care equity is urgently necessary. Integrating health equity measures into accreditation programs can increase accountability for promoting health equity and reducing disparities.

Identifying and mitigating risks that contribute to disparity and its resultant harms include but is not limited to take an equity focus in practice and training: be mindful and make others aware of the unequal distribution of health, consider the material, psychosocial or behavioral barriers that patients may be experiencing and possible solutions (eg, referrals to economic/employment advice, food banks, parenting programs, children's centers , psychological support), generating evidence: put inequalities at the heart of the design, implementation and evaluation of interventions and services, considering representativeness of participants and the possibility of differential uptake and effectiveness, the creation of examples of better practice and seizing opportunities to harness the increasing powers of safety data to further our understanding of harm.[23] Advocate for more equitable resource allocation and distribution, both within local, state and national health policies and among other government sectors.

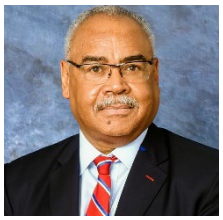
Health systems that treat equity as a core strategy can take five concrete actions to implement it.[25]

1. Make health equity a leader driven priority.
2. Develop structures and processes the support health equity.
3. Take specific actions to address the multiple determinants of health.
4. Confront institutional and structural racism within the organization.
5. Partner with community organizations.

Large social inequities, in health and health care, are causing preventable harm that is unacceptable in a nation founded on the principles of liberty, equality, and justice for all. There is inadequate recognition that dismantling racial bias in all its forms is likely to be a potent risk mitigation intervention. The urgency of this moment is fierce and demands us to organize, strategize and act.

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About the Author



Dr. Ronald Wyatt is Vice-President and Patient Safety Officer at MCIC Vermont. Prior to joining MCIC Vermont, Dr. Wyatt was formerly Chief Quality and Patient Safety Officer at Cook County Health, one of the largest public health systems in the United States. He also served as Chief of Patient Safety and Quality for the Hamad Medical Corporation in Doha Qatar. Dr. Wyatt was the first Patient Safety Officer at the Joint Commission and in that role contributed to National Patient Safety Goals.

Dr. Wyatt Co-chairs the Institute for Healthcare Improvement (IHI) Equity Advisory Group and is faculty for the IHI Pursuing Equity Initiative and is a m member of the ACGME Clinical Learning Environment Review committee (CLER) as well as faculty on the ACGME Disparity Collaborative.

Dr. Wyatt serves on several boards including the IHI Certified Professional in Patient Safety (CPPS), the Society to Prevent Diagnostic Error (SIDM) and the Consumers Advocating for Patient Safety (CAPS). He is also a credentialed course instructor in the School of Health Professions at the University of Alabama Birmingham, teaching a graduate course in health policy with a focus on safety and quality.

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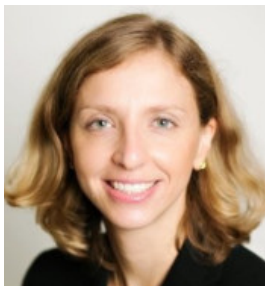


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BOARD TRANSITIONS



Mary Steffany retires from AHRMNY Board after eleven (11) years of service. Mary is a Past-President of AHRMNY. During her tenure, she held positions as Treasurer and Board of Director. She was Chair of the Education, Public Relations, and special 25th Presidents' Anniversary Committees. Mary Co-chaired the Publications Committee helping to bring about timely and informative articles in The Risk Management Journal. Mary also Co-chaired the Bylaws Committee and was instrumental in updating the organization's Bylaws.

The AHRMNY Board is forever grateful to Mary for her tireless efforts in serving the New York Risk Management and Patient Safety community. We will certainly miss Mary and wish her all the best in her retirement.



Ellen Burford retires from her position as Board of Director. Ellen has collectively served as an Officer and Director of AHRMNY for several terms. She previously held positions as Treasurer and Board of Director. Ellen chaired the finance committee and was an active member of the education committee.

We wish Ellen all the best in her future endeavors.

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Making a Federal Case Out of It: The Perils, Pitfalls & Protections for Mandated Reporters of Suspected Child Abuse

By Christopher Simone and Jason R. Corrado, Sr.

Introduction

While the possibility to someday being sued for medical malpractice looms for any physician, the same probably cannot be said for accusations of a constitutional dimension – literally. But for clinical providers who are mandated by law to report suspected child abuse, the potential is real. How such practitioners approach their assessment of potential child abuse, lodge their mandated report and cooperate with the investigative authorities can make a world of difference towards determining whether their conduct rises to the level of state action and/or affords them statutory immunity under state and federal law.

The Interplay Between Mandated Reporters of Suspected Child Abuse & Civil Rights Violation

The source of potential constitutional claims against the medical practitioner starts with the obligations under Title 6 of New York's Social Services Law. In particular, § 413(a) anoints physicians and nurses, among others, as "mandated" reporters who are *required* to alert authorities – the police or appropriate child protection agency - "when they have reasonable cause to suspect that a child coming before them in their professional or official capacity is an abused or maltreated child". Furthermore, since protecting children from harm is the statute's overarching goal, the range of potential abuse or maltreatment that triggers reporting can span injuries from a simple bruise to a brain trauma, whether unexplained or even with an explanation. While pediatric child abuse specialists would naturally stand at the forefront of the inquiry, any healthcare clinician could face such injuries at some point. If these duties are not clear enough, § 420 slaps mandated reporters with a Class A Misdemeanor for willfully failing to report. At the same time, however, the statute *protects* mandated reporters when they report in good faith by shielding them with immunity from civil or criminal suit.

But this immunity does not prevent disgruntled or offended parents subjected to the report from commencing suit for garden variety medical malpractice and other state law claims as a means to bootstrap constitutional civil rights violations under 42 USC § 1983. (Nor are they discouraged from doing so by their attorneys who stand to collect statutorily prescribed attorney's fees for their efforts.)

By way of background of the constitutional claims, 42 USC § 1983 provides for an action at law against a "person who, under color of any statute, ordinance, regulation, custom, or usage of any State . . . subjects or causes to be subjected, any citizen of the Unites States . . . to the deprivation of any rights, privileges, or immunities secured by the Constitution and law." Examples of these deprived rights those arising under the 4th Amendment (violations of search and seizure) and the 14th Amendment (denial due process), along with malicious prosecution or false imprisonment. (Traditional § 1983 litigation arises from actual government conduct, such as police misconduct and the like.)

Private citizens and entities, such as physicians and hospitals, are not generally subject to § 1983 liability. A plaintiff can sue physicians or hospitals, however, by alleging that they were de facto "state actors," requiring proof that they "acted under color of state law." Depending on the conduct at issue, this may be shown in any of three ways, namely the (1) joint action test, (2) compulsion test or (3) public function test. Joint action requires an agreement between the state and a private entity (not merely cooperation with the state) to act in concert to inflict an unconstitutional injury and an overt act done in furtherance of that goal causing damages -- essentially a conspiracy. Alternately, under the compulsion test the entity must act pursuant to the coercive power of, or be controlled by, the state. Lastly, the public function test is satisfied where the private citizen performs a function that is traditionally the exclusive prerogative of the state.

Even if deemed state actors, however, the private citizen and entity enjoy qualified immunity under § 1983 for performing a discretionary task if (a) their action did not violate clearly established law or (b) it was objectively reasonable for them to believe that their action did not violate such law. Clearly, where NY State law *mandates* reporting of suspected child abuse, a physician or hospital would not be violating any law by making the required report. They would thus be immune from federal suit as well, provided the report was reasonable. Reporting suspected child abuse itself is not state action.

Furthermore, when a private hospital admits and performs tests on a child for medical reasons, the hospital is not subject to liability under § 1983, even if concerns of abuse partially inform the decision. Once a child is no longer being held for any medical treatment, but a hospital continues to detain and test the child for purely investigatory reasons, however, the hospital itself becomes a part of the "reporting and enforcement machinery" of the investigating agency and may be subject to § 1983 liability.

Overall, federal courts recognize the potential Hobson's Choice facing clinicians: failure to report is a misdemeanor, but reporting where a subsequent entity determines the report was

"unfounded" may prompt civil liability. As such, even where courts have found "state action," to date they have uniformly applied a deferential standard to protect clinicians from civil liability, as well as finding them immune from liability. After all, qualified immunity is only necessary when the clinician's suspicions of abuse were wrong.

Minimizing the Risks to Mandated Reports

Determining state action and/or immunity in the context of private citizens and entities is a fact-sensitive endeavor. Thus, practitioners suspecting child abuse must be careful when assessing children, reporting and making recommendations to the state agency and the court system. Otherwise, they may be viewed as entangled with part of the enforcement mechanism (i.e. state actors) or as acting unreasonably (i.e. not entitled to immunity). Furthermore, the caution must continue throughout the process as the role of the mandated reporter rarely ends at the report itself. It can extend into the state's investigation and reach the inside of a courtroom. That is, the reporter or clinician involved must remain objective, report what is observed or – with good faith, suspected – but allow the *actual* state actors (e.g. – police department, child protective agencies, etc.) to conduct an appropriate investigation.

So, how can clinicians minimize the legal risks in reporting suspected child abuse and avoid the perils and pitfalls attendant to the reporting duty? This generally can be accomplished by maintaining their objectivity and circumscribing their role in the reporting process to no more than expected or needed.

The first step is proper documentation. Specifically, clinicians must accurately document their observations and, if relevant, discussions with family. Drawing *medical* conclusions, or diagnosing the patient's medical condition is appropriate, but drawing conclusions regarding *causation* of the condition should be left to investigators or police – unless a caretaker, parent or other individual with custody of the child identifies the cause, which should be documented and reported.

Next, clinicians should seek appropriate medical consultations as needed, including, for example, orthopedics, neurology, neurosurgery or radiology, to obtain objective assessments *where medically indicated*. (While photographs *absent* medical need is permitted under the Social Services Law[1], radiological examinations require medical necessity.) If available, the clinician also should seek a consultation with a staff pediatric child abuse specialist.

When to report, or how such report is viewed thereafter, is truly an objective standard. Governing New York State law repeatedly uses the phrase "reasonable cause to suspect" as the reporting trigger. For example, when defining mandated reporters, the law refers to persons with "reasonable cause to suspect that a child coming before them in their professional or official capacity is an abused or maltreated child." Moreover, § 419's immunity provision requires the report be made in "good faith," which will be presumed "provided such person, official or institution was acting in discharge of their duties and within the scope of their employment," and that reporting did not result "from the willful misconduct or gross negligence of such person, official or institution." In practice, examples of willful misconduct or gross negligence include circumstances where the report itself was not warranted under *any* objective criteria, was made maliciously to negatively affect the parent or guardian, or was completely unsupported by the information available to the clinician at the time.

Reasonable vs. Unreasonable Suspicion of Abuse

"Reasonableness" lies at the heart of the report as well as the clinician's subsequent conduct. In New York, the "reasonable basis to suspect" abuse or neglect carries a rather low threshold. Confronted with any unexplained injury, or illogical etiology or cause provided by the child's caretaker, the obligation to report is clear and eminently reasonable. Situations will arise, however, that are not so obvious; it is there that a clinician's "good faith" will be presumed unless the report is *objectively* unreasonable.

It is demonstrably challenging - if not impossible - to list each and every circumstance where a report is mandated, or what circumstances would be considered "reasonable" to the average person, clinician or court. But, identifying such situations that leave the clinician in peril are somewhat easier.

First, failing to take an adequate history can lead clinicians down the wrong path, towards potential liability. But, a thorough, well-documented history, including the specific source of the information, coupled with appropriate assessments and testing can readily demonstrate the reasonableness of the subsequent report.

Next, neglecting to adequately document the observations, objectives and assessments, diagnostic or test results, or conversations that informed the decision to report, can lead to liability. So, too, can failing to adequately communicate with colleagues, or seek consultations from appropriate specialists to more thoroughly investigate a child's condition. Clinicians are strongly cautioned against making assumptions as to the cause of a condition, but strongly encouraged to obtain as much objective information as is medically necessary, and seeking appropriate consultations to better understand the potential causes of any given condition or presentation.

Another manner in which clinicians place themselves at risk is is by striving for the conclusion by (1) forcing a diagnosis,

(2) rendering an unsupported opinion on causation, (3) overzealous advocacy or (4) ignoring equivocal clinical or historical data. It may be the natural inclination of medical providers to treat and cure. But, when a clinician seeks to protect a child "at all costs" by chasing the conclusion of abuse or neglect despite insufficient data, the clinician can lose their entitlement to immunity. In practice, this often presents when the clinician suspecting abuse or neglect pressures or enlists – overtly or subtlety – other physicians to support their deductions or conclusions.

For example, approaching another provider and merely saying "I think this child was abused; do you think that could be the cause of her condition", already plants the seed of an intended conclusion and may affect the other provider's judgment, objectivity or decision-making. If *consistent* with trauma, the provider may respond "it could be," possibly foreclosing further medical evaluation and arriving at the conclusion without considering the equivocal response.

Also, reporters can lean toward overzealous advocacy on behalf of the child they believe was abused or neglected due to the desire to protect the child. Advocating for the *conclusion*, however, is *not* the province of medical providers and places them at risk of liability. Clinicians can and should report about the objective findings, and if qualified, can render opinions regarding potential causes. But unless direct information as to such cause is actually *known*, the clinician should not play detective and opine as to the cause.

Approach the Report Clinically

In making a mandated report, clinicians should remain objective and conduct a reasonable assessment of a child given the circumstances presented. The most reasonable approach is to see what is present, observe, document and consult, without overreaching or prejudging. As always, treating the patient is paramount, and all appropriate and medically necessary tests should be ordered and performed. If circumstances warrant a reasonable suspicion of abuse or neglect, a report should be made with a clinical approach: describe what was observed, the results of lab or diagnostic tests, and if such information was learned by obtaining the data and history, the medical conclusions reached.

Reporters should remain clinical in their approach. For example, they should avoid concluding that injuries were caused by "child abuse" in favor of a more objection description as "consistent with non-accidental trauma". The difference is obvious: the former is a legal conclusion while the latter is akin to a medical assessment. Noting that an injury or a condition are consistent with trauma" or that "non-accidental trauma cannot be excluded" are equally appropriate for clinicians.

After the Report: Family Court Proceedings & Potential Litigation

The above-discussed clinical approach to making a report applies equally to post-report proceedings in which the practitioner likely will be involved in some way. Even after officially lodging their suspicion, mandated reporters must cooperate with the agency conducting an investigation and/or prosecuting a case against the alleged abuser. Moreover, proceedings may be criminal in nature, or civil actions involving removal of the child (and possibly siblings as well) from the custody of the parents. Whatever the circumstances, objectivity is in order.

The scope of a clinician's cooperation is far more nuanced, though, and depends greatly on their role (e.g., a neurosurgeon performing surgery will have a vastly different role than a pediatric child abuse specialist), their involvement with the child's care or treatment, and even subsequent contact with the child or the child's family. In Family Court removal proceedings, the prosecuting "state" attorneys often seek the clinicians involved to testify in court, and regularly seek "expert opinions."

An entire article could be dedicated to this one topic, but for sake of brevity, clinicians should speak with their risk management department and request the assistance of counsel familiar with these proceedings. At a minimum, the attorney will act as a guide through the process and help reduce the risks of potential litigation or liability concerns which may result *from* the process.

Of course, practitioners served with legal papers such as a subpoena, summons and/or complaint should immediately report it to their risk management department. If required to testify, either at a deposition or in court, they should request the assistance of counsel to protect both their and their employer's interests.

