Enhancing quality of healthcare and patient safety: oversight of physician assistants, nurses, and pharmacists in era of COVID-19 and beyond

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In the age of digitization, telemedicine services are utilized more than ever, and this trend affects health care as well. Although the utilization of technology serves as a benefit in allowing more access to care, coronavirus disease 2019 (COVID-19) has identified some of the weaknesses and discrepancies of the system. The increase in usage of technology has shed light on and increased the severity of the gaps in the regulatory and legal infrastructure overseeing this rapid growth. We aim to evaluate the strengths and weaknesses of the telemedicine healthcare system, as well as address the frequent misconduct that occurs between patients and their nurses, pharmacists, and physician assistants to highlight the necessity of a standardized method of reporting misconduct on an international, national, state, county, and local level. Our study findings should alert the healthcare community of the growing urgency to address the policy and regulatory aspects of telemedicine to provide greater quality and safety during the post-COVID era.

According to *the Journal of the American Medical Association*, as many as 225,000 people died in the United States because of the quality and safety issues within our healthcare system[1]; however, the true number is likely to be higher. Although vastly evolved to adjust to the pandemic, the healthcare industry within the United States is a complex and outdated system that involves many organizations, both public and private. Throughout these private and public organizations, it often goes unknown that Nursing Regulatory Bodies (NRBs) are the jurisdictional governing agencies responsible for regulating all nursing practices.[2] In addition, each state holds its own Board of Pharmacy

(BOP) to regulate pharmacist licenses, and uphold state laws, regulations, and guidelines. These regulatory boards are supposed to be the protectors of patients, yet they often do not deal with misconduct properly, leaving more people to get hurt in the future as nurses, physician assistants (PAs), and pharmacists can continue to practice through telemedicine, and in states other than where licenses have been revoked. Patients are kept in the dark, and more fall victim to harm as nurses, pharmacists, and PAs continue to practice freely. In the age of transparency and big data, patients rightfully deserve access to information on the medical professionals in charge of their health as the current policy is not sufficient.

Telemedicine, exponentially increasing in usage since the beginning of the coronavirus disease-2019 (COVID-19) pandemic, is defined as the delivery of healthcare services through virtual devices. This involves a vast range of practices, including diagnosing patients, prescribing medicine, and sharing information with patients. Telemedicine allows for patients to receive care through a video chat on a computer, tablet, or smartphone.[3] Since the start of the COVID-19 pandemic, telemedicine has transformed into an essential tool to help mitigate the spread of disease and protect at-risk patients. With an increase in the usage of telemedicine, we seek to discuss the dangers of telemedicine as doctors, nurses, PAs, and pharmacists without licenses can still practice telemedicine. Telemedicine is not another branch of health care but rather an extension of current health care, and the same standards applied to in-person care must also be applied to virtual care. Although telemedicine is essential to expanding healthcare services during the pandemic, it is important to address the potential limitations of the technology in addition to the benefits.

BACKGROUND

There are numerous examples of when medical professionals have failed patients, and oftentimes, these medical failures end up hurting more than the failed patient. The Lufthansa case is an example of the repercussions of doctors not following clinical practice guidelines.[4] In this instance, 150 people died in 2015 when a Lufthansa Germanwings plane crashed into the French Alpines. The co-pilot of the plane locked the pilot out of the cockpit while the pilot used the restroom, and then flew the plane into the side of a mountain, killing all 150 people on board. The co-pilot was believed to have depression and was thought to have purposefully committed this suicidal act as he was declared 'unfit to work' by a German doctor. He was also previously diagnosed with suicidal tendencies. Although this case was not in the United States, the complexity of this case calls attention to abuse and malpractice by doctors. The pilot was deemed unfit to work due to psychological issues; yet, that was not enforced as he continued to fly. The doctor failed to enforce his diagnosis on his patient, and by not doing so the doctor allowed for the co-pilot to commit an atrocity.

