5-2023

Medication Errors in Pediatric Care and Preventative Solutions

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Medication Errors in Pediatric Care and Preventative Solutions

An Honors Thesis submitted in partial fulfillment

of the requirements of Honors Studies in Political Science

By

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Spring 2023

Political Science

Fulbright College of Arts and Sciences

The University of Arkansas

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Abstract:

The research presented extensively examines previous reports covering pediatric medication errors (PMEs). Utilizing specific studies into the frequency and types of medication errors along with public surveys and policy discussion, the data and suggestions here provide commentary on the scope of PMEs, suggested institutional reform, and most importantly, legislative recommended action necessary to stymie the tide of PMEs. A significant portion of the research contained fixates on the literature review to provide ample familiarity with the background and scope of PMEs, but the subsequent sections will discuss their implication. After providing details on the magnitude of the issue, regulatory and tort system impact, organizational structure, pharmacist involvement in clinical environments, and necessary legislative reform, the work contained herein will sufficiently document the challenges patients and providers confront, including the requisite tools to remedy such an issue.

Introduction:

A typical scenario regarding a sick child seeking relief entails a visit to a doctor or physician, diagnosis, and trip to a nearby pharmacy to receive any necessary medications. The area of pediatric care is unique for its necessary involvement of a caretaker, but the additional measure of concern rests in the occurrence of medical errors that could and have led to significant financial and health negative effects. The U.S. Food and Drug Administration (FDA) has employed a definition from the National Coordinating Council for Medication Error Reporting and Prevention to describe medication errors as, “any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is the in the

control of the healthcare professional, patient, or consumer" ("Working to Reduce Medication Errors" 2019).

The scope of the issue can be found in the frequency of suspected reports made to the FDA annually: over 100,000 U.S. reports. Although the Institute of Medicine found there was limited data to quantify the financial costs of medication errors in pediatrics (*Preventing Medication Errors,* 2007), Neuspiel et al., (2018) conveyed the Physician Insurers Association of America's finding that between 2003-2012, the average indemnity for diagnosis errors was $414,455 and $207,916 for medication errors (Neuspiel and Schuman 2018, p. 32). Additionally, the authors included a systematic review and concluded that as much as 10% of all pediatric medication orders result in medication errors (p. 32).

Challenges healthcare personnel and caregivers face revolve around the vulnerability of children; in particular, the dependency upon children to provide thorough and proper communication. In tandem with communication barriers, the necessity to rely upon weight as a gauge for dosing and treatment requires fail-proof systems both within one healthcare network, such as in ambulatory care—outpatient care—and inter-network between prescribers, pharmacies, and caregivers. Through the multifaceted challenges facing the U.S. system to ensure children are properly diagnosed and treated, the research here will initially cover the different forms of medication errors that exist and their frequency. Afterwards, the attention will turn to the setting in which these issues occur and the factors creating such an environment, and finally, there will be significant conversation on the possible solutions to improve communication and practices to reduce these errors from both an occupational operations perspective and formal regulations from bureaucratic, congressional, and legislative bodies.

Briefly, there are a range of possibilities political institutions can adopt to confront the problem of PMEs in healthcare. There are several major recommendations public policy makers can utilize to effectively merge the interests of public safety for children and flexibility for medical practitioners to practice within their best judgment. Some of the main ideas presented later focus on alterations to information contained within prescriptions; federal limits on malpractice insurer contracts and tort reform; state certification procedures; restrictions on firings for employees; fluctuations in the definition of error; and necessary tools for health departments to ensure and enforce reasonable care standards for minors.

Literature Review:

The focus on PMEs covers healthcare in multiple environments, such as private clinics, hospitals, or pharmacies; however, multiple settings share a commonality in their regard for operation via policy and regulation. As such, Mary Clare Lennon and Thomas Corbett's contribution in *Policy into action: Implementation Research and Welfare Reform* (2003) are both informative and relevant. They detail how public programs are the medium to drive public policy into action while these programs are evaluated based on an implementation analysis—an examination into the goals, execution, shared goals between staff, and reflection of policy—and impact analysis, essentially answering whether such a program has achieved its targets or caused any other indirect outcomes (pg. 2). While impact analysis regards the direct outcomes after a policy's enactment, implementation analysis is defined as a range of studies reviewing policy from its origin as legislation and regulation to its development within all bureaucratic levels to grassroot organizations (pg. 40). Its analysis develops further, analyzing its internal components, political and socio-economic culture, and relationship between multiple parts and individuals

within the program (pg. 42). At page 45 the authors find implementation studies can recommend "best practices'' within a specified jurisdiction or industry—offering an inductive method to proffer predictive and effective options.

Lennon and Corbett premise their discussion with the use of the 1996 Personal Responsibility and Work Opportunity Act (PRWORA): a federal program branded to transition publicly assisted families into a self-sufficient position. PRWORA reforms are partially defined by reinvention, a shift from a tight focus on protocols to overseeing its achievement of, and reallocation, a reallocation of authority from higher government levels to local control and those directly facing the challenges—a process necessary to increase professionalization (pg. 8). They delve into the relevant factors which influence policy design. For example, they find practitioners, when deciding on policy and program, have to consider political trade-offs: the "competing values, needs, and desires," (pg. 17). One of the barriers to optimal solutions, however, are the practical limitations to implementation policies. Therefore, the target of implementation studies is to distinguish the plethora of development program styles, conceptualize practices and experiences, design it for a broader group, and infer potentially effective programs for similar groups and individuals (pg. 18). The analysis then considers strategic and operational levels' impact on policy options. Each defines public management with the former focused on overall targets elected officials and senior-appointed officials choose while the latter is concerned with the objective's implementation. The authors at 22 proscribe evaluation evidence as a framework— not an omen to drive policy direction; instead, effective policy is a consequence of creativity and appeal to public demand.

Prot et al., (2005) directly observed 1,719 pediatric administrations in Paris, France between April 2002 to March 2003 to quantify the kind and frequency of PMEs and their likely

factors. Twelve observers followed pediatric nurses in four clinical units of a pediatric teaching hospital, and the observers accompanied hospital staff every weekday morning as the nurses prepared and administered all medications (pg. 381). Prot et al., defined drug administration errors as any discrepancy between the physicians' written or digital instructions and drug delivery—a definition adopted from the American Society of Hospital Pharmacy (pg. 382). They divided potential errors into ten categories and set parameters for levels of seriousness:

> timing errors (greater than 1-hour difference compared with the ordered time), omission, unordered drug, wrong generic drug, wrong dosage, wrong formulation, wrong route, deteriorated drug, technical error in preparation or administration (e.g., wrong infusion flow rate or wrong diluent), and extra dose. A panel composed of two physicians, two pharmacists, one nurse, and one epidemiologist evaluated the seriousness of each error by indicating what their response would have been: no response (decisions normally left to nurses), minor corrective action (discussion with the nurse or telephone call to the pharmacy), additional investigations or monitoring, major treatment modification, or action to eliminate factors contributing to a life-threatening error.