References on page 41

About the Authors





Christopher Simone, a Senior Partner/Co-Chair of the Litigation/ Appellate Strategy & Advocacy Group and Jason R. Corrado, Sr., a Trial Partner in the Medical Malpractice Litigation Group at Shaub, Ahmuty, Citrin & Spratt, LLP, have successfully defended mandated reporters against allegations of civil rights violations in both Federal and New York State court systems.

THE FUTURE OF DIGITAL HEALTH
Emerging Risks, Opportunities and How the Insurance Market is Responding

By Kirsten Beasley and Doris Fischer-Sanchez



Healthcare Digital (R)evolution

The convergence of healthcare and technology is not a new phenomenon; consider the introduction of computers into the healthcare system in the 1960s, the launch of the da Vinci robotic surgical system in 2000 and increasingly sophisticated CT scan systems.

Yet, digital health innovation is a distinguishable technological transformative force that also encapsulates profound cultural shifts and an altogether new way of working within healthcare[1].

In short, eHealth/digital health:

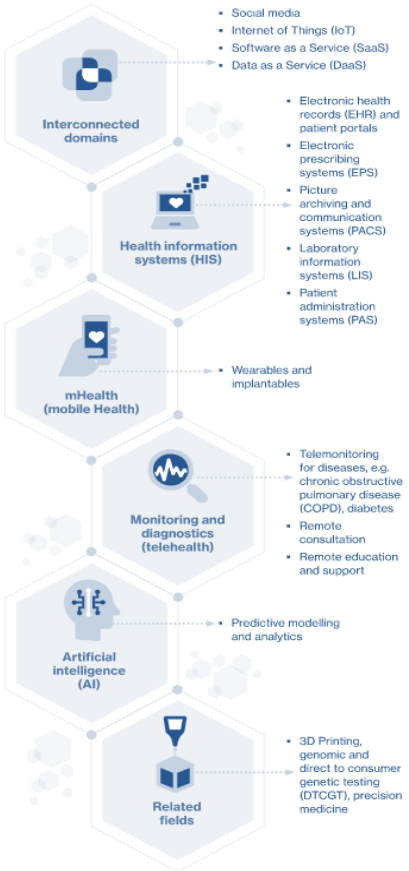
"refer[s] to the organization and delivery of health services and information using the internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a new way of working, an attitude, and a commitment for networked, global thinking, to improve healthcare locally, regionally, and worldwide by using information and communication technology"[2].

As the next frontier of technological advancement in healthcare, there are great expectations about digital health's positive disruptive potential.

There are many variant terms that are used to label this field: digital health, medical informatics, eHealth, telehealthcare, etc. Whilst there has also been much academic debate about what these terms encompass, for the purposes of this discussion we have settled on digital health or eHealth as best incorporating the broader ecosystem.

The Digital Health Ecosystem

The digital health ecosystem encompasses a myriad of technologies and concepts. Highlighted are some of the digital health segments (a list which is by no means exhaustive). There are sometimes no clear lines between 'categories' within digital health; the technologies are often interdependent.



Related Concepts

- Big Data
  - Data governance: access, storage and ownership
  - Data security
  - Secondary data use data reuse/data sales

- Interoperability and health information exchanges
- Usability considerations (ADA compliance, digital divide, heuristics, etc).



Why is it important?

The global digital health market size is estimated to be over $116 billion (as at 2019) and forecast to be nearly a $833 billion market by 2027.[3] However, interest in digital health technologies is not solely driven by the obvious economic opportunities, there are several forces that are propelling the proliferation of digital health innovations.

Most importantly, digital health tools have robust clinical utility that hold great promise to achieve better quality care, improve access, lower costs and ultimately improve health outcomes through better diagnoses and treatments.

'Big data' is the gas in the engine of most digital health innovations, thus, the sheer availability of data globally is another substantial growth driver.

Consider the global data sphere is projected to grow from 59 zettabytes in 2020 to 175 zettabytes by 2025 – a combined annual growth rate (CAGR) of 26%[4/5]; and because of the digitization of medicine, health data are amassing at an even faster pace – CAGR of 36% through 2025.[6]

A final driver has been the surge in consumer demand for digital health tools to manage their care. The demand which appeared to plateau in 2018, may have been revitalized by the forces of COVID-19.[7]

> When considering the current environment, we cannot ignore how COVID-19 has served to thrust digital health onto the world stage.

During this pandemic, multiple healthcare stakeholders have leveraged digital health technologies to facilitate necessary social distancing and enhance employee and patient safety. Thus, an interesting side effect of the pandemic has been to increase global attention towards, investment in and adoption of digital health technology.

COVID-19 has also served to escalate the 'eHealth conversation' within the healthcare property and casualty(P&C) community as insurance carriers, brokers and our clients grapple with real-time liability and insurance implications of the rapid escalation in digital health deployment, adoption, and investment.

Challenges faced by the digital health industry

There are substantial challenges that the digital health industry faces that must be considered within any insurance and liability analysis:

- Regulatory and legal frameworks that cannot keep pace within innovation, adoption and use.
- Consumer concerns about security and privacy.
- Ethical questions that inevitably arise in the adoption and use of new technologies, especially regarding the role of commercialism and monetization.
- Interoperability issues and fragmented systems – both technical (software, platforms, etc.) and 'system structure' (e.g. disparate providers, payors and regulators of healthcare).

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- Interoperability issues and fragmented systems – both technical (software, platforms etc.) and 'system structure' (e.g. disparate providers, payors and regulators of healthcare).
- Competing motivations and misalignments – payor, provider and patient (what are the priorities and how can they be agreed upon).
- Equity issues that can especially arise from swift digital implementations – e.g. digital literacy issues, digital access issues ('digital divide') and the impact on vulnerable groups (e.g. seniors – the 'grey divide').
- Usability issues for patients and providers alike.

Digital health insurance considerations

In any emerging and rapidly growing field it is important to remain attentive to shifting liability and insurance conditions.

Digital health advancements are catalyzing deployment of novel healthcare delivery and operational models that may in turn produce unforeseen perils and new flows of liability.

Digital health exposures can arise through the provision of technological products and services to patients, providers, payors and a variety of other stakeholders, both within and outside of clinical settings.

There are an extremely wide variety of digital health products and services that are increasingly being utilized in new settings and in new ways.

In such a rapidly evolving field with limited regulatory guidance and little to no legal precedent, how can risk managers and insurance professionals determine what type of insurance coverage they need.

Determining what insurance coverages are necessary requires an analysis of the insured's operations, products and services (including any contractual requirements that underpin their business) within the context of current insurance products available.

Existing relevant insurance solutions are typically siloed within a variety of standalone individual policies that address two core categories of injury: economic injury and bodily injury.



Economic Injury:	
Technology errors and omissions (E&O)	Any entity developing, designing, manufacturing, selling or implementing technology products (software, apps, hardware etc.) and services (telecoms, consulting, hosting etc.).
Privacy and security:	Any entity that touches data.

Bodily Injury:	
Medical Malpractice:	Any entity that provides professional healthcare services.
Products Liability:	Any entity manufacturing, distributing or selling a product.

Yet, digital health innovations are likely to result in new or unpredictable risks and potential harms that manifest in varying ways without regard to these traditional lines of delineation between coverages.

As operational models shift and traditional lines between risks continue to blur, insureds will be increasingly unable to distinguish the different types of exposures and potential harms when seeking insurance coverage.



- Technology E&O
- Product Liability
- Clinical trials
- Medical malpractice
- Data security and privacy

- Bodily injury
- Economic loss

To illustrate how the interaction between technology and healthcare can create complex insurance considerations, let's review a typical technology E&O loss scenario:

The client, ABC Tech, creates computer programs or applications that are required to perform in certain ways, e.g. analyze sales data and draw conclusions upon which the customer can act. However, if ABC Tech's system doesn't work, the customer may suffer financial loss as a result (lost revenue, increased expenses etc). This is a typical E&O loss scenario and technology E&O coverage can be purchased to cover the customer's financial losses when ABC Tech's product fails to perform.

But what if the services or products that ABC Tech provides are used in a clinical setting where bad outcomes can result in both financial harm to a customer, and bodily injury to a customer's patients? Which insurance policy would provide all the necessary coverage? Considering:

- Standalone tech E&O policies do not typically cover bodily injury.
- Products liability policies do not always cover economic losses.
- Both standardly exclude losses arising from professional healthcare services.

Broadly, if the technology is designed to impact people's health or even their understanding of their health (whether in conjunction with clinical professionals or not) there is the potential for bodily injury exposures in addition to the economic loss traditionally associated with tech exposures.

Similarly, if the patient interaction is facilitated or dependent on an intervening layer of technology, providers should consider whether they have more than just a traditional medical malpractice exposure.

There are a multiplicity of activities, entities and thus corresponding exposures and harms that can arise in digital health contexts:

1. Providers using, developing or implementing digital health technologies to facilitate patient interactions (diagnosis, treatment, monitoring and management).
2. Digital health platform hosts, developers and designers (software, applications, hardware), especially those that facilitate or provide patient diagnosis treatment, monitoring and management.
3. Product manufacturers, distributors, developing digital health technologies (both regulated and unregulated).

These fundamental shifts and new models have no regard for 'traditional' lines between coverage and harms; thus, digital health exposures necessitate evolutions in insurance products and underwriting approaches that address the impact of these technological innovations on risk.

Digital health exposures require coverage for:

- Bodily injury and economic loss
- Regulated and unregulated products
- Products and services often provided in cooperation with or at the direction of medical professionals.

These potentially intertwined risks demand integrated insurance solutions that creatively knit together multiple iterations of the exposures and the harms that can manifest within these novel and emerging applications of technology within healthcare.

This multi-disciplinary insurance approach is critical to avoid coverage gaps and potential disputes that may arise when seeking redress in two or three (or more?) different insurance towers for complex, interrelated, indistinguishable events.

This intertwining of coverage is not without precedent within the healthcare liability space as most medical malpractice policy forms encapsulate general liability coverages with the specific goal of minimizing potential coverage and tower disputes.

Similarly, technology E&O coverages are often written in conjunction with cyber policies due to the intertwining of coverage triggers and exposures.

However, at present, insureds with digital health exposures must cobble together coverage for their exposures in multiple towers, navigating exclusionary language and coverage terms that are incongruent.

This prevents insureds from developing a seamless and straightforward understanding of what type of loss is covered in which policy. This coverage landscape is predicated on a simplistic conceptualization of coverages and their corresponding losses wherein they each 'stay within their lanes'.

Such a perspective does nothing to address scenarios where technology is facilitating the provision of healthcare services and products outside of traditional 'lanes'. This coverage environment is further complicated by regulatory and legal frameworks that are insufficient to tackle these emerging issues due to lack of precedent (in almost every jurisdiction) and limited or lagging regulatory constructs.



Bermuda Market

The Bermuda market currently has limited ability to offer digital health risks and exposures a true multi-disciplinary coverage solution.

Whilst Bermuda has a robust and deeply experienced marketplace in each required disciple (medical malpractice, technology E&O, cyber and products liability) no carrier has developed an integrated digital health coverage alternative that addresses the increasingly blurred lines between these coverages.

Each field has its limitations:

1. Medical malpractice and products liability carriers will not provide cover for economic losses.
2. Tech E&O and cyber carriers, whilst they often write the two products in tandem, will not provide coverage for bodily injury.
3. Only medical malpractice carriers provide coverage for professional healthcare services.

U.S. Market

The U.S. market is perhaps further along the pathway towards offering integrated solutions that attempt to address increasingly intertwined and complex risks.

Carriers that specialize in the life sciences and technology industries have developed forms that endeavor to provide a suite of coverages, including cyber, technology E&O and products liability.

However, many of these solutions exclude professional healthcare services. The healthcare liability market is lagging behind their counterparts in offer multi-disciplinary solutions, with only one U.S.-based carrier offering a solution that provides medical malpractice, technology E&O (and products liability), and cyber coverage in one policy.

U.K. Market

The U.K. market has developed two market leading, innovative products which provide cover for digital health risks offering a multi-disciplinary coverage solution. Both solutions cover medical malpractice, tech E&O, cyber, public and products liability for digital health risks and are available to digital health risks located in the U.K., Worldwide and U.S. However, appetite for U.S.-based risks is somewhat more limited and approached on an individual risk basis. Additionally, Worldwide appetites can be constrained due to the complexities of cross border digital healthcare and regulations. These products do have varied approached to different healthcare segments and seem focused on entities with primarily digital health exposures. We look forward to an expansion of these products into traditional healthcare segments; this will address emerging digital health

exposures of healthcare providers seeking to expand their technological offerings.

Aside from these innovative products, integrated solutions in the London market are limited with largely siloed coverage solutions required to address the differing exposures. For example, healthcare liability carriers are seeking to limit their potential exposure for bodily injury arising from data privacy and security events. Thus, clients must increasingly seek this coverage from cyber carriers. However, the cyber market's appetite to provide coverage for bodily injury harms is extremely limited and there are very few cyber insurers who will consider the removal of the bodily injury exclusion (and still may only offer coverage on a sub-limited basis). These gaps are common and are not able to be 'elegantly' addressed when coverage must be cobbled together via siloed products.

Australasian Market

Whilst it is recognized there is a growing need for a dedicated solution in this region, product development is not keeping pace with evolving risks and technology, with only one Lloyd's based hybrid product currently available to digital health companies.

Currently, few insurers have the capability, appetite or necessary licences to underwrite coverage across multiple classes which include cyber, technology liability and healthcare malpractice. As with other territories, cyber insurers are reluctant to remove bodily injury exclusions, creating a fragmented approach to insuring this emerging area.

As market conditions continue to harden in this region, insurer appetite is becoming increasingly conservative. New product development, which is common in softer market conditions, has been largely abandoned as insurers shift their focus from growing market share to portfolio remediation. Given this move in appetite, insurers have not turned their minds to developing new digital health solutions that fully address the wide range of exposures created by this emerging sector. Additional risk identification work will need to be conducted by the insurance market to understand the complexities and implications of digital health companies' liability and regulatory exposures before they can consider developing innovative blended solutions that meet this need. In the interim, digital health companies must consider the placement of multiple policies with different insurers to address their risks, creating potential gaps in cover and uncertainty in respect to claims handling.

Conclusion

The pandemic has propelled digital health onto the global stage, as healthcare providers around the world seek to leverage technology to help combat the crisis.

This, in combination, with worldwide trends towards the digitization of medicine, has resulted in rapid technological adoption and accelerating digital health transformations.

> This digital health (r)evolution will profoundly and permanently reshape how healthcare is accessed and provided; a metamorphosis that is likely to produce novel and unexpected risks (and consequent liability).

We have already seen evidence that the convergence of technology and healthcare can produce both economic and bodily harms.

These injuries are often covered within a variety of different insurance products; yet it is increasingly clear that these traditionally siloed approaches to insurance coverage may be inadequate for digital health risks and exposures.

It is imperative that the insurance market consider how to weave together these products to provide integrated solutions that more seamlessly address emerging digital health perils.

In our continuing Digital Health Series, we will explore the insurance and liability considerations within a variety of emerging digital health domains, such as mHealth, artificial intelligence and 3D printing.