Some doctors are still allowed to continue their practice in other states and through means of telehealth, despite having been caught for malpractice. For example, plastic surgeon John Siebert was caught having an intercourse with a patient in New York, and after looking at his case, the New York State Medical Board claims Siebert to show 'moral unfitness to practice'.[5] He had his license suspended for 3 years, and has a permanent requirement for a female chaperone to be in the room for every procedure. However, despite the prior circumstances, Siebert continues to practice in Wisconsin and has been appointed to an endowed chair at the University of Wisconsin-Madison. Although there are only a small percentage of doctors who lack integrity

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within their practice, their wrongdoings affect thousands of individuals, and it is crucial for patients to achieve more transparency to prevent future misconduct.

Policy (medical licenses in the United States for nurses and pharmacists)
Obtaining a nursing license varies state by state. However, while each state has its own specific requirements, there are some standard requirements between all of the states. Those commonalities include graduation from a state nursing programme, passing the NCLEX® examination, English language proficiency, and 'sound moral character', which is tested through a series of questions. PAs gain their licenses through graduating from an accredited PA program and subsequently passing the Physician Assistant National Certifying Examination. As for pharmaceutical licenses, pharmacist candidates must graduate from a PharmD program, and take the North American Pharmacist Licensure Examination, and depending on the state, either the Multistate Pharmacy Jurisprudence Examination or a jurisprudence examination.

The process of acquiring a nursing, PA, or pharmaceutical license is rigorous; however, these licensed professionals still can be dangerous to patients and go without punishment. Annually, only 1% of nurses receive some sort of discipline in regard to their license.[6] When discipline is needed, the Board of Nursing within each state decides on the action they feel is necessary. This discipline rarely involves a license revoking, and most often is a fine, the imposition of some sort of monitoring, or education remediation. If a license is revoked, individuals can still work in jobs such as nursing assistant, medical assistant, and a home-aid. In addition, nurses with revoked licenses can apply to have them reinstated. The State Board of Pharmacists is in charge of regulating, enforcing, and rescinding pharmaceutical licenses. Complaints against pharmacists are given to an investigator within the State Board of Pharmacists. The investigators collect data on the situation and report it back to the board, who decides upon what disciplinary action needs to be taken. In other circumstances, formal administrative hearings may be necessary and are conducted before an administrative law judge. A pharmacist can appeal the judge's final decision to a state court. Finally, the Physicians Assistants Board provides both disciplinary action and non-disciplinary action. The non-disciplinary action includes citations, while the disciplinary action involves suspension of license.

Regulation of nurses
Telemedicine allows nursing professionals to efficiently and conveniently care for patients, especially during the pandemic. As the provision of healthcare services via telemedicine expands during the current COVID-19 emergency period, nursing professionals must be aware of their organization's policies, their state practice act, and laws regarding telehealth services. When nurses are aware of the risks, they can take steps to protect themselves as they care for others during these difficult times. During the nationwide public health emergency due to COVID-19, some of these statutes and regulations may be waived, so it is important for nurses to be aware of what the requirements are both during and following the emergency period.

Laws regulating medical professionals other than medical doctors are primarily at the state level. State regulations specify the legal duties of a nurse to patients, other medical personnel, and the community.[7] However, the Nurse Practice Act is not enough to define or regulate their restrictions, especially in the case of telemedicine. As the usage of telehealth services has increased, more organizations have published updated telehealth guidelines to boost COVID-19 care.

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For nurses, the American Association of Critical-Care Nurses was the first to define and publish authoritative guidelines, specifically for the emerging teleICU nursing practice.[8] Especially as states temporarily suspend and waive practice agreement requirements during the pandemic, there is a necessity for stricter regulations to ensure the highest quality of care and avoid malpractice cases.

Other laws impact practice, stating that other medical boards play different roles determined on a case-by-case basis. For example, nurse-midwives are regulated by a Board of Midwifery or various types of boards (i.e. medicine, nursing, and health) in some states.[9] In other states, however, Clinical Nurse Specialists are not included in the Nurse Practice Act as opposed to a Certified Nurse Practitioners, meaning that Clinical Nurse Specialists are not held to the same scope of practice as other registered nurses within the state.[10] Some states do not allow nurse practitioners (NPs) the full extent of their professions, preventing them from acting as the primary caretaker when it comes to basic health services. However, recently they have begun to gain autonomy and practice independently of physicians; the definition of autonomy differs in the United States from other countries, such as England.[11]