In providing the results, the authors provided the different forms of medical attention, opportunities for error, the most common form and type, and by whom these errors occurred. Prot et al., concluded 145 patients (43%) had experienced at least one error, and 109 nurses (39%) were the responsible party for these errors. Of the potential 1,719 opportunities for errors, 467 led to an error, creating an error rate of 27.2%; but as an aggregate, there were 538 administration errors for a rate of 31.3%. Excluding timing errors though, the rate decreased to 17.6%, or 302 errors. Most mistakes in route administration involved a nasogastric catheter, and the authors found its cause to be facilities' Patient Care System software omitted the term

"nasogastric catheter." They also discovered risk for error increased when the administrator was a "nurse intern, temporary staffing agency nurse, or pool nurse," (pg. 383). However, they reported no evidence to support any indication of a relevant risk factor due to the nominal number of drugs provided through infusion per nurse.

Table 4 Error rate

	Total
Number of errors	538 (31.3)
Administration errors other than timing errors	352 (20.5)
Timing errors	186 (10.8)
Number of opportunities with at least one error (error rate)	467 (27.2)
At least one administration error excluding timing errors	302 (17.6)
Timing errors only	165 (9.6)
Seriousness of errors	
No corrective action needed	144 (8.4)
Minor corrective action	240 (13.9)
Additional investigations or monitoring	20 (1.1)
Major treatment modification	63 (3.6)
Potentially life-threatening error	0

N (%) for qualitative variable. Percentages are given within parentheses with the number of opportunities for errors as the denominator. [1]

[1] Prot et al., "Drug administration errors and their determinants in pediatric in-patients," *International Journal for Quality in Health Care,* August 22, 2005, pg. 386

Table 5 Categories of administration errors with examples ($n = 538$)

Error categories	*N* (%)	Examples
Wrong time	192 (36)	Ciprofloxacin IV 2 hours late, amikacin more than 1 hour late
Wrong route	102 (19)	Crushed valproic acid tablets administered by nasogastric tube instead of p.o., vitamins given by nasogastric tube instead of p.o. although the written prescription specified that the oral route should be used to stimulate the suction reflex
Wrong dose	83 (15)	Threefold increase in the dose of metoclopramide; vancomycin, and amikacin given twice a day instead of every 2 days
Unordered drug	52 (10)	Ciprofloxacin and amoxicillin IV continued despite an order to stop on that day
Wrong form	41 (8)	Furosemide oral solution prescribed, but solution of IV vials given orally
Omission	27 (5)	Acebutolol, prednisone, and fluconazole
Wrong administration or preparation technique	17 (3)	Oxacillin as IV bolus instead of as an infusion after dilution, six wrong solvents, one wrong solvent volume, seven wrong diluents, and one wrong rate of administration
Deteriorated drug	13 (2)	Half tablet of hydrocortisone in an open blister, oral morphine kept in a urine examination bottle
Wrong drug	11 (2)	Hydrochlorothiazide instead of spironolactone
Extra dose	0 (0)	

Percentages are given within parentheses with the number of administration errors as the denominator. [2]

While the researchers noted a widely held belief regarding oral administration as safer than intravenous routes, their results found the opposite. Other risk factors were found due to unrelated medications discovered in patients' rooms, impacting prime storage conditions and an unknown dispensing source, as well as pharmacy departments providing pediatric doses from adult forms. While the misplacement of unrelated medications is unpredictable scenario rooted in individual circumstances, the latter, Prot et al., claim, buttress previous motions for pharmaceutical industries to provide dosage forms appropriate for pediatric patients. Finally, the authors determined errors were less likely under the care of full-time nurses rather than part-time or traveling nurses: as such, the authors encouraged hospital staff and operators to focus on operational training and education. The authors found two potential limits to their findings. One, the observers only operated during the weekdays during the morning shift; however, these hospital staffing schedules were consistent throughout the weeks, reducing scheduling discrepancies. Secondly, their research did not consider PME's impact on ultimate patient

[2] Ibid.

outcomes, limiting the relational knowledge between error and outcome; although, the experts concluded approximately 20% of the errors "would have led to major treatment modifications or to additional investigations or monitoring," (pg. 385). Prot et al., summarized their efforts demonstrated a considerable issue in PMEs, and they urged healthcare providers and researchers to continue developing and implementing network-systems to further reduce such events.

Table 3 Characteristics of opportunities for error (n = 1719)

		Total
Number of opportunities for error per patient	1–2	158 (47.0)
	3–4	79 (23.5)
	5–6	44 (13.1)
	7–8	24 (7.2)
	≥9	31 (9.2)
Prescription		
Computer printout		1589 (92.4)
Handwritten prescription		120 (7.0)
Oral prescription		6 (0.4)
Oral prescription written down by the nurse		4 (0.2)
Statements on the drug license		
Appropriate for children, with no age or weight restrictions		271 (15.8)
Appropriate for children, with age or weight restrictions		1053 (61.3)
Reserved for adults		55 (3.2)
No statement about age		334 (19.4)
Contraindicated in children		6 (0.3)
Dispensing system		
Origin		
Medication store in the unit		353 (20.6)
Unit-dose drug dispensing by the hospital pharmacy		1018 (59.2)
Obtained by a visit to the hospital pharmacy		12 (0.7)
Untraceable medications		267 (15.5)
Refrigerator in the unit		69 (4.0)
Prepared by the hospital pharmacy		201 (11.7)
Administration		
By mouth or by gastric catheter		1391 (80.9)
Intravenous infusion		219 (12.7)
Aerosol		77 (4.5)
Other routes[1]		32 (1.9)
First administration		61 (3.5)
Capsule, tablet, or pouch		619 (36.0)
Vial, powder, solution, or syrup		907 (52.8)
Infusion bag or ampoule		72 (4.2)
Other		121 (7.0)

N (%) for qualitative variables. Percentages are given within parentheses with the number of administrations as the denominator.
[1]Other routes: transcutaneous, transmucosal, ophthalmic, rectal, nasal, vesical, and auricular.

3

Hudgins et al., (2018) performed a cross-sectional analysis of new drug applications to the FDA to quantify how many sponsors complied with the 2003 Pediatric Research and Equity Act (PREA). Prior to PREA, more than 50% of drugs had no information regarding their efficacy or safety for children. The federal government enacted PREA to encourage drug manufacturers

[3] Ibid., pg. 385

to research and publish data regarding new drugs' impact and accessibility for pediatric use. The act empowers the FDA to require such information from drug companies; however, certain exceptions apply when a medication is either irrelevant or unsafe for children. Furthermore, Congress and President Obama in 2012 "permanently reauthorized" PREA with the Food and Drug Administration Safety and Innovation Act (FDASIA). The researchers reviewed drug applications to the FDA from December 2003 to July 2012, and they quantified the percentage of those who supplied data on pediatric use at the time of approval with a final review in 2016.