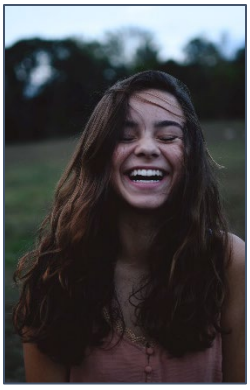
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About the Authors





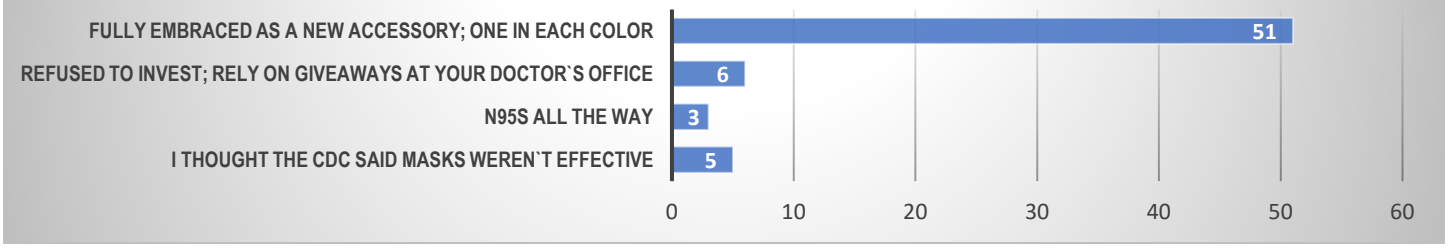
Kirsten Beasley is Head of Healthcare Broking, North America and Doris Fischer-Sanchez, Clinical and Enterprise Risk Management Leader at Willis Towers Watson.



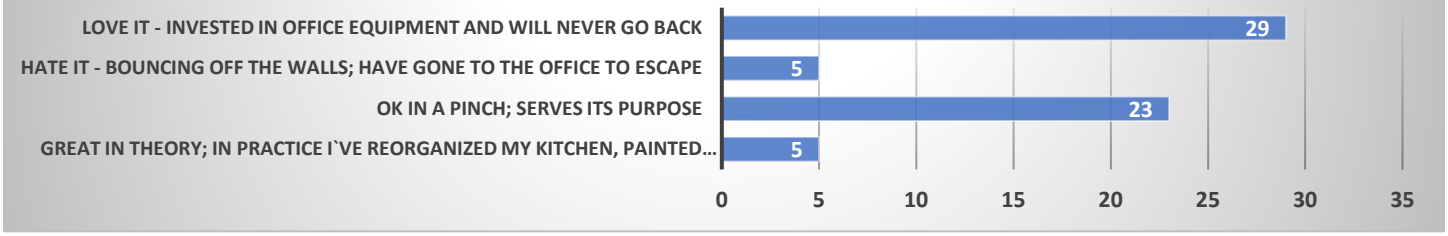
AHRMNY POLL RESULTS

It's hard to believe that a year has gone by since the COVID-19 pandemic began. In some respects, it seems like just yesterday we were reading about a virus on the other side of the world and wondering how it would impact us. In other respects, it seems like it has been a decade since we've been to a ball game or a Broadway show. Regardless of whether you are feeling like time has flown by, or stood still, or even a combination of both, it's pretty likely that you could never have envisioned, on March 1, 2020, the date of the first COVID case in NY State, what March 1, 2021 would look like. And because this year has been filled with so much tragedy, hardship and pain, we thought it might help to look at the lighter side of things for a moment. Here are the results of our poll conducted around the one-year anniversary of the pandemic. We hope they will give you a smile or even a chuckle or two. Not only can laughter help improve your mood and outlook, it has also been reported to strengthen your immune system, diminish pain and protect you from the damaging effects of stress. **Laughter truly is the best medicine.**

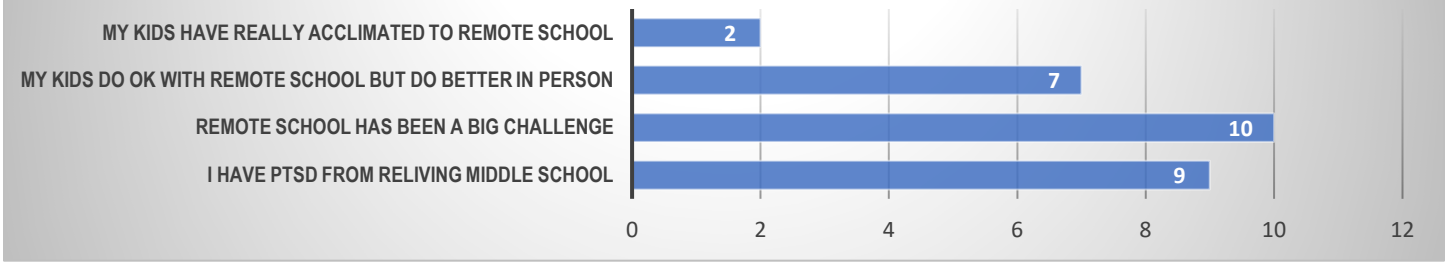
1. Thoughts on Masks



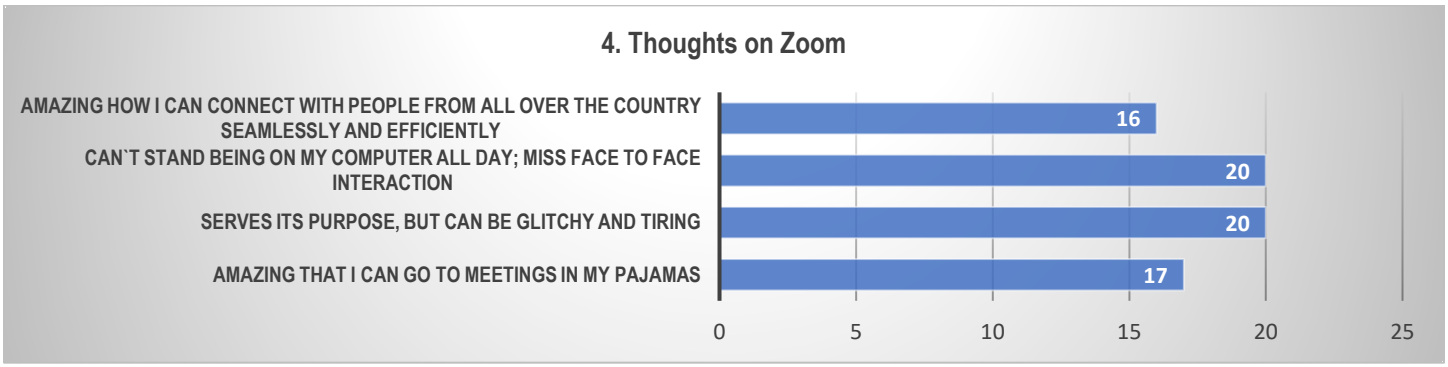
2. Thoughts on Working from Home



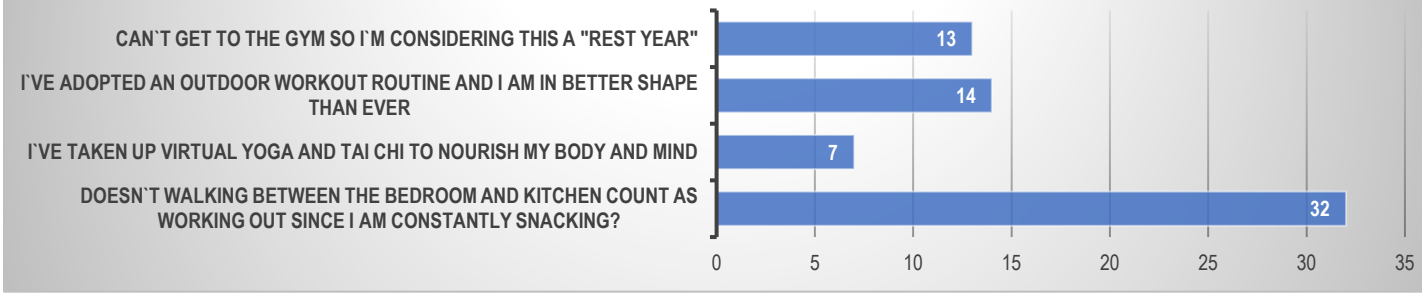
3. Thoughts on Remote School



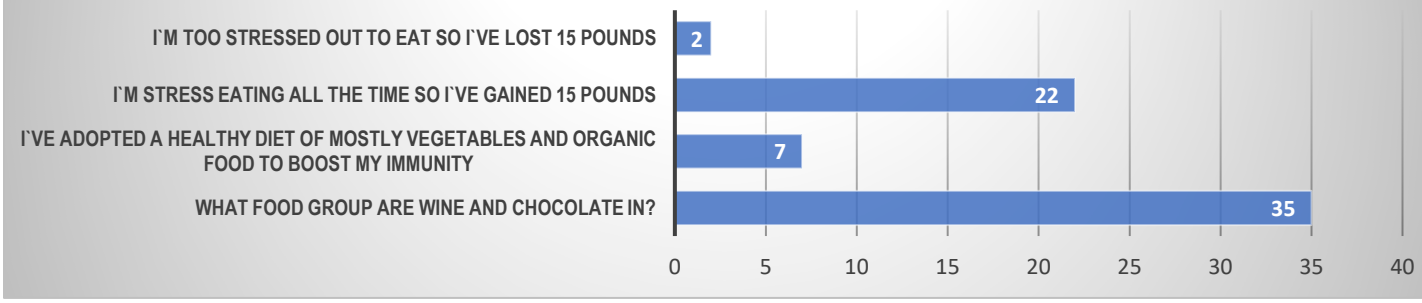
4. Thoughts on Zoom



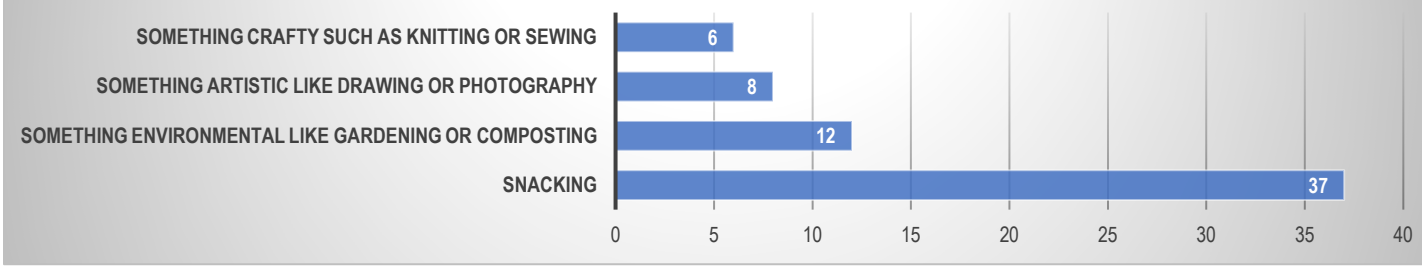
5. Covid Fitness



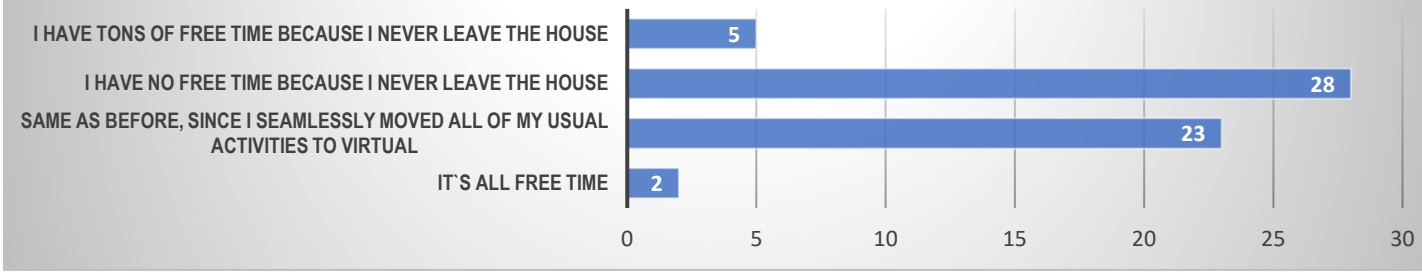
6. Covid Diet



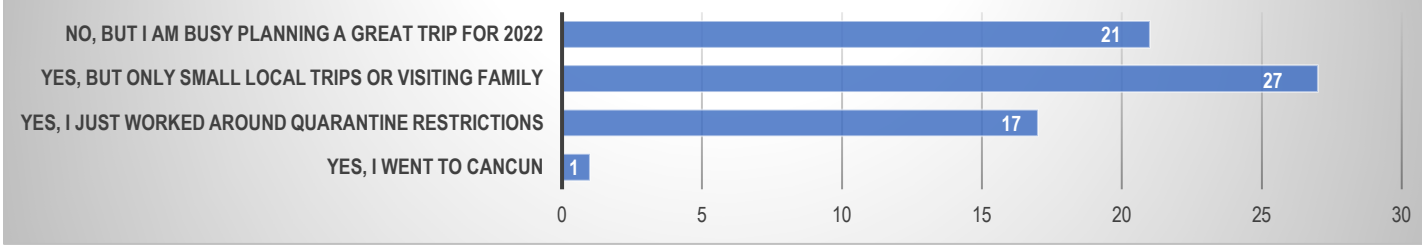
8. Covid Hobbies: I've taken up _____ since the pandemic:



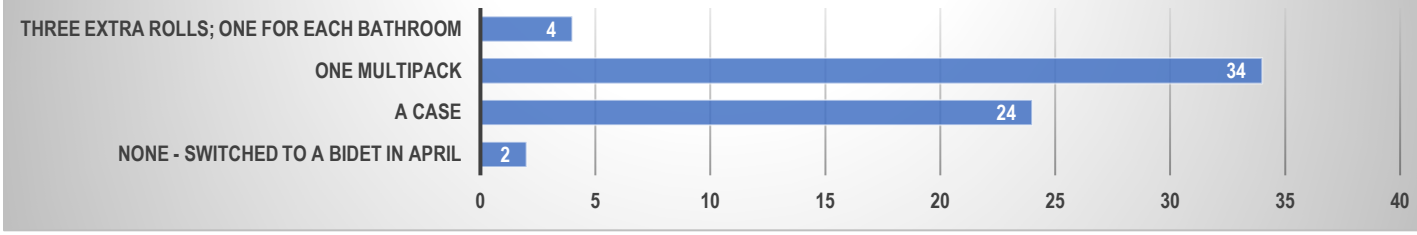
9. Thoughts on Free Time



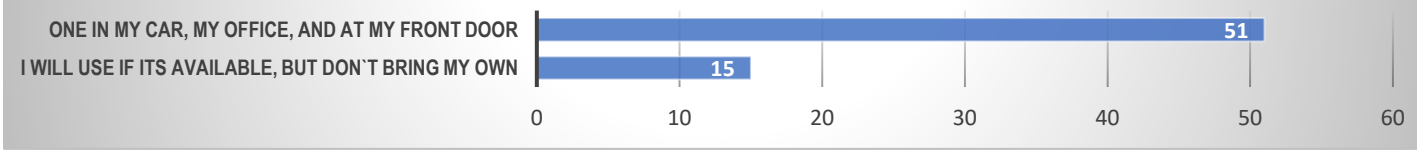
10. Did you travel during Covid?