The risks of negligence and malpractice cases against nurses continue to arise during the pandemic. As the need for the highest quality of medical assistance increases, the number of immunity laws protecting healthcare workers from lawsuits also increases, as per the recommendation of the AMA.[12] Nursing homes, in particular, are heavily protected by these laws. In April 2020, Brenda Anagnos saw her mother shivering from outside a window of the locked-down nursing home and had to call the front desk for assistance. She began to fear for her mother's life and the quality of care that was provided behind closed doors, and these fears only escalated when a family friend visited her mother the next day and saw, through the window, her mother lying on the floor. She died the next morning.[13] Situations like this are not unique; many families with loved ones in nursing homes have similar experiences. As of early May 2020, more than 28,000 deaths have been reported in nursing homes.[14] Although the presence of cases of COVID-19 in a nursing home does not automatically indicate noncompliance with federal requirements, there is still a need for stricter regulations in these environments, especially as nursing homes continue to push for emergency protection from claims of inadequate care. Medical errors also include medication errors, which are the most common types of errors in terms of patient safety.[15]

Medication errors are not uncommon on an international, as well as domestic, scale. A study conducted in 2016 analyzed 585 different cases of medication errors against nurses in Sweden, which were considered malpractice cases the first of which was from January 1, 1996, to December 31, 2006. These cases were not limited to specific healthcare settings. All nurses were registered; however, a total of 613 medication errors were found in the 585 case files. These medication errors and their contributing factors are not unlike the ones found around the world.[16] Unfortunately, there are overlapping definitions of what constitutes a 'medical error', and decisions regarding malpractice can be subjective.[17]

This need also translates to telehealth. In 2018, the Enhanced Nurse Licensure Compact was passed, allowing licensed nurses in 29 states to use telehealth services to treat patients in other states.[18] Differences in the state-to-state laws can

put nurses practicing telemedicine at risk. These discrepancies in telemedicine regulations are constantly changing, and healthcare groups are issuing different guidelines about the standard of care that applies to telemedicine.[19] For example, in 2016, the American Medical Association adopted ethical guidance on telehealth and telemedicine[20], and in 2015, the American Academy of Pediatrics issued a recommendation of telemedicine in pediatric health care[21]; however, the rules and regulations addressing NP requirements differ from state to state, and this variability creates confusion for NPs involved in the practice of telehealth. We see a similar pattern today as the federal government has issued waivers on telehealth restrictions. Many lawsuits are not even getting accepted; in Houston, medical malpractice lawyers have been rejecting malpractice lawsuits to protect their healthcare workers, keeping many families from receiving justice.[22]

Regulation of PAs

PAs are regulated by the respective State Medical Boards. Each state determines the scope of practice for PAs through state licensing requirements.[23] In terms of supervision, state policy specifies whether the supervisory relationship between PA and physician is determined at the practice or state level. As of August 2019, however, there was a case for a separate PA state board, allowing the profession to self-govern[24], so this may change. Primary prescriptive authority is determined at the practice level. PAs have no authority to function independently of a physician and must register to practice under the supervision of a licensed physician.

Similar to NPs, most states allow the supervision of PAs through physicians via telecommunication. Delaware, for example, allows licensed physicians to delegate certain medical authority to the PA, so long as the physician is able to supervise and communicate effectively via telecommunication or chart review.[23] Most laws do not explicitly state whether this supervision can happen from a different city in the state; however, all physicians usually have practice and supervision plans that allow them to be readily and easily accessible through means of telecommunication. Some states, such as West Virginia, have more of a collaborative than supervisory language between a physician and PA. This specific state law does not require the personal presence of the collaborating physician at the healthcare service (see Table 1).

In all cases, the supervising physician must be licensed. There must be strict regulations for both medical professionals. In Lopez vs. Ledesma, a case proving medical misconduct by three doctors and two PAs, the Legislature was not given clear direction on how to apply section 3333.2, subdivision (c)[2] to PAs, due to the uniqueness of the situation.[25] Regardless, both PAs treated the plaintiff's daughter, Olivia Sarinanan, without following proper supervisory guidelines, breaching regulatory obligations. Olivia died as a result of medical negligence. In unacceptable cases such as this, retraining and supervision of the progress of PAs and their respective physicians are vital. As experience in medical offices, hospitals, and clinics translate to telemedicine visits, it is just as important that PA laws surrounding telehealth are also given strict regulations.