Regarding methodology, the researchers selected all new drug applications and supplements in the aforementioned period. They provided a 4-year period from the initial end date of 2012 to review those applications and determine whether a pediatric assessment had been included. Pediatric assessments are defined as reports using relevant formulas to derive data illustrating a drugs' safety and effectiveness for children, containing instructions on dosing and administration route for each pediatric age group. All drug applications were reviewed on the Drugs@FDA website, and the authors examined all drug labels and approval packages—collections of the FDA's statistical and medical reviews of drug submissions—to determine which qualified under PREA. Furthermore, the study excluded those drugs which received PREA waivers or orphan drugs (those designed to treat, diagnose, or prevent a rare condition or disease), given their inherent PREA exempt status. The FDA approval letters were the source of status for drugs' non-, partial, or full compliance with pediatric assessments. Hudgins et al., divided the applicable drugs into those which provided an assessment at the time of approval and those which received a waiver; furthermore, each new drug received a rating on its level of completeness. Full assessments provided data on all relevant pediatric age groups, partials contained research and data for a "subset of the relevant age groups," and non-compliance (pg.

162) represented those without any data whatsoever on the relevant pediatric age groups. Any necessary revisions were made at the final review in July 2016. The authors then compared post-PREA drug applications' pediatric assessments to drug applications pre-PREA to understand the law's impact. The data analysis procedure calculated the average time period and standard deviation between drug sponsors' FDA approval status and submission of full or partial pediatric assessments.

Out of the 184 new drug applications approved during the time of the study, 92 (50%) qualified for submitting a pediatric assessment. Of the 92 requiring such a report, 22 dealt with infectious diseases, 13 for psychiatric conditions, and 9 for endocrine disease. They found 20 (21.7%) had a full pediatric assessment at the time of approval, 9 (9.8%) had a partial assessment, but the majority, 63 (68.5%), had no pediatric assessment but approved, nonetheless. Considering those with PREA deferral, 72 drugs, the average time between approval and the deferral deadline was 3.9 years. However, only 3 (4.2%) met the deadline with a full pediatric assessment, 8 (11.1%) had a partial assessment, and again, the majority, 54 (75.0%) had submitted no pediatric assessment. According to the authors, 7 received deadlines beyond the July 2016 timeframe. For those with a deferral, 57 (79.2%) retained one because it still needed pediatric review while 15 (20.8%) required additional testing for its safety and effectiveness data in adults (pg. 163). In the end, 39 (42.4%) had full assessments, and for the other 57.6%, there were 12 (13.0%) with a partial assessment and 41 (44.6%) with no assessment.

TABLE 1 Pediatric assessments for new drugs approved from December 2003 to July 2012

	New Drugs, N (%)
Pediatric assessment at time of drug approval (N = 92)	
Full pediatric assessment	20 (21.7)
Partial pediatric assessment	9 (9.8)
No pediatric assessment	63 (68.5)
Pediatric assessment at time of PREA deferral deadline (N = 72)	
Full pediatric assessment	3 (4.2)
Partial pediatric assessment	8 (11.1)
No pediatric assessment	54 (75.0)
Deferral deadline outside study period	7 (9.7)
Pediatric assessment at time of final review (N = 92)[a,b]	
Full pediatric assessment	39 (42.4)
Partial pediatric assessment	12 (13.0)
No pediatric assessment	41 (44.6)

Abbreviation: PREA, Pediatric Research Equity Act.

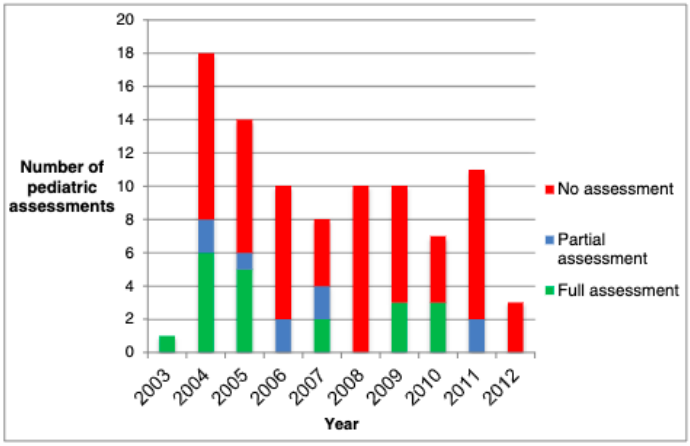
[a]Final review was performed July 1, 2016, providing a mean of 8.6 years (range 3.9-12.6 y) between drug approval and review.

[b]Includes 5 drugs with a partial assessment at time of approval that went on to have a full assessment, 8 drugs with no pediatric assessment at time of approval that completed a partial assessment, and 14 drugs with no pediatric assessment at time of approval that completed a full assessment.

[4]

Furthermore, the trend of pediatric submission of full assessments at 4, 6, and 8 years was 5.6% (4/72), 20.3% (12/59), and 31.3% (15/48), respectively. The authors began at 4 years because of those without a full assessment at their time of approval, no sponsor submitted a full pediatric report 2 years after initial approval. In comparing pediatric data of new drugs prior to and post PREA, the researchers found 154 drugs available for the time period between 1998 and December 2003. In that period, 32 (20.8%) were approved with label data on safety, efficacy, and dosing instruction for pediatric use. Hudgins et al., found 142 non-orphan drugs and only 29 (19.1%) included pediatric data on the labels.

[4] Hudgins et al., "Pediatric drug information available at the time of new drug approvals: A cross-sectional analysis," November 17, 2017, pg. 164



[5]

The authors claim since PREA's passage, many new drugs continue to lack pediatric assessments. Moreover, drug sponsors enjoy an incredible delta of time between adult approval and eventual submission of any pediatric data. Of those approved without pediatric data, only 22% went on to provide a full assessment, with an average of more than 6 years between drug approval and published data for children. To combat the prevalence of off-label and nonevidence-based drug use in pediatrics, the authors argue focus should be on decreasing the length of time between drug market entry and follow–up data on pediatric assessment.

TABLE 3 Time to pediatric assessments among new drugs approved without pediatric data, N = 63

Time Period	Years (95% CI)
Mean time between drug approval and full pediatric assessment (n = 14)	6.5 (4.1-8.9)
Mean time between drug approval and partial pediatric assessment (n = 8)	5.8 (3.3-8.3)
Mean time between drug approval and any pediatric assessment (n = 22)	6.2 (3.9-8.5)

[6]

[5] Ibid.
[6] Ibid.