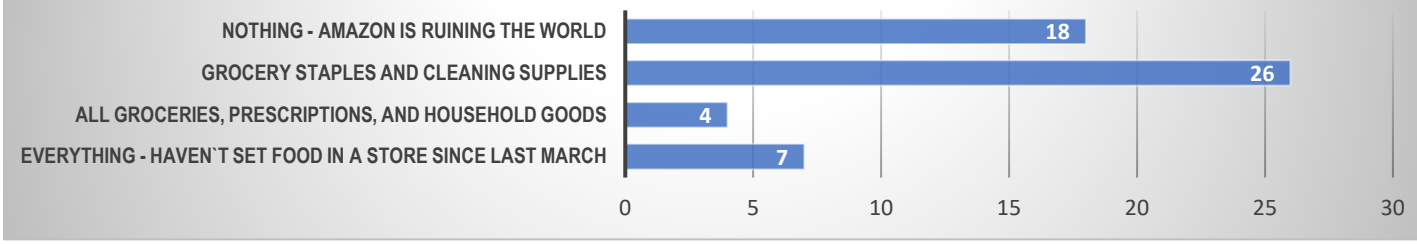
11. How much toilet paper is in your basement?



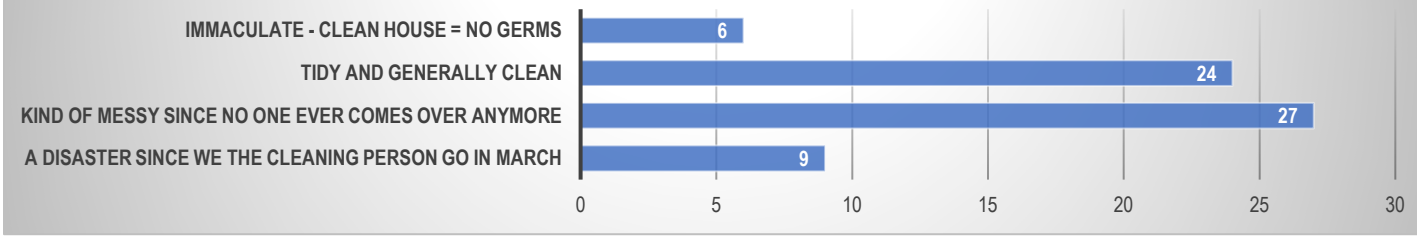
12. Thoughts on hand sanitizer



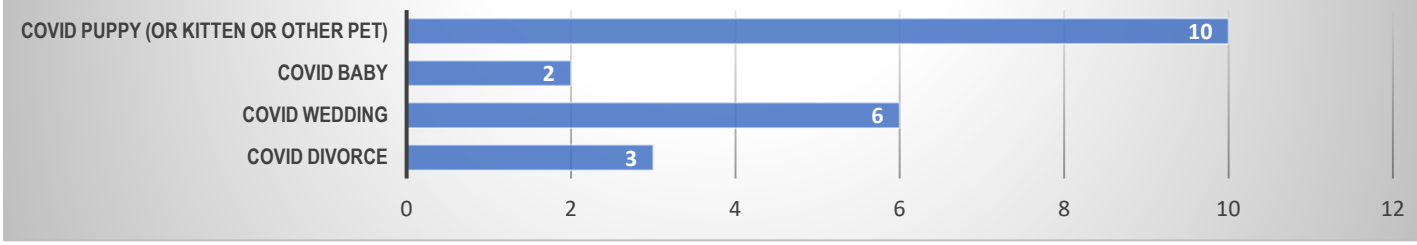
13. What do you buy online that you used to get in person?



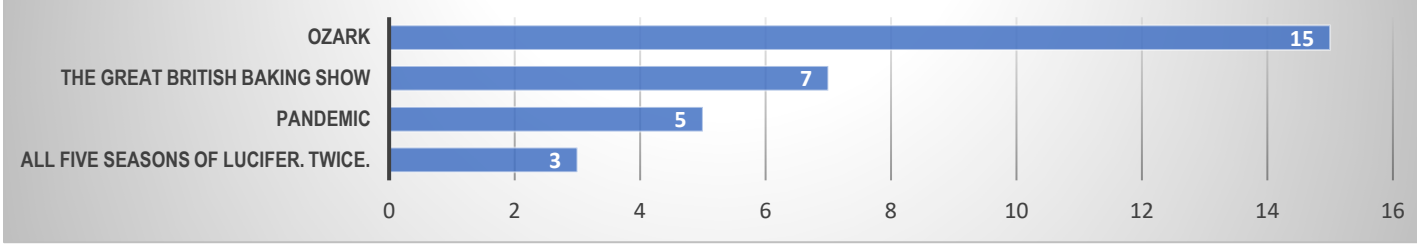
14. The condition of your house

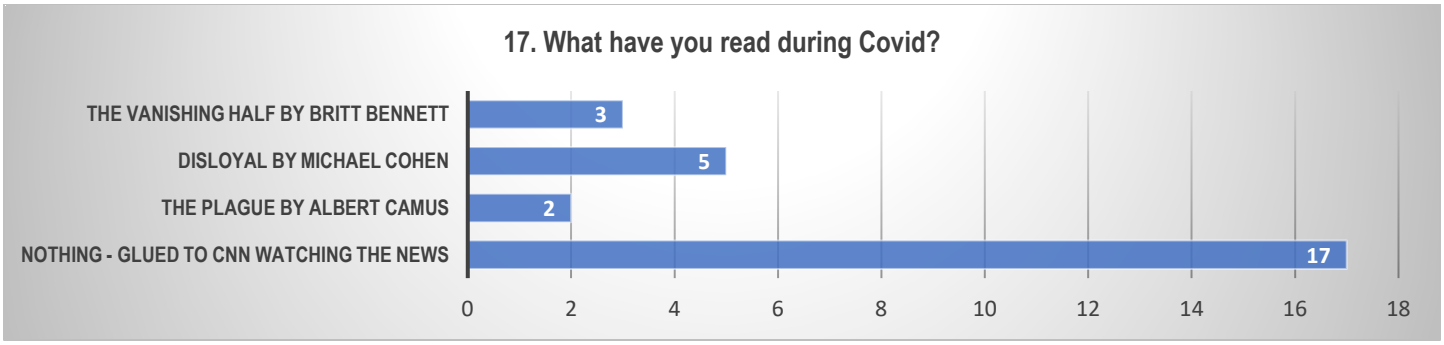


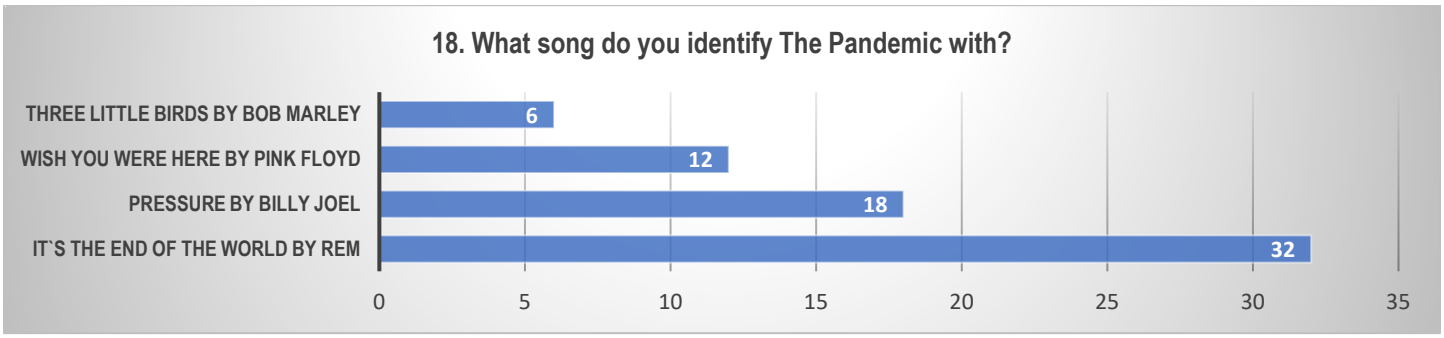
15. Covid Life Events

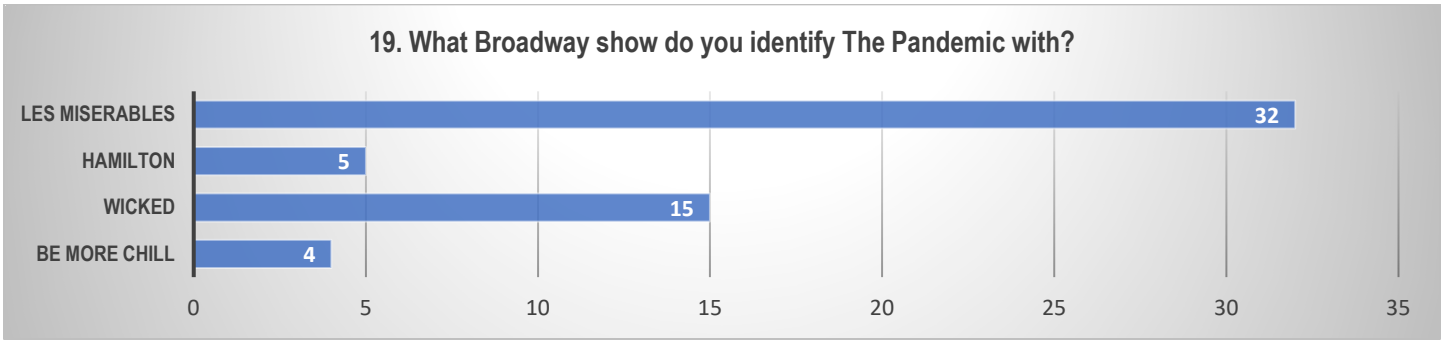


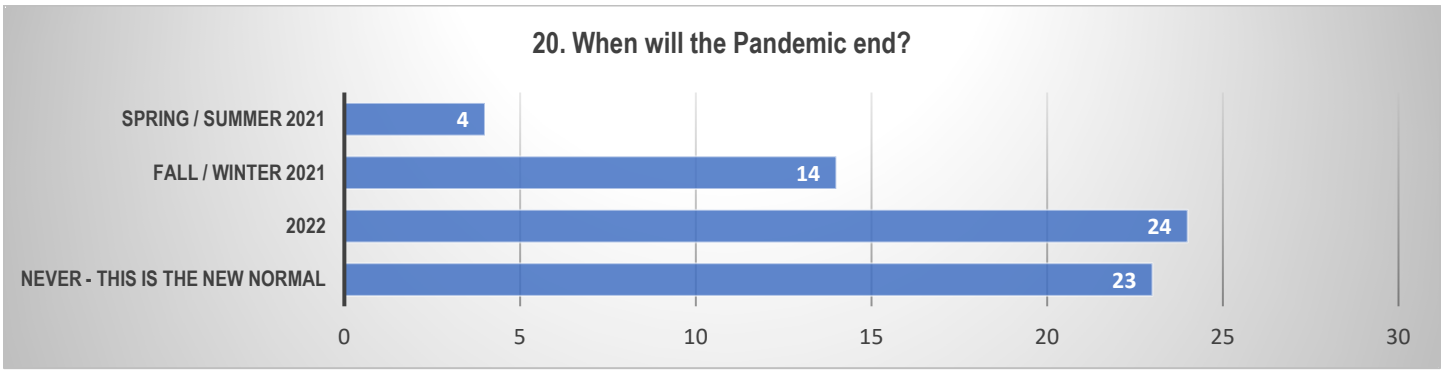
16. What have you watched on Netflix during Covid?











[Click here to read how laughter can improve your health]
[Learn how to harness the powerful benefits of laughter and humor.]

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The AHRMNY Publications Committee hopes you enjoyed participating in this poll.

Terminating the Physician-Patient Relationship

By Annemarie Provencher

Questions about terminating the physician-patient relationship are among the most frequent calls to Coverys' risk management telephone consultation service. Some physicians ask whether they should terminate care, while others ask when and how to end their relationship with a patient. The reasons for wanting to terminate the physician-patient relationship include:

- Verbal abuse or threats of physical harm.
- Treatment non-adherence.
- Patient demand for money or threatening to sue.
- Failure to meet financial responsibilities.
- Problematic substance use.
- Personality conflict/lack of trust/deterioration in the therapeutic relationship.
- Repeated failure to keep appointments.
- Practice-related criminal activity (for example, forged prescriptions).
- Divorced parents who disagree on care delivered to a minor.
- The physician has insufficient skills to provide adequate treatment to the patient.

Other reasons for which termination might be indicated include unrealistic expectations on the part of the patient, stalking, sexual advances, a change in the patient's insurance coverage, or the physician's withdrawal from the provider panel of the patient's healthcare insurer.

Some physicians believe they do not have a right to terminate their professional relationship with a patient. Others fear that termination may lead to allegations of abandonment. Still others worry that terminating the professional relationship will exacerbate an already volatile situation. Termination of the professional relationship with a patient is a process, not an event. Under the best of conditions, this process requires a discussion with the patient in an attempt to understand and, if possible, remove the barriers that are interfering with the professional relationship. When termination is inevitable,

- Provide a written notice to the patient.
- Include healthcare options.
- Memorialize the termination by documenting the entire termination process.

This article explores the most commonly asked questions about the termination process along with applicable risk management recommendations and guidance.

Reasons for Termination

When is it acceptable to end the professional relationship with a patient?



Termination may be appropriate whenever the trust that once marked the physician-patient relationship is so diminished that the physician's ability to give optimum patient care is compromised.

Are there any reasons when it is NOT appropriate to end the relationship with a patient?

Reasons that cannot be used for termination include limited English proficiency, gender, race, religion, sexual preference, or any other status within a protected category under federal or state legislation.[1] In addition, patients protected under the Americans with Disabilities Act (ADA) may be dismissed from the practice but only for one or more of the lawful reasons that a non-disabled person might be dismissed, not because of the disability.

Risk Management Recommendation

- Seek legal advice when confronted with a situation in which federal or state discrimination laws may apply.

Abandonment Allegation

When could termination be considered abandonment?

Terminating the professional relationship with patients in medical crisis, those undergoing or needing treatment for an acute problem, and pregnant women who are at more than 20 weeks gestation may be considered abandonment. Abandonment may also be alleged if termination took place so abruptly that the patient did not have time to find a new physician to take over treatment and if the patient suffers injury as a result of the physician's haste or carelessness in terminating the professional relationship. According to the AMA's Council on Ethical and Judicial Affairs, a physician may not discontinue treatment of a patient as long as further treatment is medically indicated, without giving the patient reasonable notice and sufficient opportunity to make alternative arrangements for care.[2]

Risk Management Recommendations

- Resolve the crisis; wait for the acute problem to pass and/or delivery occurs before initiating termination in any of these situations.
- Continue to treat the patient for a reasonable period of time (30 days in most states) to allow the patient to arrange for alternative care by another provider.

Termination Process

Do I have to tell the patient the reason for termination?

Yes. Openness and honesty are as much a part of the termination process as they are a part of the physician-patient relationship.

What is the best way to go about the process of termination?
In most cases, terminating the patient-physician relationship should not be the first choice. Before proceeding with termination, consider the patient's current state of health and course of treatment, exploring alternative options and having a discussion with the patient giving them an opportunity to change behavior. It may be possible to resolve the problem with a payment schedule, a mutually agreed upon contract, or other promise that makes termination unnecessary.