Few states specify PAs in their telemedicine laws. However, some states have passed laws, allowing their healthcare practitioners to practice telehealth during the pandemic. New Jersey, for example, enacted A3860, allowing their healthcare practitioners to practice telehealth for the time being.[26] With this change, PAs will now

Table 1. Comparing state policies regarding PAs

States that require a certain number or percentage of PA charts to co-sign (20)	States that have stablished limits on the number of PAs a physician can collaborate with or supervise (39)	States that authorize PAs to prescribe Schedule II-V medication (44)	States that prohibit PAs to prescribe Schedule II-V medication (7)	States that regulate PAs by the medical board (42)	States with a separate and independent regulatory board (8)
AL, CA, CO, IN, KS, KY, LA, MS, MO, MT, NE, NV, NJ, OH, PA, SC, TN, UT, VT, VA	AL, AZ, CA, CO, CT, DE, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, MD, MO, MT, NE, NV, NH, NJ, NY, OH, OK, OR, PA, SC, SD, TX, UT, VT, VA, WA, WV, WI, WY	AK, AZ, CA, CO, CT, DE, FL, ID, IL, IN, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WI, WY	All except AL, AR, GA, HI, IA, KY,* WV *Lacks the authority to prescribe legend drugs	AL, AK, AR, CO, CT, DE, FL, GA, HI, ID, IL, IN, KS, KY, LA, ME, MD, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, SC, SD, TX, VT, VA, WA, WV, WI, WY	AZ, CA, IA, MA, MI, RI, TN, UT

Source: American Medical Association Advocacy Resource Center.

have more freedom to deliver services through telehealth. Not all states include PAs as eligible healthcare providers in health laws regarding telemedicine. The implementation of these new telemedicine laws in states like New Jersey has allowed for more accessible healthcare service options during the COVID-19 pandemic; however, there has not been much feedback regarding the effects of these laws, as they are relatively new.

Regulation of pharmacists

Laws regarding pharmacists include conscience clauses, which give pharmacists the right to refuse to perform certain services if they violate any personal beliefs or values. Most of these policies focus on pharmacists distributing emergency contraception.[27] These conscience clauses were enacted after the Supreme Court decision in the Roe v. Wade case. Typically, these clauses concern contraception prescriptions. States with laws that explicitly do not allow pharmacists to distribute emergency contraception include Arizona, Arkansas, Georgia, Idaho, Mississippi, and South Dakota.[28] Permission granted by the state regarding the distribution of emergency contraception widely varies, as some states also require physician permission or physician collaboration. Pharmacists are regulated by their respective State Boards of Pharmacy, as well as the Food and Drug Administration (FDA), and the Drug Enforcement Agency (DEA), The Joint Commission (TJC), and the National Association

of the Boards of Pharmacy (NABP). The BOP regulates pharmacist licensing and sets state laws or requirements[29], the FDA approves what drugs can be sold in the United States (regulates what pharmaceuticals can be distributed)[30], the DEA investigates violations and ensures that all distributed substances are legal[31], the TJC accredits and certifies healthcare organizations[32], and the NABP assists BOP by ensuring consistent standards.[33] The consensus in regulations across these boards is essential in pharmacy, especially since a majority of the incidents related to preventable patient harm are drug-related.[34]

As multiple agencies regulate pharmacists, there are many risks for pharmacists when practicing, which creates conflict in regulation. To comply with regulations, many states use interstate prescription data sharing. Massachusetts, for example, uses the Massachusetts Prescription Awareness Tool (MassPAT) to search for out-of-state prescriptions.[35] These prescription drug monitoring programs (PDMPs) are electronic databases that track controlled substance prescriptions in a state to better protect patients.[36] Forty-nine states have operational PDMPs, while Missouri does not.[37] Although the interstate prescriptions are using this technology, pharmacists must continue to exercise caution as BOPs change legislature. The Montana BOP, for example, has issued a temporary emergency rule, MAR 24-174-75, to suspend the requirements for monthly in-person inspections of telemedicine pharmacy sites until August 5, 2020, in response to the COVID-19 pandemic.[38]