The authors acknowledge progress found in FDASIA's provisions increasing oversight of the timing and planning of pediatric studies for potential new drugs. However, the authors find four limitations. First, there was no central source for product specific PREA status; therefore, the researchers were left with publicly available sources like the FDA website and approval packages. However, Hudgins et al., found no inconsistencies in their study design and mirrored the research style used for other federal reports. Secondly, they did not include a qualitative review; as such, it lacks any analysis on the data type, applicability for clinicians, or utility. Third, for those drugs approved prior to PREA, only certain products were available due to drug labeling information. Finally, the study ended 4 years after the approval date to allow for a final review, yet it is unknown whether sponsors supplied some or a full pediatric assessment after the final analysis in 2016. Despite these challenges, the authors conclude with a call for further research and policy design to investigate reducing the time gap between adult approval and pediatric review, especially given the breadth of sponsors which did not comply with PREA standards—even with deferred deadlines.

Author and clinical ethicist John D. Banja (2005) contributes to the discussion of PMEs as well through his work *Medical Errors and Medical Narcissism*. It examines the relationship between medical errors and psychological and environmental factors impacting both its occurrence and disclosure. Banja's work began with the creation of the Board of Surgery in 1928, and he found healthcare providers confronted malpractice suits, pressure from administrative staff, and a psychological tendency to dismiss acknowledgement for serious harm-errors. On page 3, he described an increasing trend in which practitioners forsook honest disclosure of such.

At the outset Banja defined "'errors.'' He distinguished errors from harm because risk managers and policy need flexibility to define such errors. Therefore, he defined errors as "'...an unwarranted failure of action or judgment to accommodate the standard of care'" (pg. 7). He included author James Reason's work from *Human Error* and his three cognitive-based errors. Reason cited skill-, rule-, and knowledge-based errors with the first dealing with cognitive-behavior routines disrupted with new demands, resulting in "'monitoring failures."' The knowledge-based errors involve applying either the wrong procedure or failing to know the right process regardless. The final category is a result of ignorance or misunderstanding the situation. However, knowledge-based errors can be further divided into three categories: the availability heuristic wherein the first set of data to reach the mind is used; the confirmation bias illustrated when only buttressing information is considered valid; and the overconfidence tendency where one's selection of a plan is valid because the actor chose it (pg. 8).

Within the context of these definitions of error and the multiple forms in which it can appear, Banja digresses to emphasize one point: error is inevitable. He argues error is a natural by-product of a complex, multi-dimensional healthcare system; where technologies, professionals, and patient-provider relationships continuously evolve, it only becomes realistic such an outcome will occur (pg. 8). Although errors will occur in some manner, "'systems'" can enable "'latent failures'" by omitting procedures or failproof checks to thwart such predictable results (pg. 10). To create a transparent ethical error disclosure system, organizational structure must operate against a backdrop where error's definition is expressed, its causational relationship to harm objectively affirmed, and a patient's right to know respected. Psychological tendencies to protect staff hurt progress and present a perpetual challenge (pg. 15).

After discussing error's nature, the clinical ethicist focused on the exogenous factors impacting error disclosure, such as regulation and insurance recommendations. Banja included RI.1.2.2 of the Joint Commission on the Accreditation of Healthcare Organization, and he found it merely requires a clear explanation when the outcome of a procedure "'differ[s] significantly'" from the anticipated outcome; however, it does not require citing errors or explaining any casual action (pg. 21). He complains malpractice insurers regularly incorporate contractual clauses preventing the insured from accepting any liability when conversing with a patient. Moreover, several states, he finds, have barred patient-plaintiffs from introducing trial evidence of a physician admitting guilt (pg. 22). Section 8.12 of the Council on Ethical and Judicial Affairs *Code of Medical Ethics: Current Opinions* acknowledges that an ethical patient-centered relationship respects a patient's right to learn the occurrence of an error and make an informed decision—irrespective of any legal concern for liability (pg. 22-23).

After the regulator and payor discussions, the text considers the personal characteristics that impact error reporting and disclosure. Highlighting narcissism, Banja takes the reader into an examination of the impact it has on physicians. Akin to rationalization to support nondisclosure, narcissism, Banja claims, interferes with the patient's right to know of any medical errors, but he divides the discussion between health and medical, also called pathological, narcissism. He defines the latter as exhibiting three traits: unemphatic toward patients, "'insistent treatment-oriented focus,"' and utilizing a communication style designed to control, rather than inform, a patient's beliefs and decisions (pg. 47-48). For Banja, narcissism in healthcare professionals exists on a continuum, but more importantly, he finds pathological narcissists evince these behaviors to buttress fragile self-portraits to maintain a construct of one who is competent and capable (pg. 48). The author juxtaposes the two narcissistic forms, but he

notes healthy narcissists become pathological as one remains fixated in "'unproductive feelings'" or cannot maintain healthy social relations. After consulting a series of studies from Paul Watson at the University of Tennessee, Banja found what delineated the healthy from pathological was self-esteem: moderate amounts led to reasonable pride and assertiveness while a dearth of self-esteem created overcompensation—with one becoming exploitative and fragile (pg. 49).

Despite the many challenges, Banja in Chapter 6 provides a series of potential remedies to address the multiple factors confronting healthcare providers. To encourage honest disclosures, Banja finds there are three reforms necessary. The first is to establish and enforce an educational curriculum whereby students can learn to mirror idealistic, humanistic approaches to medicine. Moreover, professionals can learn to monitor and recognize their internal attitudes and feelings, enabling them to retrospectively analyze their reaction to anxiety-inducing circumstances like error disclosure (pg. 119). The second area is to organize healthcare facilities in an environment structured to encourage error disclosure and repudiate concealment; to achieve such a target, Banja claims it necessary to retain support staff and healthcare professionals. Additionally, he finds it conducive to create an institutional practice devoid of punitive measure and consequences for unintentional error—a theory necessary to encourage the trepidatious physician (pg. 119-120). The final remedy is tort reform. Though its moral relationship to error disclosure is weak, Banja argues its practical impact is unavoidable; as such, it's necessary to free or dramatically reduce malpractice actions' reach to healthcare professionals if there is any legitimate expectation to have responsible parties come forward (pg. 120).

Banja explores the three topics in more depth, focusing initially on tort reform. With a recent rise in malpractice insurance premiums, physicians and healthcare providers have threatened to reduce their services or relocate altogether, which would lower public good

services and potentially create a dearth of accessibility for those in remote areas (pg. 121). Some of Banja's tort reform ideas include caps on claims for "'noneconomic damage,"' eliminating joint and several liability so defendants owe according to their participation, not merely lumping them together. In effect, this would reduce awards if patient-plaintiffs contribute to the error such as not adhering to the physician's instructions, impose stricter qualifications for one to be considered an expert witness, cap punitive damages, and limit compensation for attorneys (pg. 121-122). However, critics have argued such measures, admittedly deemed physician-insurer-oriented, are morally deficient, and they fail to address rising premium costs. To find a compromise, Banja includes two legislative measures in enterprise liability and no-fault which have been branded as sufficient to address such a conundrum (pg. 122-123).