Risk Management Recommendations

- If all efforts have been exhausted and there is a decision to terminate the physician-patient relationship, verbally communicate this to the patient and the reasons for dismissal.
- Follow up with a formal written termination letter that includes the following information:
  - Reason for termination.
  - Effective date of termination, usually at least 30 days from the date of the letter.
  - The importance of the patient's finding continuing medical care, if such care is required.
  - Notification that care should be sought at a local emergency department if medical attention is required after the 30-day period and before a new provider has been selected.
  - Referral source the patient may use to find another physician of like specialty in the community (i.e., state medical society or patient's insurance carrier).
  - Offer to send the medical record to the new provider at the patient's request. Include a release form with the termination letter.
- Send the letter by both regular and certified mail, return receipt requested.
  - Keep copies of all the materials in the patient's medical record including mail receipts.
  - If the letter is returned because it is undeliverable, file the unopened letter in the medical record.
- Specify in a letter from a group practice whether the professional relationship is being terminated only with the physician signing the letter, with several group members (name each group member with whom the relationship is being terminated), or with the entire practice.
  - Make sure the physician with whom the relationship is being terminated signs the letter.

Are there any organizations or agencies I need to contact if I'm planning to terminate a relationship with a patient?

Some managed care plans, state agencies, and other insurers may have specific requirements concerning termination.

Risk Management Recommendations

- Consult with organizations with whom you contract with to provide patient care.

Abide by any termination rules they may have to avoid breach of contract issues.

Notification Period

Is the 30-day notification of the patient a hard-and-fast rule?

Notification periods vary by state. There may or may not be a legal mandate depending on the state. However, 30 days is the generally accepted minimum period of time to allow the patient to find a new provider. There may be exceptions to the 30-day notification period. For example, when patient behavior is so egregious that it damages the physician-patient relationship beyond repair. This could include when a patient threatens or commits violence against the physician or office staff, the patient commits a criminal act involving the practice, falsifying medical records, or blatant sexual advances.

Verbally Abusive Patients

I have a patient who is verbally abusive to my staff. At his last visit, he became disruptive in the waiting room and verbally threatened my front desk staff. I do not want him back in my practice. Can I terminate care immediately, or do I have to give reasonable notice?

Although rare, there are some patient actions that call for immediate termination with no intermediate treatment period. While physicians have a duty to the patient, they also have a duty to protect the safety of staff and other patients.

Risk Management Recommendations

- Discuss behavior issues with patients who are verbally abusive. Warn the patient if the behavior continues, they will be terminated.[3]

- Document the discussion, and if the patient continues the unacceptable behavior, start the termination process. As mentioned in the above situation, in cases where threatened or actual violence is directed toward the physician or staff, termination may be verbal and immediate. Again, clear documentation of the patient's behavior in the medical record can support your decision to terminate the relationship should the patient allege abandonment of care.

Non-Adherent Patients

I have a patient who I have been treating for years who is non-adherent to her treatment plan. She doesn't keep appointments, follow screening recommendations, or take her medications. I would prefer not to terminate my professional relationship with her. However, I feel that I need to do something. What are my options?

One of the basic ethical principles of medicine states that every person has the right to make informed decisions about their healthcare and that healthcare professionals should not impose their own beliefs or decisions upon their patients.[4]

Risk Management Recommendations

- Have a discussion with this patient to determine the patient's expectations of you.
- Identify any barriers or factors that are driving this behavior and how you might be able to work together in developing treatment recommendations.
- Discuss any problematic behavior with the patient and any attempts you have taken to address the patient's reasons for non-adherence.
- Make sure the patient is informed and understands the risks of non-adherence.
- Consider having the patient sign a document to acknowledge informed refusal of preventive care, including screening.

If compromise seems unlikely, you may wish to reconsider termination.

Litigious Patients

A patient who is suing me has made another appointment. Do I have to see her, or is the suit justification for terminating the professional relationship?

The decision to continue or terminate treatment really depends on the patient's comfort level receiving care and the practitioner's comfort level providing care, as well as the type of care provided. If the patient is being treated for an acute condition, termination is not an option until the acute condition is resolved. It may be difficult to determine whether or not an acute condition exists until after the patient is seen.

The filing of a medical professional liability suit or a complaint with the medical board does not automatically terminate a patient-physician relationship. If the patient is calling you for continuing treatment of an ongoing acute problem, you should probably see her unless another lawful reason for termination is present.

Patients Who Request Monetary Compensation

I am a plastic surgeon, and I have performed numerous cosmetic surgeries on a female patient who has expressed displeasure with the scar left by one of the procedures. I revised the scar at my own expense. However, the patient is still unhappy with the results and is now requesting monetary compensation. Do I have sufficient reason to terminate the professional relationship?

When the patient is unhappy despite all the efforts of the physician, termination may be the best recourse. The physician should let the patient know that he or she has done all within his or her professional power and, with the patient's interests at heart, feels that it would be in the patient's best interest to continue care elsewhere. Whenever treatment for an acute condition is still underway, termination should be deferred. Returning all or part of a professional fee to an unhappy patient is a business decision that must be made by each practice on a case-by-case basis.

Risk Management Recommendation

- Consult an attorney or your medical malpractice insurance company if you are considering fulfilling a patient's request for monetary compensation.

Patients With Unpaid Bills

Can I terminate a patient for non-payment?

When considering terminating a patient from care non-payment of fees, evaluate the need for continuity of care as well as determine whether a contract such as an HMO or PPO obligates the continued provision of care. If the patient is in the middle of active treatment or experiencing a medical crisis, seek legal advice before terminating the patient from care. If the patient is stable and refuses to establish and follow a mutually agreed upon payment plan, then they may be discharged from the practice.

Patients Requesting Pain Medication

I am an internist prescribing opioids to a patient who suffered severe injuries in a motor vehicle accident. He continues to request increasingly higher doses of stronger medications, specifically opioids. Recently he began calling the office for early refills, claiming his prescription had been lost or stolen. I suspect he is selling the prescription medication. Can I dismiss the patient from my practice?

The patient may be self-adjusting his pain medication using a higher-than-recommended dose, or he may be selling his medication. Termination should not be initiated because of a

suspicion, no matter how strong. At best, the patient is in pain and needs active pain management. Alternatively, he may have become addicted to opioids and require referral to a detoxification program. Discharging the patient from the practice may not only affect patient safety, but could form the basis of a patient abandonment allegation and can be a missed opportunity to provide lifesaving information and treatment. According to the Centers for Disease Control and Prevention (CDC), "Identification of substance use disorder represents an opportunity for a clinician to initiate potentially life-saving interventions, and it is important for the clinician to collaborate with the patient regarding their safety to increase the likelihood of successful treatment."[5]

Risk Management Recommendations

- After ensuring that the patient no longer has a medically related need for opioids, discuss the patient's requests for excessive amounts of pain medication.
- Share concerns about drug dependency, and inform the patient that you cannot continue to prescribe opioids in the quantity apparently needed to control the pain.
- Consider suggesting that the patient either (a) switch to a non-opioid drug therapy, (b) help the patient enroll in a licensed detoxification program, or (c) refer the patient to a physician specifically registered to help with the detoxification process.

If the patient is found to be engaging in criminal activities of selling the prescribed medication, termination could be immediate. This process should include recommendations for ongoing care with resources for access.

Demanding Patients

I have been treating a patient for several years for a chronic condition. We have had a good relationship until this year when the patient began demanding specific, unnecessary tests and treatments. We cannot compromise on the treatment plan, and we both agree it would be in his best interest to seek another provider. May I give him the names of specific physicians who do have openings and are taking new patients?

It is far better to offer a referral source than to give specific names. The patient who has a negative experience with someone whose name you offer may blame you for that experience and, in a worst case scenario, involve you in litigation. In addition, referring a problem patient to a colleague may be perceived negatively by that colleague.

Patient Who Miss Appointments

Is there a rule about the number of times a patient can cancel or not show for an appointment before considering termination?

No. Practices must decide for themselves the number that works most effectively for them. Some organizations consider three consecutive missed appointments as reason to consider termination. However, extenuating circumstances, for example, lack of transportation or a pressing family situation, may point to a need for discussion rather than termination. Forgetfulness is the primary reason patients give for not showing up for their appointments.[6]

Risk Management Recommendations

- Inform new patients of the practice's policy for no-show appointments and re-enforce as necessary.
- Consider implementing a patient engagement strategy such as automated appointment reminders via text, voice, or email based on the patient's preference in order to proactively reduce the number of missed appointments.

Parents Who Disagree on Minor's Care

The parents of my patient are divorced and have joint rights to determine the child's care. They disagree over everything, make constant demands on my staff, and impede my care as the child's doctor. Can I dismiss the patient from my practice?

It is important that the pediatrician establish and communicate boundaries. The physician should not take sides or be a conduit of information between the parents. If the parents' post-divorce conduct is impeding delivery of care and the physician cannot meet appropriate standards, consider terminating the physician-patient relationship. If the physician is concerned about risk of current or future abuse or neglect, the physician should report to child protective services.[7]

Terminated Patient Presents to On-Call Physician

I was the on-call cardiologist when a patient I had terminated from my practice for noncompliance came in to the hospital's ED. The patient needed follow-up in the office. What is my responsibility to this patient with whom I had an extremely difficult relationship in the past and whom I do not want to see in my practice again?

A physician who cares for a patient in the ED should see that patient at least once in the immediate post-ED period. In this situation, be sure to advise the patient that his visit to your office is a one-time event, that ongoing care is important, and offer resources to help him find another physician.

Risk Management Recommendations

- If the patient's medical condition is acute, do not simply assume the patient has found another provider.
- Follow up and make sure the patient is under the care of another practitioner.
- Notify the patient's primary care physician (PCP) of the ED visit and to let him or her know, in writing, of the need for follow-up.

I began the termination process and notified the patient that I would see him during the 30-day period only for urgent medical conditions. We are still in the 30-day window, and the patient is demanding to see me for an "urgent" condition. Should I see the patient or refer him to the ER?

This is an area that can be risky. If your termination of care letter states you will see the patient for an urgent condition and then you refuse to see them when they are acutely ill, it may be viewed as abandonment. The better option is to see the patient and document in the record that the patient was seen because they claimed an urgent need. If the condition was not urgent, document the patient's claim along with your assessment of the patient's condition. During the patient encounter, reinforce the fact that the termination process is still going forward.

If the patient is suffering from an urgent condition, treat the patient as stipulated in your letter. If additional care is needed and falls within the transition period specified in your termination of care letter, document these events and move forward with the termination process. If the patient needs care that extends beyond the termination date, the termination process should be stopped. The process can be reinitiated once the treatment period has ended.

Conclusion

Physicians have a right to practice in an atmosphere that is safe, be paid for their services, have themselves and their staff respected, have their schedules honored, have their professional ability valued, and have their word trusted. When those rights are violated or irretrievably compromised by the patient's actions or inactions, healthcare providers have the right to terminate the professional relationship as long as they do not violate state or federal laws. For assistance with patient- or practice-specific issues involving termination, physicians should contact their attorney or the risk management department of their medical malpractice insurance company.

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About the Author



Annemarie Provencher is a senior risk specialist for Coverys member companies Medical Professional Mutual Insurance Company and ProSelect Insurance Company. She works closely with healthcare providers, office managers, and hospital clinical and administrative staff to identify and provide solutions for risk management exposures in clinical practice.

She is a registered nurse with 18 years of critical care nursing experience and more than 20 years of clinical and risk management experience. Before assuming her position at Coverys, Provencher was the risk manager and infection prevention coordinator for a community hospital in the Berkshires.

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EYE ON THE INDUSTRY

What's Happening in the Market Place? Is it a Perfect Storm?

By Bonnie Boone

When I first began writing this in December 2020, my outline addressed utilizing healthcare Captives in a transitional marketplace, sighting the increase in claims severity, increase retentions, the reduction in limits/capacity and restrictive coverage terms and what this would mean to Captives.

Since then, the entire marketplace has changed, and all of the classic symptoms of a transitional market exist. The reasons are many, some are mentioned above. I termed it a 'perfect storm' that combined a transitional market with loss severity and frequency, and the unprecedented pandemic. This article will examine what we are seeing in the market and the way healthcare providers are using Captives to help with your risk transfer.

The New York marketplace is seeing the same as other parts of the country. There are extenuating issues associated with the state, for example section 18 of the Medical Malpractice Reform Act (NYS section 18), the excess coverage for physicians. This will add finding a market to front for an offshore option to your process. Remember an RRG's can reinsure the Captive.

Medical Professional Liability

In 2020 the medical professional liability industry underwriting results deteriorated for the seventh straight year. The top ten Medical Professional liability carriers have a combined loss ratio of 113%, according to the Conning Report. This translates into poor profitability for the carrier with barely any investment income opportunity. The exit of major carriers from the market was a clear sign of where we are. With new capital and carriers coming in the market, what's next? Let's watch!

Claims severity and frequency are the culprits with inadequate rate/premiums. There have been more than 30 verdicts in excess of $10 million generated – an aggregate total of more than $1 billion in medical liability verdicts. While 2019 represented a decline in the number of $10 million and over verdicts, the underlying trend reveals that the number of large verdicts continues to increase, according to the MPL Medical Professional Association.

In 2019, we saw continued changes with claims. For example, a verdict that awarded $35 million in Long Island prompted the judge to send the jury back to deliberate, saying the plaintiff's pain and suffering awards were out of line with
what the state appellate courts have allowed in similar cases.

All this comes on the heels of prolonged market softness when carriers were competing on price and underfunded to absorb the losses.

Every major insurance carrier or reinsurer supports that the market has transitioned, underwriting the risk for exposures (total loss cost underwriting). Insurance carriers started notifying brokers and insureds as early as December 2019 of this new direction.

The underwriters are analyzing exposures the way they viewed them in 2008, or for that matter in the 1990's. Some of these exposures were not prevalent in the earlier market shifts including opioids, telemedicine, physician contract relationships and the COVID-19 pandemic. However, severity in obstetrics and neurosurgery, and misdiagnosis in the emergency room are consistent issues today as in past market transitions.

A perfect storm was developed

Reinsurers and insurance carriers were placing moratoriums on new business. What did COVID-19 mean to their books of business?

- Carriers developed questionnaires for clients and conference calls were mandated.
- Some markets excluded any losses as a result of COVID-19, and some placed specific, maintenance deductibles per patient.
- Some of these exclusions were specifically related to professional liability and general liability, or employer's liability.
- There were lots of discussion about 'Batch wording' and how it responds to COVID-19 losses.
- The concerns were across the board on automobile liability, executive management lines, cyber liability, etc.
- We are continuing to monitor for new changes the pandemic may have on the marketplace.

Many clients were not concerned because they had Captives, and what did these market conditions mean to them?

As a result of COVID-19, the balance sheets of most acute care facilities saw March and April 2020 revenues decrease drastically. May 2020 seemed to be a better month, with governmental supplements supporting hospitals.

Reinsurers were asking questions about confidence levels of funding. Tort immunities were granted Federally and on a state-by-state basis. The questions became whether they would apply to offshore Captives, should the Captive move back onshore, and can we assume these excluded exposures ourselves?

The economy, insurance marketplace, pandemic and the social unrest across the country made it a top priority to inform management that 100% reinsurance may not be possible.

How Captives may mitigate challenges

With all of issues discussed above, did some Captive owners think they did not have to worry because they had a Captive? To properly assume the risk of COVID-19 in a Captive, if reinsurers have excluded the coverage, you need to properly fund for the risk /exposures. What type of wording would the Captive have if excess limits are involved? You need to get their permission for drop down features. Concurrency and contract certainty will be important when considering the Captive retaining COVID-19 exclusions.