Some cases also rule that pharmacist malpractice is not considered medical malpractice. In Franklin v. Walmart 2019, JoAnn Franklin claimed that she was dispensed lithium while already using hydrochlorothiazide, resulting in drug interaction and toxic effects. Her lawsuit claimed that the pharmacist had breached a duty of ‘informed consent’, as the pharmacist who dispensed the lithium allegedly failed to inform the patient of potential interaction with hydrochlorothiazide. The pharmacy moved for dismissal of the case, contending that the doctrine of informed consent applies to physicians and not to pharmacists. Ultimately, the court also sided with the pharmacy, arguing that the role of informing the patient falls solely on the physician.[39] If this continues to be the case, then pharmacy and medicine will not be treated the same. Medical professionals other than physicians are also important, even if they are not treated independently. Pharmacists have a duty to learn their patients’ education.

As pharmacists dive deeper into the world of telemedicine, more opportunities have opened for them in the digital era. One of the studies evaluated a 6-month outpatient interprofessional telehealth chronic care management pilot program and found that integrating a telepharmacist enhanced clinical services in 2018.[40] Pharmaceutical technicians can also play key roles in facilitating the connection between the pharmacist and the customer and ensuring safety. They are essential to pharmacy teams, even if state laws prohibit them from the administration of vaccines.[41] Perhaps, pharmaceutical technicians can be trained to become telemedicine technicians and facilitate the process of moving to telemedicine.

DISCUSSION

Although these specialists are often overlooked in comparison to physicians, their presence in telemedicine is pivotal to the success of telemedicine programs. Traditionally, nurses and PAs assist in caring for patients and managing physical, psychological, and developmental patient needs. Both of these roles include serving patients and acting as a liaison between patients

and doctors, ensuring that a patient has proper and accurate care. Within the scope of telemedicine, there is a shift in the role of a nurse and a PA. Their roles may shift to more triage work and aiding in patient access to the online telehealth system. They may also work separately to help patients with medical issues in circumstances where a doctor is not necessary, like dealing with minor injuries, or helping patients with pre- and postoperative care. Depending on the state, telehealth nursing does not always require a license or any certification. Especially with the COVID-19 pandemic, the government has relaxed regulations in regards to telemedicine, which allows medical parties to practice without regulations required within states.[42] While the work of pharmacists includes patient care through dispensation drugs and/or devices to cure, prevent, or eliminate a disease or symptoms, telepharmacy follows the same practices but through remote pharmacy and remote dispensary. In addition, telepharmacy still must abide by policies and regulations in the state that the patient is located.[43]

As health care expands due to the increasing number of people needing medical attention throughout the COVID-19 pandemic, the roles and quantity of nurses, PAs, and pharmacists changes. The increasing number of patients in need makes the role of these professionals even more grave, which is concerning due to the barriers that are being removed to allow for medical professionals to be hired more readily. The efficacy and efficiency of telemedicine programs would not be possible without the presence of these medical professionals.

CONCLUSION

During the COVID-19 pandemic, telemedicine may provide the safest option for both patients and healthcare workers, but without a nationwide push to train and retrain staff, successful efforts to sustain telemedicine programs could be limited to large, well-funded health centers or eventually falter. Physicians are not the only medical personnel that should be given strict regulations. In the era of COVID-19, stricter discipline is mandatory, especially in the presence of differing regulations. As a solution, regulations at the international, national, state, and local levels should be imposed and interdependent. As these digital technologies have come in, we must consider not only the benefits but also the responsibilities of increased utilization. Enforcing these responsibilities is key to not only deeper quality but also the lives and safety of patients.

Given that each specialty has different but extremely important roles in telemedicine, policies must address these professions as well. We may pay attention to the quality of care across all medical professions, especially during the pandemic. In a post-COVID era, perhaps, we can capitalize on enforcing regulations that allow for better protection of privacy in the presence of technology. As more medical professionals are required to take on stronger roles and as technology is deeply ingrained in all aspects of medicine, it is important to not only address these shortcomings but also call for stronger action.

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