The two terms are general in nature but potentially effective in confronting previous claims of an unrestrained civil justice system. Enterprise liability is an umbrella term encompassing other liability forms, such as vicarious, agency, and corporate liability. Vicarious incorporates hospitals into a civil claim via their status as employers. Agency liability reasons since hospitals are the authority source for self- or salaried employees, they're liable in tort action (pg. 123). Corporate liability theory finds a hospital vulnerable to civil suit when it knew or should have known a substantial risk existed for patients—whether it lies in questionable staff or insufficient resources, such as non-sterile equipment (pg. 124). Enterprise liability is more logical to have a hospital as the sole defendant because it will represent error as systemic and not perchance, encourage hospitals through financial exposure to restructure, and lead organizations to identify and remedy "'unprofessional or unskilled behaviors"' that illustrate staff practices (pg. 123-124).

Where enterprise liability consolidates the defense and requires the element of fault or negligence, no-fault systems only look at injury causes from an event and those significant enough to trigger a claim; and the event must be caused by either a hospital action or one or more of its personnel (pg. 128). Banja says its proponents favor its state-run system using experts to determine the outcome and using an established formula to calculate awards—payouts provided gradually rather than in lump-sum. Its supporters also find it will open the avenues of justice for patient-plaintiffs who cannot attract an attorney due to low pay-out opportunities or higher burdens of proof (pg. 128-129). However, little evidence exists on no–faults' impact on medical errors; moreover, Banja finds it to be a system premised on correcting deficiencies in the current tort system rather than an independent solution (pg. 130-131).

Though Banja separates the next two sections, the research here will consolidate them as his work considers environments conducive to supporting error reporting as well as the ethical and moral motivations to disclose errors. Facilitating a blameless and non-punitive environment recognizes humans are imperfect, especially when many situations are multifaceted and dynamic. Furthermore, it is more likely professionals will report errors when organizations adopt policies and retain staff to encourage and support physicians and nurses when they err—as opposed to punitive measures, especially when most errors are a result of system failure. Such a failure exists either when the individual provider adheres to a policy leading to a failure; or a system fails to catch a preliminary error, which leads to a subsequent adverse event (pg. 132-133). Banja delves into a conversation of how healthcare providers can transparently investigate false perceptions of perfection and honestly engage with reality. A reality, he finds, where errors provide an opportunity to be mindful, humanistic, and actively engaged with patients—to foster the belief and attitudinal system to encourage morally-guided error disclosures. Acting as an

antidote to the anxiety induced when a mistake occurs, such positive behaviors and strategies will lead providers to communicate in a more patient-oriented and authentic manner (pg. 164).

Concerning all medication errors, Witman et al., (1996) studied patient attitudes regarding their preference for disclosure. The study first considered different levels of error severity and physician response. Medication errors were labeled either minor, moderate, or severe with physicians either disclosing or not disclosing such an adverse event. Witman et al., surveyed 149 randomly chosen participants from an "academic general internal medicine outpatient clinic." The results found nearly all respondents (98%) reported some desire of acknowledgment of an error, even minor ones. Patients demonstrated a preference to locate an alternative provider at 14%, but the percentage increased to 65% for severe errors. They also studied litigation. Patients were more likely to pursue civil litigation for moderate and severe errors; for example, 12% of patients indicated support for suit if a moderate error were disclosed, but it increased to 20% of patients if a similar error were undisclosed and discovered later. In essence, Witman et al., provide support for their claim that patients have a demonstrable attitude to learn of medication errors, including minor events. Additionally, risk for litigation potentially decreases for circumstances in which an event is disclosed; thus, the authors conclude reaffirming the need for and importance of open patient-provider communication.

Sullivan and Buchino (2004) began their review of PMEs with an overview of medication errors generally. They defined medication errors as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer." They noted 20% of all medication orders have some error. For example, one study reported 31% of in-patient individuals experienced one error while 12% had two or more. They provided a list of potential errors and

categorized them into either prescribing, processing, dispensing, administrative, or monitoring error. While they noted the Institute of Medicine (IOM) Report *To Err Is Human* was a watershed moment for the public realization and attention on medication errors—as one person in the United States dies every day because of such errors—it is reported most of such errors do not lead to patient harm. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) was found to follow the IOM's report with national requirements for public healthcare facilities to modernize systems and practices to reduce the potential for medication errors: the authors include some examples of changes, such as "'read[ing] back'" verbal prescriptions and refining clinical systems.

The authors' text then shifts specifically to PMEs and its relevant factors exist. They first discuss the prevalence of such errors, as pediatric errors are found to be three-times more likely to occur than in adults; furthermore, because pediatric doses are tied to weight and body surface, minute mistakes in neonatal care can cause even a 10-fold error. The researchers identify other difference makers in absorption, metabolic processes, distribution throughout the body, and excretion levels as they may change with age. Additionally, as pediatric assessments required by FDA labeling may not exist or be incomplete, questions on efficacy and safety are potentially compromised with off-labeling prescribing. Children are found to exhibit more communication barriers, considering their immaturity or unwillingness to be forthcoming about adverse events and experiences with medication. Sullivan and Buchino then state the previously understood differences in pharmacokinetics and pharmacodynamics between children and adults, including the adjustments over time in how drug metabolism processes may change according to an infant and child's development stage. While federal efforts have struck at the problem, the authors find 75% of prescribed medications lacked adequate pediatric studies, which was prior to FDASIA

and not long after PREA. Although, it demonstrates a reality which exposes children to potential medical misadventures. Thus, they encourage academic medicine, society, and drug manufacturers to synergize their efforts and further protect children and infants from potentially preventable medication errors.

Later, they focus on the multiple sources, administrative, and calculative errors. They find the initial topic with prescribing errors, and nearly 50% of all errors in adults that were possible or preventable are a result of this kind. While 34% were characterized as an incorrect dosage, 75% of these medical discrepancies were flagged by the pharmacist or nurse prior to the patient accessing any medication. However, Sullivan and Buchino describe a plethora of potential causes for a prescribing error, such as ineligible handwriting, miscalculation, incomplete lab tests, or a misunderstanding of patient information. The authors recommend the increased use of preprinted order forms for certain, sensitive medications to reduce the potential for prescription order errors.

As for administration errors, there is a potential roadblock in gathering complete information as these errors are self-reported. So, while they are statistically lower than prescribing errors, there is a potential problem in data collection. Nonetheless, the kinds of administration errors are treating the wrong patient, incorrect drug usage, incorrect route of administration, timing, dosing, and appropriateness for a patient. To combat such occurrences, the authors promote the “Five Rights’’ which are: the right patient, drug, time/rate, dose, and route of administration.