Healthcare organizations view risk differently than large manufacturing risk, or Fortune 500 corporate giants. Some of the industries that were most affected by the virus/ pandemic on a systematic basis, like the hospitality industry, began analyzing the

risk. They developed corridor layers, etc. to assume these risks. As a reminder, it's advisable to develop drop down wording for excess layers. Questions they are asking include; Did reinsurers know enough to exclude the exposure of COVID-19 at this juncture? What type of claims were expected? Was there a standard of care developed, and how can negligence be proven?

Let's look at an example of what could happen to your Captive and questions you should consider:

- Are there any opioid exclusions and what is the underwriter looking for? What kind of losses can be attributed to opioids? Some of the attorney generals across the country were bringing criminal actions against hospitals and doctors (note: criminal acts are typically already excluded from most policies).
- The market is responding by some carriers exiting; those carriers exiting had done so prior to the pandemic. Are your Directors and Officers (D&O's) (the corporation) being held to standards of the CDC or, the Federal government? Will they be held negligent? Are there D&O allegations?
- We all collected large amounts of data and information, and it's unclear what purpose that served. Do we now know how much the average defense cost for a COVID-19 claim is, do we know if employers liability will continue to be scheduled on umbrella policies?

What the markets think:

We talked with a few underwriters to get their input on reinsurance and Captives in this market:

- Erin Mullen, Manager of Coverys Custom Accounts – Coverys thinks Captive financials, loss triangulations and the jurisdiction are important to their underwriting process. They think the COVID-19 concerns are lessening. As far as New York market specifically, they think the distinction between Upstate and Downstate is a critical factor when they consider the risk. Coverys has a physician's RRG product that is very active in New York.
- Pat Cirelli, VP, Healthcare Professional Liability Berkshire Hathaway Specialty Insurance (BHSI) – Information important to BHSI includes funding studies, loss data and triangulations and the Captive's policy language. BHSI is supportive of Communication and Resolution Programs (CRPs) and values partnerships, understanding patient safety and risk mitigation efforts.
- Cathy McDermott, Vice President of Facultative Medical Professional Liability at Transatlantic Reinsurance – What's important to TransRe? We want to hear the Captive's story as told by them (face to face or virtual meeting). During this meeting we like to hear about loss mitigation tactics, claims outcomes/results and financial performance. Complete ground up loss data, recently valued NOT capped losses, cutoff at the retained amount. The Judicial Hellhole report cites New York City as #2 Judicial Hellhole in the nation. Venue is important to TransRe. Cathy is an advocate for defending cases where feasible.
- Noeleen Doelger, Chief Operating & Financial Officer of Healthcare Risk Advisors (HRA) – HRA, along with its sister company, Hospitals Insurance Company, a New York medical malpractice carrier, provide malpractice risk transfer and alternative risk solutions to hospitals and physicians. An integrated approach to claims and risk management is important to her organization, they understand the New York market place clearly. They support, like the other reinsurers, off-shore Captives, and Vermont domiciled. As a leader in this industry, HRA/HIC believe it's important that clients are committed to a partnership.

Success with Captives in a transitional marketplace

In summary, if you want your Captive to work for you in this transitional marketplace, here are some tips:

- Put together a good team that includes an actuary, Captive manager and consultant, reinsurers, broker and your senior leadership team (include a clinical/ patient safety persons).
- Check all wording, policy forms, buffer layers, binders, drop down features, utilize your Captive for gaps, coverage shortfalls, but do so properly. Remember there is a difference between assuming risk and going bare.
- Consult your attorneys to determine if off-shore Captive meetings can be held remotely.
- Pick the right domicile, if you need to address physician risk, HMO reinsurance, etc.
- Read the binders and terms, if you are reinsuring the Captive make sure everyone is on the same page. It is not a syndicated excess program where every insurance carrier can have their terms, they are reinsuring your Captive form.
- The definition of professional services and products liability, definition of an event or claim reporting requirements and cyber exclusion, must have concurrency.
- Discuss who will write the policy with your leadership team, broker, reinsurer and general counsel, and recommend a team effort.

Many clients /insureds feel a moral obligation to domicile their Captives in their respective states. The question should be is what the best domicile for a risk transfer program is. As a reminder in 2018, three major hospitals were accused of making profits on a Captive. The end result a Captive feasibility study is money well spent.

About the Author



Bonnie Boone is a producer and client executive for Gallagher's risk management practice group. She develops strategy and places professional liability and other casualty lines for a broad range of large clients. Her expertise includes large physician groups, healthcare organizations (hospitals, MCO), large academic medical centers/ universities, financial institutions, manufacturing companies, reinsurance facultative and treaty and start- up bio tech companies. Her focus is on captives, cash flow-loss sensitive programs, and coverage analysis in these areas. She co-chairs the Managed Care Practice Group. She also manages overall coordination of Gallagher's resources as well as account management for her business and is responsible for producing new business.

Keeping the Patient's Perspective

By Samantha E. Quinn, Pamela Monastero, and Dr. Julie Monroe

For our second column, we are discussing the topic of sensitivity in diagnosis and treatment. What follows is the story of an innocent teenage girl who was traumatized by the lack of sensitivity of the doctors treating her. Although changes in the delivery of health care since the 1970s make it unlikely that such a scenario would occur today, the underlying principle – sensitivity to the patient and patient's rights -- is a timeless subject and one which should always be in the forefront of practitioners' minds.



TOPIC 2
Sensitivity in Diagnosis and Treatment

From the Patient's Perspective

Way back when--when I was still in utero--my mother tripped and fell during her first trimester of pregnancy and was on the verge of miscarriage. I was her first pregnancy and she was just devastated. Her obstetrician/gynecologist (OB/GYN) prescribed Diethylstilbestrol (DES), an estrogen first manufactured in 1938 as a "synthetic estrogen." From 1938 to 1971 United States (US) physicians prescribed DES to pregnant women to prevent miscarriages and avoid other pregnancy problems, with the result that between 5 to 10 million pregnant women and their children were exposed to DES. DES was prescribed on the theory that miscarriages and premature births occurred because pregnant women did not produce enough estrogen naturally. At that time, DES was thought to be safe. In 1971, the Food & Drug Administration (FDA) issued a Drug Bulletin advising physicians to stop prescribing DES as it caused a rare vaginal cancer in girls and young women who were exposed to DES in utero.[1]

When I was an adolescent, I began to experience abnormal bleeding and my mother brought me to her OB/GYN, the very same provider who had prescribed the DES to her 16 years prior. This OB/GYN, who had an excellent reputation in our community and treated my grandmother and my aunts, was in his seventies and his bedside manner was reflective of the times. Recall that in the good old 1970s, there was no discussion about patient rights or any sensitivities around women's issues—you did what the doctor told you to do without question. Of note, I was a very innocent 16-year-old and, at the time, only girls who were "in trouble" (e.g., pregnant or with a sexually transmitted disease) visited an OB/GYN. The fact that I was innocent made me somewhat of an anomaly, with the result that I often felt like a lab rat—more on that later. My recollection of that innocent 16-year-old girl was that the OB/GYN provider was brusque, condescending and judgmental until he actually examined me. Thereafter, his demeanor changed 360 degrees and he displayed compassion. In all honesty, I have blocked out much of this experience and have no recollection as to whether my mother was present for this exam; regardless, had she been there, she did not (and would not) contradict the provider. Needless to say, the source of my abnormal bleeding was a result of the DES medication. To his credit, the OB/GYN was completely transparent and very contrite about his prescribing DES, advised us of the new medical studies on the effects of DES and referred me to the premiere DES GYN oncologist expert—this expert was the provider that other OB/GYNs sent their wives and daughters to for oncologic consultation. Of course, patients did not really sue their medical providers in the early to mid-1970's—this era immediately preceded the late 1970's-1980's medical malpractice boom—a time of rising claims and rapid growth in insurance premiums.[2] One theory is that hospital origins were in religion and charity care and ultimately evolved into public or tax supported municipal hospitals and the later development of for-profit facilities.[3] Needless to say, the thought of suing the OB/GYN provider or the pharmaceutical manufacturer of DES never entered my mother's thoughts.

The GYN oncologist, who was in his fifties, possessed a somewhat softer demeanor than my mother's OB/GYN but, nonetheless, the *doctor knows best* mentality continued to be the mantra, with no consideration of the sensitivities in treating a young, innocent adolescent. I was ultimately admitted for a cone biopsy, which was the treatment at the time for the pre-cancerous condition caused by the DES. While I adored the GYN oncologist (who, by the way, looked exactly like Edward Mulhare (the ghost) in the TV series of *The Ghost and Mrs. Muir),* during this admission, I was nonetheless subjected to indelicate physical examinations by a horde of male OB/GYN residents. Recall the 1970s was also pre-chaperone days, however, I was fortunate enough that a nurse took pity on me and held my hand during each exam as I cried. My tears and emotional response to this went unacknowledged by the medical team and I distinctly recollect the feeling of being violated at that tender age. Rather defiantly (for the times), I later asked by GYN why he had so many strange men looking at me and examining me, his eyes teared up and he simply explained that they rarely had the opportunity to examine someone like me and that he had to show

them what my "insides" looked like so that they could learn and treat other patients. Amazingly, I was satisfied with his response but remained somewhat scarred by the experience. Thereafter, I followed up four times annually for many years and, fortunately, did not have any adverse sequelae until I became pregnant as DES placed me in a high-risk pregnancy category.

In conclusion, I am grateful every day that I did not develop cancer and suffer as so many others with DES did, many losing their lives. Writing this was very personal for me and I can only say that I am very proud of the great strides we have made in healthcare over the decades and sleep comfortably knowing that most modern providers are much more cognizant of patient sensitivities.

From the Lawyer's Perspective

As noted above, the sequence of events which conspired to set the stage for Pam's experience is unlikely to occur today. Her rendition of this situation, though, is both moving and instructive, and demonstrates some key ideas which are as true today as they were over four decades ago.

First of all, regardless of how inured a physician may be to viewing body parts, particularly of patients of the opposite gender, most patients are very sensitive when it comes to exposing themselves to their doctors. Today, chaperones are routine during examinations, and this is always recommended, both for the patient's comfort and also to protect against any future claims of impropriety. However, in addition to the presence of a chaperone, the examining physician should always be aware of the sensitivities of the patient, especially where adolescents are concerned. There should always be a staff member of the same gender as the patient in the room during any examination. When appropriate, and if the adolescent consents, the parent should be in the examination room.

Secondly, even though teaching young doctors is important, it should never be prioritized over the patient's comfort and security. A patient's consent should always be obtained before an examination by residents or for teaching purposes is conducted. A patient has the right to refuse such an examination, and if unaware, she or he should be so advised. In the case of an adolescent, the parent's consent should also be obtained. Moreover, a discussion about the purpose and scope of the examination should be conducted BEFORE not AFTER it occurs.

Finally, judgment should never be a part of medical treatment. Pam's story is troubling from a number of perspectives, not the least of which is that the OB/GYN who initially treated her was passing judgment on her based upon erroneous assumptions. It is worth noting that he later changed his demeanor when he realized that the source of her issue was, in fact, out of her control and not because of promiscuous behavior on her part. But that should have been his demeanor from the outset; it is not the place of doctors, nurses or other medical personnel to pass judgment on why a patient sits before them; it is simply to treat the patient. Attitudes like those described by Pam – judgment, condescension, "doctor knows best," - are incompatible with a patient being an active and informed participant in his or her treatment. In fact, such attitudes lead to avoidance of treatment and lack of candor of patients for fear of recrimination, both of which can have devastating consequences.

From the Physician's Perspective

I agree that this scenario is one which is unlikely to occur in today's modern era of medicine. On the one hand, it is somewhat refreshing to hear how the physician was open and honest about the connection between his prescribing the DES and the patient's condition. Having only started practicing in the early 1990s when malpractice litigation was much more prevalent, it's hard for me to relate to him being able to disclose such information in a matter-of-fact manner.

I do, however, remember the early days of my training when an attending physician would make rounds with a posse of residents and medical students trailing behind. We would walk in to the room and many times startle the patient awake in the early morning hours so that the attending could ask the patient questions about how they were feeling and examine them in front of the group. Sometimes the topics discussed including bowel movements and urinary habits were rather sensitive. The attending physician would often turn to the medical students and talk to them about the patient's diagnosis as if the patient wasn't sitting right there in the room. My initial reaction as a first-year medical student was that this did not seem right. How could we not respect a person's privacy for the sake of teaching doctors-in-training? Perhaps even more bizarre was how patients went along with this as if they didn't expect to be treated any differently.

But times have certainly changed. Even back then, I noted the younger attendings seemed to show more consideration for a patient's privacy and would often peak around the curtain into the patient's bed first to ask if it was ok for the group of residents to round on them before pulling back the curtain for all to see. Similar to how society has changed and treatment of individuals in the workplace has become more sensitive to individuals' feelings and perspectives, medicine too has evolved to allow patients more respect and autonomy.

I often have pre-med students shadow me during my office hours. The days are rushed and busy but I always take the time to go into the exam room myself first and ask the patient if they would mind if a medical student sit in on the visit before having them come into the room and introducing them to the patient. Most of the time the patient consents and has no issues with it but occasionally, I'd have a patient who says "I'd rather not." I respect their wishes and reassure them that it's not a problem to decline. The patient's comfort should come before any teaching moment for a student.

While respecting a patient's privacy may be more of a norm in medical care today, avoiding judgment can be a more insidious problem to tackle. There are certain medical diagnoses such as mental illness, HIV or alcohol or drug dependence that often lead physicians to subconsciously pass judgments on patients. It's important for physicians to recognize these biases and avoid making any generalized assumptions about the patient and certainly avoid making the patient feel liked they are being judged or treated any differently because of their diagnosis.

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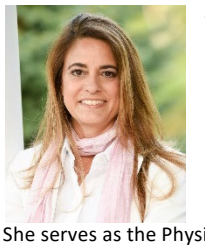
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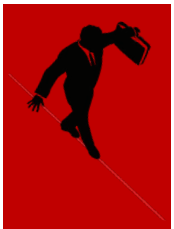
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R I S K Y B U S I N E S S

Med Rec or Med Wreck: The Evolution of Medication Reconciliation

By Pamela Monastero, MBA, CPHRM

WHEN COMMON SENSE IS UNCOMMON

This issue's column is dedicated to the process of medication reconciliation (*Med Rec)*. There is a plethora of information on *Med Rec* and our focus is on why the process continues to be a struggle for many hospitals. Studies of *Med Rec* have revealed unintentional discrepancies in prescriptions but no clear evidence that clinically important outcomes are improved.[1]

Origins:

According to the 2006 *Preventing Medication Errors*[2] report, the average hospitalized patient is subject to at least one medication error per day and "experience from hundreds of organizations has shown that poor communication of medical information at transition points is responsible for as many as 50% of all medication errors and up to 20% of adverse drug events in the hospital. Each time a patient moves from one setting to another where orders change or must be renewed, clinicians should review previous medication orders alongside new orders and plans for care, and reconcile any differences. If this process does not occur in a standardized manner that is designed to ensure complete reconciliation, medication errors may lead to adverse events and harm." It is believed that many of these errors would be averted if *Med Rec* processes were in place. In concept, *Med Rec* should be a straightforward, simple process but often it is not because it is time and resource consuming as the process involves many different staff in diverse roles with different skills and knowledge and at different points in care transition (e.g., admission, upgrade, transfer, discharge, etc.).