Finally, they provide a range of potential computational mistakes which could lead to an adverse event, such as decimal point placement or confusing a total daily dose for an interval dose amount (e.g., 5 milliliters per day vs. 5 milliliters twice daily). Given the earlier

commentary of weight-based orders, the authors opine that such a mistake dramatically increases the potential for a severe adverse event. To prevent such occurrences, the authors encourage hospitals to use the Broselow tape—a color-coded tape that lists drugs according to their volume. However, they caution users to confirm the volumes providers use are the same concentration as those used on the tape because healthcare providers sometimes are required to perform quick and precise equivalency ratios or risk further complications.

Sullivan and Buchino offer potential solutions to a range of possible medication errors. Their commentary initiates with a recommendation for educational platforms and additional programs to address medication errors—a solution proven effective. Such possibilities range from annual, mandatory meetings to review relevant literature, or healthcare facilities and administrations improving one-on-one reviews and mathematical competency exams for physicians, nurses, and pharmacists. Another highlight they emphasize is the use of computerized physician order entry (CPOE). According to sources like the American Medical Association, IOM, and others, CPOE has demonstrated an incredible ability to reduce the prescription order error rate, as it eliminates the possibilities for misinterpretation. Moreover, CPOE has the potential to identify adverse drug-drug interactions, look-alike-sound-alike (LASA) medications, or possibly incorrect dosage amounts for a patient. However, they do acknowledge its limitation to identify errors in dosing or intervals, but they note this is an area for improvement.

The analysis for solutions continues with attention drawn to the in-patient and pharmaceutical setting. As for the former, the authors suggest a few managerial and procedural adjustments. First, they recommend akin to several neonatal and pediatric critical care centers, pediatric units should introduce pharmacists to the care team for a child. As medication therapies

and conditions become more nuanced, it's important to have a knowledgeable team that can identify potential drug interactions, adverse reactions, or potential medication errors. In fact, they include a study from Fortescue et al., (2003) *Prioritizing strategies for preventing medication errors and adverse drug events in pediatric inpatients* that found such an adjustment led to the potential prevention of 98.5% of all medication errors. Furthermore, relocating drugs like concentrated potassium solutions to a pharmacy where it's secured, prepared, and dispensed can reduce potentially fatal errors. In terms of the work between prescribers and pharmacy staff, the authors emphasize the permanent suspension of abbreviations in prescription orders, such as "'u' for 'units,'" and providing weight in terms of pounds rather than kilograms. In the pharmacy itself, they stress the need for pharmacy managers to segregate medications that sound or look the same, especially those with similar labeling to reduce potential confusion.

The key topic Sullivan and Buchino examine is the role of discipline and self-reporting. To ensure quality care and improved practices, they stress administrative structures should be built on encouragement and reflection rather than punishment for errors. They included Frey et al., *Does critical incident reporting contribute to medication error prevention* (2002), which recognized most errors as system errors, and found when minor errors were anonymously reported, it led to systemic changes and the ability to track trends. However, the authors are crucial to note monitoring of errors must follow with implementation changes and not simple recognition of pattern.

Using the database MEDLINE, Neuspiel and Taylor (2013) reviewed synthesized literature over medical errors for those aged 0-18 years—limiting their search between 1996 and 2012. After processing sources for relevancy, abstract information, and quality of information,

the authors provided an overview of contemporary scholarly research into PMEs in the outpatient, emergency unit, inpatient, and home setting.

The authors began with the outpatient environment, as it faces most pediatric encounters. Their analysis notes the prevalence of a variety of error occurrences; for example, from 47 medication errors emanating from 14 pediatric practice centers, they found 55% were order errors, 30% = the failure to order, 11% dealing with administration, 2% with translation, and another 2% from dispensing, according to Mohr et al., (2005) *Learning from Errors in Ambulatory Pediatrics.* From McPhillips et al., (2005) *Potential medication dosing errors in outpatient pediatrics,* the authors found among 1,933 randomly selected children prescribed new medications, 15% were either over- or underdosed; those weighing less than 35 kilograms (77 pounds) experienced higher error rates at 33%; children between the ages of 4 and 12 experienced an error rate of 13%, while those under the age of 4 had a rate at 20%. However, their study did not find any impact with the use of an electronic order.

Neuspiel and Taylor continue their consideration of outpatient care, but the authors then delve specifically into special groups of children. They start by introducing information on the increased risk children with chronic illnesses or multiple medications face. For example, over a two-month study at one center, researchers studied the medication errors children with acute lymphoblastic leukemia experienced. They found there was at least one error in 17 (9.9%) of the 172 medications prescribed, and of the 17, 12 dealt with administration and 5 with prescribing errors. Out of the 69 study patients, 13 (18.8%) had at least one medication error, and all were either faulty dosing or the failure to administer a necessary medication. Furthermore, the authors considered inpatient and outpatient, finding 451 medication errors involved antidepressants for those under 18-years old. However, the authors do not provide the nominal number of cases

overall. Using the MEDMARX database, the researchers examined anonymous error reports from 2003-2006; their studies reveal that of these errors, 95% were not caught before it reached the patient and 77% involved off-label medications. Additionally, the medical misadventures occurred at administration (33%), dispensation (30%), transcription (28%), and the prescription order (7.9%). The research indicates there were higher levels of dispensing errors for outpatients than inpatients as the transcription process occurred at the sight of treatment for the latter.

As language enables the facilitation of any healthcare relationship between patient and provider, Neuspiel and Taylor reflect upon previous research to extrapolate communication barriers between providers and patients. Using Wallace et al., (2010) *Evaluation of consumer medical information and oral liquid measuring devices accompanying pediatric prescriptions* as well as Sharif and Tse's *Accuracy of computer-generated, Spanish-language medicine labels,* Neuspiel and Taylor illustrate the difficulty caregivers experience as translation resources are not adequately utilized. The former covered a study of 20 different retail pharmacies from Tennessee, Georgia, and Colorado using liquid medications, and their efforts found 3 pharmacies included no materials to measure the amount, one-third provided tools that required multiple measurements, and many of the instructions provided were at a 9th-11th grade reading level—a level the authors claim is too high for many parents. In conjunction, the latter surveyed 316 pharmacies in the Bronx area, examining the accuracy of computer software to translate English instructions to Spanish. Their results indicated among the 286 who participated, 209 (73%) provided Spanish labels; however, of those, 86% used software programs, 11% used employees to translate labels, and 3% used professional interpretation services. They also discovered that while pharmacies could provide some labels in Spanish, there were overall inconsistencies and grammatical errors, which lead to further medical errors. After evaluating 76 medication labels

that were created by 13 different computer programs, 32 (43%) had incomplete Spanish translations—with a mixture of English and Spanish—while 6 had incorrect spellings and grammatical mistakes. Thus, there was a 50% error rate.