In January of 2006, the Joint Commission (TJC) issued a Sentinel Event Alert (SEA, Issue 35, January 25, 2006)[3] titled "Using Medication Reconciliation to Prevent Errors." Per the SEA, the process goal appears to be simple--maintaining and communicating accurate patient medication information. In essence, *Med Rec* is to be performed to create the most complete and accurate list possible of a patient's current medications, compare the list to those in the patient record or medication orders and hopefully avoid medication errors, e.g., omissions, duplications, dosing errors, drug interactions, etc. *Med Rec* should be done at every transition in care in which new medications are ordered or existing orders are rewritten. *Med Rec* is a 5-step process: (1) develop a list of current medications (including supplements, herbals, vitamins, over-the-counter medication, vaccines, etc.; (2) develop a list of medications to be prescribed; (3) compare the medications on both lists; (4) make clinical decisions based on the comparison; and (5) communicate the new list to the appropriate caregivers and to the patient.

AHRMNY Survey:

In a 2019 informal survey of AHRMNY members with a risk management title (there were only 16 respondents across hospitals and physician practice groups), all responding facilities report using an electronic health record (HER, e.g., Epic, Allscripts, MediTech, NextGen, Cerner, etc.). When asked if *Med Rec* is performed at key points in care, 80% responded mostly, 13% responded sometimes and 7% responded robustly. In terms of whether *Med Rec* is performed perfunctorily given the EHR, 60% stated yes and 40% stated unknown. 50% stated that Med Rec would likely fail with respect to maintenance medication vs. other medication (pain medication, etc.). General comments offered by the risk managers on the *Med Rec* process include the lack of electronic hard stops or mandatory line reviews before meds are pulled through the system (e.g., if medication is not removed from the active list, it continuously carries over into the medication list) and budgetary issues for appropriate resources to assist in *Med Rec.* Staff education and random chart audits for compliance were recommended as actions taken by the respective responding organizations to this survey.

Studies and Reviews:

A review of modern medication safety in academic can be traced to the late 1990's. The review is not clear as to who or what entity actually coined the phrase "medication reconciliation" and a search done attributes this term to the 2005 TJC Patient Safety Goal for *Med Rec*. However, the term "medication reconciliation" is first found in a 2003 article by Pronovost et. al. in the Journal of Critical Care.[4] The authors state "one strategy to reduce preventable adverse drug events is to reconcile the medication orders between the two transition points, such as the intensive care unit and the

regular nursing unit….as part of an effort to improve safety in our intensive care units (ICUs), we implemented a medication reconciliation program….Hospital-based *Med Rec* is defined as the process of identifying the most accurate list of a patient's preadmission medications—including the name, dosage, frequency, route, last does taken and assessment of adherence, comparing them to the current medication orders, recognizing and addressing discrepancies, and documenting any changes. The use of *Med Rec* was associated with a dramatic reduction in medication errors in patients (transferring from an ICU at an academic medical center)…..The process of *Med Rec* is based on the safety principle of independent redundancy—having independent providers ensure that key steps in a process are present." Lessons learned include: (1) nurses play a vital role in advocating for quality and safety and can partner with patients, families and physicians to improve patient safety; (2) performing *Med Rec* requires a collaborative culture; (3) tools must be kept simple; and (4) discharge surveys can be used as a tool to improve medication safety. The lessons learned cited in this 2003 article still apply 18 years later in 2021.

In a study reported in 2016[1], a review of *Med Rec* in the United States (US), United Kingdom (UK) and Canada cites that *Med Rec* is a "major change in system responsibility, workflow and healthcare professional priorities, without accompanying personnel or information technology support and was based entirely on literature using avoidance of 'potential medication errors' as a primary outcome." The authors state that *Med Rec* Required Organizational Practice (ROP) in the US had to be "scaled back due to the failure of proponents to recognize the complexity and costs of the process, and hospitals' inability to meet requirements for widespread Med Rec across the continuum of care." In addition, in Canada, hospitals "struggle to meet ROPs for admission Med Rec with 57.4% overall compliance" and issues with *Med Rec* on discharge and transfers (which, at the time of this study, did not capture *Med Rec* at transfer). The authors state that "while studies have documented medication discrepancies based on *Med Rec*, noted suboptimal communication strategies around medication management, or offered commonly held views as to why *Med Rec* is not reaching its goals, no studies were identified (in our literature review) that carefully detailed current processes to understand barriers preventing success, or to document resource usage." The authors further state that, based on their literature review, "well done *Med Rec* reduces unintended medication discrepancies but the impact on clinical outcomes is uncertain…and there is no evidence of beneficial effect on mortality or hospital readmission, although low quality evidence suggests a trend towards decreased emergency department (ED) contact. This has led to a strong recommendation that medication reviews be undertaken only as part of a well-designed randomized trial, and include expert physicians able to directly determine and implement appropriate changes. Given that *Med Rec* is carried out primarily to inform and improve the quality of medication review/management, these cautions bear heeding given the many competing priorities for healthcare resources…Even if *Med Rec* has a small and as yet unproven benefit on clinical events or resource usage, its cost-effectiveness may well be highly unattractive."

The 2016 study[1] used process mapping (a toolkit component of the Multi-Center Medication Reconciliation Quality Improvement Study {MARQUIS study[5,6]}) to understand the current state of *Med Rec* processes and to perform a gap analysis. The study objective was to identify gaps in efficiency and safety, and to provide recommendations to improve the process. The study looked at three Canadian hospitals and the "objective was to apply process mapping methodology to *Med Rec* to clarify current processes and resource usage, identify potential efficiencies and gaps in care, and make recommendations for improvement in light of current literature evidence of effectiveness." Process steps utilized included: (1) defining patient values based on literature reviews, discussions with frontline staff, patients and consultants in the field, identifying what a patient values in the process to ensure that interventions were aimed at increasing patient satisfaction; (2) process mapping (observations of frontline staff performing *Med Rec*); (3) validation of process maps (providing feedback on process map to frontline staff an adjusting process map accordingly); and (4) planning change based on gap analysis and development of value added activities. Of note, the authors state that the initial medication history collection (in the ED) took about 1-5 minutes and 'final admission' *Med Rec* was performed by pharmacists took about 45-60 minutes (with or without pharmacy technicians) for Best Possible Medication History (BPMH)--capacity to complete this was only ~60% of all admitted general internal medicine patients, thus many patients were missed. For admission *Med Rec*, time constraint issues identified included communication with outside pharmacies; discharge *Med Rec* took about 15 minutes on average and was carried out entirely by physicians. Lessons learned include opportunities to better capture medications information (e.g., provided by patients/caregivers such as those 'taken as needed' or over-the-counter, outside pharmacy data), that all available medication sources were not utilized, that there was duplication of effort creating inefficiencies (e.g., lack of trust in ED's *Med Rec,* resulting in asking patients about medications again during the course of admission), lack of timeliness of completion of BPMH inconsistent and

untimely involvement of pharmacy resources, issues around patients admitted overnight or on weekends), lack of standardization in the *Med Rec* process (variance in completion of *Med Rec*) and inadequate and inconsistent communication among staff around *Med Rec*. Recommendations include: (1) improving timeliness of pharmacy-led BPMH completion (requires additional pharmacy staff or restructuring) and develop an automated system to secure community pharmacy profiles; (2,3) as this study was done performed using electronic health records (EHRs), recommendations were made to standardize a section of medical record to record and locate *Med Rec* and pursue implementation of an EHR; and (4) increased patient/caregiver education, especially regarding accurate discharge *Med Rec*. The study concludes that process mapping contributes valuable information towards improving quality and efficiency of Med Rec and a more accurate measure of resource uses and cost; however, questions around cost-effectiveness remain unanswered.

Another article[7] explores problems with *Med Rec*. The authors refer to the implementation of TJC's mandated universal medication reconciliation and suggests that this was based on imperfect evidence, citing prior studies in support of this position. The authors suggest that these "mandates were driven by frequent anecdotes of adverse drug events (ADEs) related to *Med Rec* errors and strong face-validity of preserving and communicating medication information across patient encounters. Unfortunately, although some organizations mobilized substantial resources to comply with these mandates, other organizations undoubtedly improved documentation of *Med Rec* (as per the mandate requirements) rather than actual medication safety." The article acknowledged gaps between the benefits shown by *Med Rec* interventions and largely unreported outcomes of *Med Rec* efforts that patients in most hospitals are likely to experience. Therefore, there is a lack of cost-benefit data in academic literature "makes hospitals less likely to expend resources. Paradoxically, it is exactly these resources that are required for *Med Rec* interventions to succeed." Problems cited are: (1) resource intensiveness of *Med Rec* process—e.g. for obtaining admission medication history, it take about 46 minutes per patient at a cost of about $44 per pharmacist, resulting in 11 full time personnel to obtain medication histories for a hospital with 23,500 annual admissions; (2) it requires a comprehensive approach that involves pharmacists and other resources (e.g. reconciling medication on admission, at discharge, education at discharge, assessing non-adherence, communicating with other providers and post-encounter follow-up with patients), "suggesting that *Med Rec* interventions may act synergistically or that intervention breadth is needed to yield any results"; and (3) accurate measurement of the benefit of these interventions (e.g., detecting discrepancies and errors in medication orders) is in itself labor-intensive and may be rarely done. Therefore, organizations implementing interventions to improve *Med Rec* may not see tangible results due to deficiencies in intervention intensity, intervention breadth and/or difficulties of measurement." Other challenges highlighted are organizational commitment to *Med Rec* interventions (is the goal to increase medication safety or to meet regulatory requirements?), generalizing *Med Rec* interventions that affect complex workflows that vary across and within services and campuses, and variation in out-patient workflows. The article further explores challenges pharmacists face in obtaining BPMHs, lack of standardized protocols, time constraints (to admit, discharge or transfer patients) and cites possible solutions including: (1) pharmacist-based interventions (high cost, resource intensive); (2) information technology (IT)--implementation of EHRs--which are associated with a marked increase in medication history errors likely due to a combination of factors including EHR design, local implementation and use by providers. The authors conclude that *Med Rec* interventions "have strong face validity and have been shown to improve processes, but are problematic in that they have been difficult to replicate outside of studied institutions."
Recommendations include:

1. Recognize that most evidence for improving medication safety comes from resource-intensive, pharmacist-based interventions, and that half-hearted efforts to improve *Med Rec* may just waste resources and even worsen medication safety;
2. Ensure that designated personnel have sufficient time and training to conduct *Med Rec (e.g.* hiring and training dedicated pharmacy technicians to obtain medication histories may represent a good use of resources);
3. Recognize that, in most cases, obtaining an accurate medication history early in the hospitalization (ideally while the patient is still in the ED) is optimal, because fixing these errors downstream (after orders have been written, or after discharge) is both unsafe and inefficient;
4. Determine which groups of *Med Rec* interventions are most likely to serve patient and organizational goals. Institutions focused on post-discharge outcomes (e.g., readmissions) may find that *Med Rec* at discharge and post-discharge phone calls are good places to start;
5. Prioritize which patient populations (e.g., high-risk patients) would benefit the most from *Med Rec* intensive interventions to ensure responsible use of resources;
6. Clearly delineate roles and responsibilities for those personnel involved in *Med Rec* interventions, including a designated order of intervention

components, to reduce known ambiguity about which personnel are responsible for which parts of each med rec intervention and when they should occur;

7. Consider the role of Information Technology (IT) in *Med Rec*, including the potential for propagation of medication history errors. While customizing EHR off-the-shelf *Med Rec* modules may not be possible from an IT perspective or may be expensive, even minor changes to user permissions (e.g., giving pharmacists or technicians the ability to edit home medication lists) or to the default appearance of certain screens could have substantial benefit.
8. Clinicians should:
    a. Ensure that organizational efforts focus on sound processes and patient outcomes, with consideration of the National Quality Forum (NQF) process measure *(Measure 2456: Medication Reconciliation: Number of Unintentional Medication Discrepancies per Patient. 2014. http://www.qualityforum.org/qps/2456, accessed 19 Aug 2015)*, rather than just regulatory requirements;
    b. Disseminate and model the philosophy that ordering providers are ultimately responsible for the quality of *Med Rec* because good *Med Rec* is required for safe medication orders. This does not require providers to complete the process alone. Indeed, they should leverage work done by other providers. However, they still must verify accuracy, and must address cases with questionable accuracy (e.g., call a physician's office that was closed at the time of admission). Investigators should:
        i. assess *Med Rec* interventions across the care continuum using patient-centered outcomes, with attention to interactions between interventions and the cultural context of institutions;
        ii. explicitly measure the costs and benefits of various *Med Rec* interventions (e.g., using pharmacy technicians in certain *Med Rec* roles), with attention to subgroups that might derive the most benefit;
        iii. study how large vendor EHRs can best be used to improve *Med Rec*, mindful of varying cultural contexts, implementation idiosyncrasies, and local customizations; and
        iv. learn how *Med Rec* interventions can best be integrated with existing workflows and made compatible with larger system pressures. For example, unit-based pharmacists (vs. centralized pharmacists) may be better positioned to provide discharge medication counselling to patients without postponing discharge.

<u>One article[8,9] suggests that accurate *Med Rec* jumped from 32.3% to 94.2% after pharmacists took responsibility for assembling patient medication histories, as well as adding medication progress reports to patient charts at the time of admission.</u> In this review, the reporting facility identified the following:

- Pharmacists led *Med Rec* on patient admissions from the ED from September 2012 through March 2013;
- Pharmacists reviewed patient charts to identify disease states and medical histories and to look for unidentified medications, any potential errors, or non-evidence based treatments;
- Pharmacists interviewed patients in person to gather medication histories. And, if they deemed it necessary, they contacted the patients' pharmacies, family members, and physician offices for further information;
- Pharmacists then entered their assessments into the EHRs and added printed versions to patient charts;
- Pharmacists added progress notes to the charts to update any and all medication changes and any possible recommendations for medication changes of adjustments.

At baseline, complete and accurate *Med Rec* occurred 32.3% of the time at admission, and 16.7% of the time at hospital discharge. As soon as the pharmacists started taking charge of reconciliations, the accuracy rate jumped to 50% at admission and 25% at discharge. By the end of the study period, 94.2% of medication reconciliations were complete and accurate at the time of admission. Data on the discharge percentage at the end of the study period was missing from the analysis. The team noted that the most common *Med Rec* errors were in medication omission and frequency of administration, followed by dose, incorrect medication, dosage from errors and therapeutic duplication.

<u>High-risk patients</u>

High-risk patients present a unique *Med Rec* challenge. Given the co-morbid conditions and multiple medications prescribed, inclusive of high alert medications, inadequately performed *Med Rec* for high-risk patients can result in catastrophic medication errors. The MARQUIS study[5,6] suggests risk stratification of patients (high vs. low-intermediate risk based on patient characteristics (e.g., number of preadmission medications). *Med Rec* for high-risk patients would "ensure that high-risk patients have medication histories obtained and medication counseling performed by the most highly skilled personnel with time and resources to perform an 'intensive' medication reconciliation bundle." Some facilities have implemented separate *Med Rec* workflows for high-risk patients using various scoring methodologies.

How does your *Med Rec* process measure up?