Before reaching their solutions, Neuspiel and Taylor then reviewed the medication errors within inpatient care. Amongst a collection of other studies, the authors include Al-Jeraisy et al., *Medication prescribing errors in a pediatric inpatient tertiary care setting in Saudi Arabia* (2011) and Chua et al., *Drug administration errors in pediatric wards: A direct observational approach* (2010); each demonstrating the type and frequency of inpatient PMEs. The former surveyed a general pediatric ward and pediatric intensive care unit (PICU), and from 2,380 medical orders, they found a 56% error rate. From the errors, dosing errors were the most common at 22.1% with administration errors behind at 12.0%. Additionally, there were clarity (11.4%), frequency (5.4%), incompatibility, wrong drug choice, and duplicate therapy errors. The latter gathered evidence from 2 pediatric wards. Chua et al., found from 857 administered drugs 100 (11.7%) had dosing errors, but it decreased to 7.8% when timing errors were not included, as incorrect administration timing was the most frequent at 28.8%. Finally, there were incorrect drugs prepared (26%), omitted errors (16.3%), and faulty doses (11.5%).

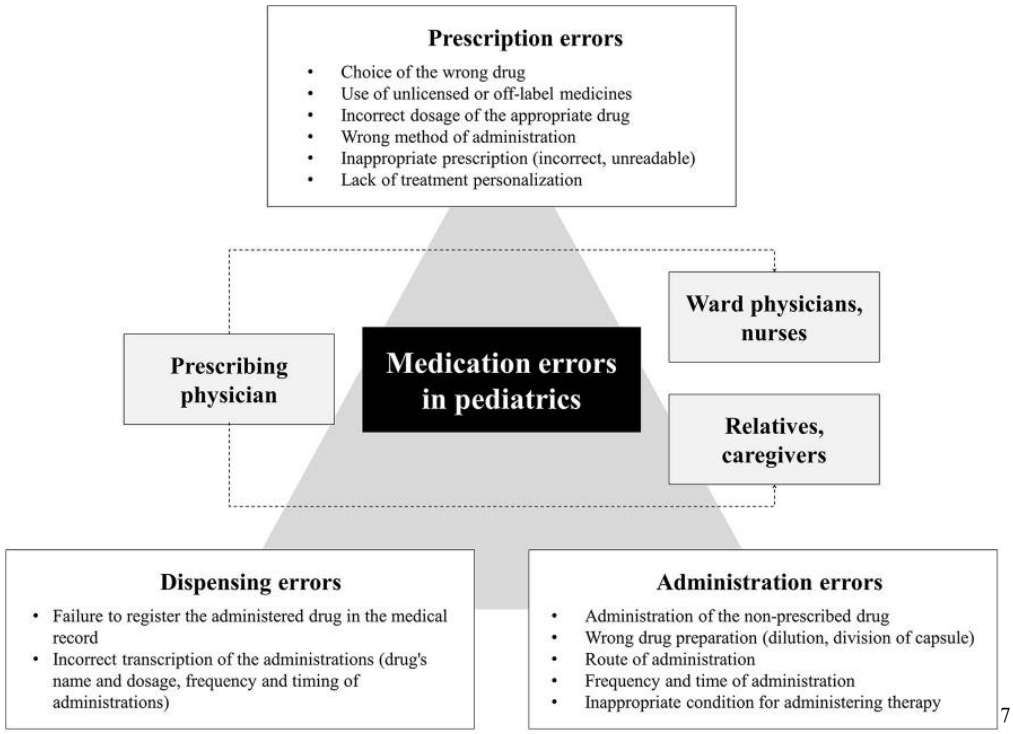
Despite the challenges presented, the authors suggested improvements—providing commentary and quantitative studies to substantiate and realize areas of additional research. They begin with electronic prescriptions (E-scribes), and using Kaushal et al., and Stultz and Nahata, they find E-scribes have been demonstrated to reduce medication errors in the former while the latter further clarified such a system used in conjunction with computerized clinical decision support (CCDS) can enhance effectiveness. While they suggest additional research necessary to study the CCDS' impact on weight verification or drug interaction alerts for

example, there is evidence to illustrate its benefit in decreasing error frequency and adverse drug events (ADE). Additionally, CCDS has led to reduced calculation errors and inappropriate doses for certain age groups. They also found from Morris et al., barcoding systems led to a "47% reduced risk of preventable ADEs." Finally, the authors review the impact of including clinical pharmacists into the rotation for inpatient care. From Fernández-Llamazares's (2012) study *Impact of clinical pharmacist interventions in reducing pediatric prescribing errors* as well as Virani and Crown's (2003) *The impact of clinical pharmacist on patient and economic outcomes in a child and adolescent mental health unit,* they found pharmacists' interventions were routinely accepted and positively impactful. The former's work evaluated clinical pharmacists' contribution among 61,458 orders in 14,713 pediatric patients. These pharmacists made 195 incredibly significant interventions, and there were 1,357 prescribing errors. Of these, 833 (61%) were classified as dosing errors, 30 (2.2%) as potentially deadly, and 194 (14.3%) as medically serious; however, the pharmacists' recommendations were followed 94.3% of the time. The latter found from a 4-week study period in an inpatient child and adolescent psychiatric facility, clinical pharmacists intervened 48 times. The leading physician accepted 47 of these interventions, and 86% of these were found to have a positive impact on the overall care. There were a range of errors with 32 drug problems found: 12 dealt with ADEs, 6 underdoses, 6 drugs not indicated, 2 incorrect medications, 1 overdose, 1 drug indicated but not prescribed, and 4 other forms of error.

The SingleCare article covering medication error rates begins by noting the FDA annually receives over 100,000 reports related to medication errors. After adopting the FDA's definition of medication errors, the document notes the environment for an error can occur in the home, hospital, or pharmacy; additionally, it can be an effect of consumer or healthcare

providers. It further defines medication errors into nine categories: prescribing errors, the failure to prescribe, administration, or dispensation, receiving a medication untimely, incorrect drug, faulty use of a medication, incorrect dosage, administration error, the lack of account for patient conditions or drug-drug interactions, and non-adherence to the physician's instructions. What the report found is that while over 7 million US patients are impacted because of medication errors every year, 10% of hospital patients are exposed to medication errors. Overall, SingleCare found almost 20% of medical doses are given erroneously for inpatients, and there are approximately 530,000 injuries annually for outpatients due to medical errors. Additionally, it revealed the U.S. spends over $40 billion each year for patients exposed to these errors, and preventable errors cost over $21 billion annually in consideration of all healthcare settings, including the home. Finally, SingleCare found the root causes of medication errors to be physicians ordering the incorrect drug, faulty drug preparation and dispensation, improper patient medication use, and transcription errors.

D'Errico et al., noted the dearth of research attended to the area of errors in pediatric care. The issue of errors is amplified as there are differences in metabolism and growth changes in the body between infants, children, and adolescents. Use of adult-dosage prescriptions and off-label use also determines the scope of risk; the most frequent form of error is therefore use of adult medications. Inpatient settings reveal 7.5 million medication errors occur in the U.S. annually, and some estimates declare 14-31% of PMEs could be fatal while the US Pharmacopeia (USP) Medication Errors Reporting Program found errors were higher for pediatric patients at 31% compared to 13% for adults.