As noted above, in evaluating the efficacy of an organization's *Med Rec* process, the following should be considered:

1. Conduct Gemba walks or random observations of frontline staff performance of *Med Rec* to determine if the practice is standardized across the organization. Staff observations should include staff who "collect" medication histories and staff responsible for performing the actual "reconciliation" process (e.g., observe attendings, residents, advanced practice providers, nurses, medical assistants and any other staff charged with collecting or reviewing patient medication information). It is also helpful to solicit information via frontline focused staff interviews or surveys in order to gauge staff understanding of their roles and responsibilities in the *Med Rec* process, e.g., is there an appreciation of the clinical component of *Med Rec* (e.g., to foster patient safety by obtaining the BPMH) or are staff solely focused on completing the necessary EHR fields and "clicks?"
2. Is the organization's policy and procedure for *Med Rec* aligned with the terminology used in the EHR software? Does the policy clearly delineate roles and responsibilities for each process step in *Med Rec*?
3. Is staff training and education (both formal on-boarding and on-the-job training) aligned with the organization's *Med Rec* policy? Is the education robust and supportive, e.g., are there refresher courses and other resources, e.g., *Med Rec* Tip Sheets *Med Rec* champions, etc.*?* Is there a clear understanding of policy expectations?
4. If using an EHR, is the *Med Rec* component user-friendly with clear language or is it clunky with redundant steps/"clicks" and ambiguous language?
5. Is the organization's *Med Rec* process supported by pharmacy resources? If not, should it be? Does executive leadership and corporate culture support and emphasize the importance of *Med Rec* in promoting patient safety?
6. Has the organization considered the challenges presented by high-risk patients and potential to develop separate *Med Rec* workflow for them?
7. Are there unique Med Rec challenges in the organization's out-patient settings or in virtual/ telemedicine encounters?
8. Does the organization's incident reporting program adequately capture *Med Rec* issues (e.g., if an electronic incident reporting system, is there an event field that captures *Med Rec* exclusively?) Does the organization have (or does it require) a venue to review and vet Med Rec issues (e.g., medication safety committee to review incidents, adverse events and root cause analyses related to *Med Rec* issues)?
9. Has the organization taken steps to address the issue of health literacy, patient ownership of their healthcare and medications and any associated social detriments of healthcare? It is important to remember that discharge instructions, inclusive of medication, is ultimately for the benefit of the end user—the patient. These documents need to be issued in clear, plain language, without ambiguity and clearly delineate changes in existing medication and any newly prescribed medication and usage of these. Organizations could consider implementing patient focus groups to evaluate discharge documents and recommend opportunities for improvement around user-friendliness.

Regardless of whether an organization utilizes an electronic or hard copy *Med Rec* workflow, the MARQUIS[5,6] study is an excellent resource.

In conclusion, patient harm is a real possibility if someone is discharged on the wrong medication, with the incorrect dose, with a contraindicated medication or with unintended multiple medications for the same condition (e.g., unintended multiple anticoagulants, etc.). Ideally, properly performed *Med Rec* to obtain the BPMH and BPMDP would prevent such errors. Most importantly, poor *Med Rec* can erode patient confidence in the organization and clinical providers, e.g., if a patient repeatedly shares their medication history and it is not properly reflected in the record.

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About the Author



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COVID-19 and Psychiatry: Legal and Clinical Implications

By Carolyn Reinach Wolf and Stewart B. Levine

The COVID-19 pandemic seriously impacted the legal and clinical services available to those individuals suffering from mental illness and their loved ones who often seek assistance on their behalf. Over the past year, physicians and mental health professionals have faced unique challenges in healthcare facilities, including caring for psychiatric patients who test positive for COVID-19, taking measures to prevent the spread of infection on the unit and expanding the use of telehealth services. Providers must protect against the risk of legal liability related to providing mental health services during the pandemic.

Inpatient Psychiatry Units

For some hospitals in New York, and possibly across the country, psychiatry units were closed at the height of the COVID-19 pandemic in 2020. Psychiatric patients were discharged or transferred to other hospitals so that the psychiatry units could be re-purposed to treat COVID-19 patients. Psychiatrists and the hospital staff were redeployed. In the case of one Manhattan hospital, the psychiatry unit just reopened in May 2021, more than one year after it closed.

Where psychiatry units continued to operate, hospitals implemented new safety protocols and procedures. Throughout the course of the past year, these protocols were constantly modified, without much notice, as the COVID-19 illness spread and then, thankfully, as the vaccine became available. The threat of spreading COVID-19 immediately prompted the use of facial masks and personal protective equipment by staff and patients. Social distancing measures were enforced wherever possible. This meant reduced or eliminated congregate meals and group activities. Visitation policies were modified, affecting the ability for outpatient treatment teams to visit their clients in the hospital and for family members to visit or participate in meetings on the unit. Most of these meetings were converted to telephone calls or video conferences.

In cases where a psychiatric patient tests positive for COVID-19, hospitals across New York handle this situation differently. Some hospitals can isolate the COVID-19 positive patients on the unit, limiting interaction with peers and staff until safe. Some larger hospitals converted an entire psychiatric unit (or part of a unit) to a COVID-19 unit to continue treating the psychiatric patients without a significant interruption in care. Unfortunately, other hospitals are not equipped to handle a COVID-19 positive patient and transfer such patients to another psychiatric facility, often across county lines, further away from the patient's home and outpatient providers.

A clear written record for each patient can improve a treatment team's overall functioning and reduce potential liability exposure. The patient's compliance, or non-compliance, with COVID-19 protocols such as wearing a mask and observing heightened personal hygiene protocols should be documented in the patient's record. To effectuate a transfer to another unit or facility when a patient tests positive for COVID-19, hospitals must keep diligent records and execute the required legal documents in a timely manner. Records that are kept consistently and according to a thoughtful system can minimize exposure. Documentation can help the hospital show that it acted reasonably.

Inpatient Psychiatry and the Legal System

The Mental Hygiene Parts were some of the first in New York State to transition to virtual hearings even before Governor Cuomo issued an Executive Order mandating telecommuting or "work from home" procedures.[1] Mental hygiene legal matters in New York that affect the rights of patients on inpatient psychiatric units were considered essential.[2] Hearings for the retention of psychiatric patients, treatment over objection and Kendra's Law applications for Assisted Outpatient Treatment, among others, transitioned somewhat seamlessly to our new virtual world, with everyone participating from remote locations.

The ability to hold mental hygiene hearings remotely, with the treating psychiatrist and patient participating from a conference room or other secure location in the hospital, reduced certain liability concerns for the hospital. Doctors and patients are no longer transported to a courthouse or other hospital for court hearings. This decreased any disruption on the unit that may have been caused by the absence of a doctor and staff on the unit for hours at a time. The patient can quickly return to his/her room or the unit milieu after the hearing. Security is readily available, if needed, which was more difficult to access in the courtroom. The risk of elopement during transportation to and from court is eliminated.

Transferring a psychiatric patient who tests positive for COVID-19 to a medical unit or to a different psychiatric facility changes the patient's legal status and invalidates any court orders obtained. Court orders obtained by a hospital for the administration of psychiatric medication over a patient's objection[3] do not follow that patient when he/she is transferred to another facility. This means that the accepting hospital will have to re-evaluate the patient's compliance with the prescribed medications and apply to the court again for continued treatment over the patient's objection.

Outpatient Psychiatric Services

The spread of the COVID-19 pandemic led to unprecedented changes in the provision of psychiatric care in the community. Without clear guidelines, mental health professionals have adapted their practices to provide quality mental health care to an already vulnerable population.

Many outpatient facilities, medical or professional offices and clinics were forced to close at the height of the pandemic. Outpatient mental health programs and offices that remained open implemented COVID-19 safety protocols such as screening questionnaires, taking a patient's temperature before entry, requiring a facial mask, and following social distancing guidelines. Practitioners reduced their patient loads to avoid crowded waiting rooms and often resorted to appointment-only policies rather than permitting walk-ins, even in an urgent-care setting.

In New York, court-ordered Assisted Outpatient Treatment (AOT) programs in each county that heavily rely on in-person, outreach-based practices[4] were forced to rely upon virtual communications by video conference or telephone. Assertive Community Treatment (ACT) Teams, case managers and/or social workers who are generally required to make in-person visits have often been unable to safely do so in the past year. These outpatient services are valuable tools for mentally ill individuals who refuse mental health services in the community and are frequently hospitalized. The AOT program, for example, is proven to reduce hospitalization by providing support in the community and monitoring medication compliance.[5]

Unfortunately, some counties in New York delayed acceptance or processing of community referrals for AOT during the height of the pandemic.[6] As of May 2021, some counties have started reopening their community referral process and treatment teams have been able to safely resume in-person visits.

The Increase in Telehealth/Telepsychiatry Services During COVID-19

The COVID-19 pandemic forced many psychiatrists and mental health professionals to adjust the way they deliver care and embrace the use of telehealth services. Before the pandemic, regulatory and reimbursement restrictions significantly limited the use of telehealth services. Since March 2020, temporary waivers of federal and state regulations expanded a provider's ability to initiate or continue mental health treatment. For example, waiving penalties for HIPAA violations enabled medical and mental health professionals to use virtual platforms such as FaceTime or Skype.[7] The loosening of state licensure regulations allowed for telehealth services to be offered across state lines.[8] Additionally, many providers have been able to bill for telehealth services as if they were provided in person, significantly expanding access to essential mental health services.[9]

Before a provider takes advantage of the ability to use telehealth services, he/she must consider and address certain potential liabilities. There must be clear communication with new and existing patients, notifying them of all new policies and procedures implemented during the pandemic. Providers must use consent forms, explaining what the patient can expect from the telehealth visit, the benefits and risks of telehealth services, fees for telehealth services, and confidentiality measures. The provider should discuss confidentiality issues and get the patient's informed consent in writing before the first telehealth session.

Documentation is essential in protecting against legal liability related to providing telehealth services during the pandemic. Providers should document the details of the conversation about informed consent in the patient's record. Document each telehealth session as if it were an in-person visit. If an existing patient declines to engage in telehealth, document the conversation in the patient's record. Record all outreach attempts and referrals offered. If planning to return to in-person treatment, document the conversation with each client/patient about new policies, procedures, and safety measures. Providers should continually review state and federal laws and regulations to ensure the existing waivers, described above, still apply. It is recommended that these providers seek input from legal counsel and/or a risk management professional to clarify these laws and regulations and how they pertain to their ongoing practice. When those waivers expire, immediately notify all patients, and explain the procedure to be followed in compliance with those laws and regulations.

Conclusion

The COVID-19 pandemic triggered drastic changes to the provision of mental health services in both the inpatient and outpatient settings. Telehealth, which previously accounted for a very small portion of mental health services, has become the new norm and may be here to stay long after the pandemic ends.[10]

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COVID-19 Cases Against Long-Term Care Facilities Belong in Federal Court

By Andrew D. Silverman and Marc R. Shapiro

The floodgates are beginning to open for COVID-19 related lawsuits against long-term care facilities (LTCs). The first two dozen of what may be tens of thousands of cases have already been filed by the families of long-term care residents who contracted COVID-19. The plaintiffs typically allege that the facilities were negligent or otherwise violated various state law duties of care in their response to the COVID-19 pandemic. And the plaintiffs almost universally file suit in state court. The initial battle in these cases is now clear: whether the cases will be litigated in state or federal courts.

LTCs have wisely been attempting to remove these cases to federal court. They've faced mixed success. A district court in the Central District of California recently found one suit entirely preempted by federal law and the facility entitled to immunity, whereas other district courts have remanded cases back to state court[1]. The issue is now heading to the federal Courts of Appeals, which will begin to settle the law in their respective circuits.

They should find in favor of federal jurisdiction. LTCs were at the center of an all-hands-on-deck federal response to the COVID-19 threat, and their conduct cannot be judged independent of the federal direction they received. That makes a federal forum the proper forum under two different doctrines: federal officer removal and complete preemption.

Federal Officer Removal

Congress established a broad standard for federal officer removal to ensure a federal forum not just for federal officials, but for those who assist them. To successfully invoke federal officer removal, a defendant must be (1) acting under a federal officer and (2) the suit must be one relating to any act under color of such federal office. The defendant also must have a colorable federal defense. Suits against LTCs participating in Medicare and Medicaid programs that raise claims related to the COVID-19 mitigation and prevention precautions undertaken by those facilities are such suits and therefore belong in federal court.

LTCs participating in Medicare or Medicaid "acted under" federal officials because officials at the Centers for Medicare and Medicaid Services ("CMS"), working to ensure that the CDC's public health guidance was being implemented, conscribed those LTCs into the federal response to COVID-19.[2] Because they house the most vulnerable population in the country, LTCs were at the very front lines of the government's efforts to prevent COVID-19 deaths. From day one, CMS directed a response that, to use the words of the Supreme Court, went "beyond simple compliance with the law" but rather required LTCs to "help[] officers fulfill [the] basic governmental task[]" of protecting a vulnerable population during a pandemic.[3] CMS dictated the "standards for infection prevention and control" believed necessary "to provide safe, high quality care."[4] CMS issued, and then continuously modified, guidance on visitor access, PPE use, testing frequency, monitoring of staff, and dealing with residents with COVID-19.[5] CMS also ordered compliance checks to ensure LTCs complied with the federal direction.[6] CMS's frequent and pervasive direction to achieve the federal function of protecting a vulnerable population means LTCs "acted under" those federal officials.

The suits also relate to such acts. To qualify for removal, only the "circumstances that gave rise" to the suit need relate to the federally directed acts.[7] Given the pervasiveness of CMS's direction, in all but the rarest case, a suit challenging a LTC's COVID-19 response will relate to the acts directed by federal officials. And, as discussed next, many of these cases will turn on whether LTCs are immune under the federal Public Readiness and Emergency Preparedness (PREP) Act, which establishes a federal immunity defense in times of public health emergencies that should be resolved in federal court.

Complete Preemption

The second basis for removal is complete preemption based on the PREP Act. When a federal statute "displace[s] entirely any state cause of action," federal jurisdiction is proper because the only possible claim is a federal one.[8] The PREP Act is such a statute. When the Secretary of Health and Human Services (HHS) declares a public health emergency, the PREP Act confers immunity "from suit and liability under Federal and State law" for any "covered person … with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure."[9] The sole exception to a covered person's immunity is in cases of willfulness and, even there, the remedy is an exclusive Federal cause of action before a three-judge court in the United States District Court for the District of Columbia. This structure—pairing preemption with a sole federal cause of action—is the defining feature of statutory schemes that completely preempt state causes of action.[10]

Many claims against LTCs will fall within the PREP Act's preemptive scope. The Secretary has designated masks, respirators, and COVID-19 tests as "covered countermeasures," meaning the PREP Act applies to any claims against "covered persons" relating to the administration or use of those countermeasures.[11] The Secretary has also made explicit that this immunity broadly applies to claims concerning both the use and the failure to provide countermeasures (such as when limited supplies lead to prioritizing certain uses at the expense of others).[12] Because Congress afforded the Secretary unreviewable discretion to designate such countermeasures, this determination should receive significant judicial deference. And it is beyond dispute that LTCs are "covered persons" entitled to the Act's protection—they "administer[]" and "dispense[] such countermeasure[s]," and "provide[] a facility" where countermeasures are "administer[ed] or use[d]."[13] Indeed, the Secretary has taken the position that the PREP Act "completely preempts" claims in this area.[14]

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Federal jurisdiction makes good sense. Federal officer removal exists in part to protect those who work with the federal government from anti-federal government bias in state courts. It ensures those with colorable federal defenses will receive fair treatment of those federal defenses by ensuring they are adjudicated in federal court. LTCs warrant that protection for actions they took in conjunction with the federal government's national response to the COVID-19 public health emergency.

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