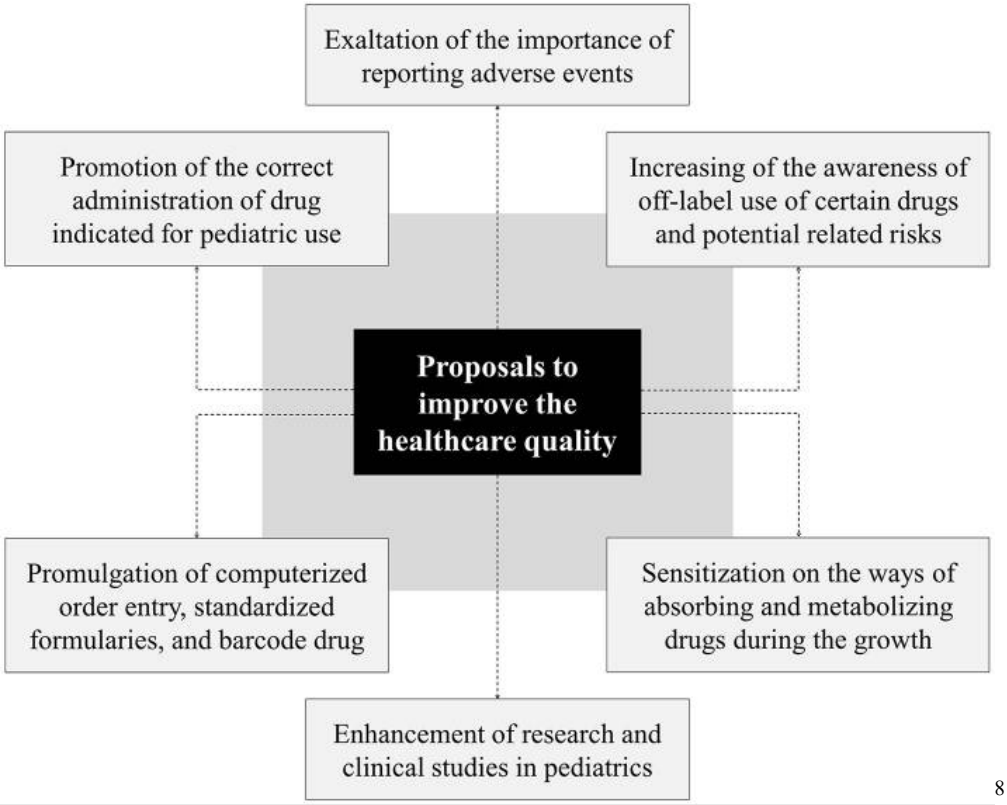


[7]

In the PICU, D'Errico et al., estimate there are between "22 and 59 errors per 1,000 doses, seven times more frequently" compared to other PICUs. In the end, the authors reach into the preventative strategies available to healthcare professionals and caregivers to reduce PMEs. Through increasing the use of CPOE, administrative measures, encouraging reporting adverse events, continuing education for new and current pediatric staff, and informing caregivers on the importance of adhering to provider instructions, D'Errico et al., recognize the potential to dramatically address and decrease medication errors in this field. The figure below encapsulates

[7] D'Errico et al., "Medication Errors in Pediatrics: Proposals to Improve the Quality and Safety of Care Through Clinical Risk Management," January 14, 2022.

the way these measures can coordinate in unison to achieve such a task.



[8]

Burton et al., found 60% of interviewed anesthesiologists find at least one pediatric medication error annually while 15% of these anesthesiologists experience at least one monthly. In terms of emergency care, 10-31% of PMEs are found to be related to incorrect weight or unit of measurement; additionally, the multifactorial nature of the context is pivotal. While dosage and administration are the most reported errors, the most common context is found in the use of unlicensed and off-label administration, 7-10% and 18-64%, respectively. The relative higher occurrences are specifically in off-label, antibiotic, and intravenous use. Without standardized dose regimens for children, the use of calculations and multiple methods increase the risk of dosage errors. Finally, in the context of inpatient care, distractions can contribute to error.

[8] Ibid.

Stratton et al., concluded that half of the nurses interviewed cited incessant interruptions and fatigue as the most common along with ignorance of drug knowledge and illegible handwriting. These factors operate in tandem with complex work demands and LASA drugs to create a recipe for mistakes, especially in the event of communication breakdown. Reporting isn't as frequent in the outpatient setting as communication failure is often when harmful effects are absent. However, the most cited problems lie in incorrect dosage, route of administration, drug insufficiency for the disease, lack of follow-up, misunderstanding of drug interactions, and miscommunication. From a study of 1,933 prescriptions, 15% had potential dosage errors and 33% incorrect weight measurements; and the statistic was higher for those under 4 years of age with multiple prescriptions.

Neuspiel et al., have identified several areas of medication errors and some examples of costs over the recent years. The Physician Insurers Association of America found that between 2003-2012, there was an average indemnity of $414,455 for diagnosis errors and average of $207,916 for medication errors. The authors' review found as much as 10% of all pediatric medication orders were errors, according to an October 2017 issue of *Contemporary Pediatrics*, "Safety first: How to avoid missteps when prescribing medication." These challenges are due to children's vulnerability, difficulty eliciting proper communication from children and infants, the strong reliability to use weight as a gauge for medication, and lack of inter-network communication between doctors and staff, pharmacies, and caregivers. Thus far, the previous sources have demonstrated a plethora of factors contributing to the occurrence of such a phenomenon; moreover, the figure above concisely illustrates how each subgroup can negatively influence the process of care for children in the US healthcare system to create such adverse events.

Analysis and Reforms

I. Necessary Federal and State Legislative Action

The discussions have demonstrated the severity of PMEs and their impact—both health and financial wise. However, there is ample opportunity for institutional actors, like state and federal government and agencies, to involve themselves. This section will extensively cover the way these forces can avail themselves of their tools to combat the prevalence of PMEs, beginning with the state government, which through federalism overlaps with the federal government, and finally, room for executive agencies to act.

State governments have the burden of accreditation and protocol for healthcare personnel; therefore, because the studies have shown dependence upon weight for children and customer preference for transparency, states should act accordingly. Thus, the first two recommendations are to mandate as a part of healthcare certification an acknowledgement from practitioners of their understanding of the importance of notifying patients when an error occurs, and accordingly, an agreement to notify all involved parties and a reporting system. According to the IOM's *To Err is Human* (2000), due to the challenges organizations and states face in encouraging voluntary or mandatory reporting, states should establish a hierarchy of reporting (pg. 101). To intertwine the two schemes of a hierarchy and accreditation, ideal legislative reform in this area would accomplish two criteria: it would first require the practitioner to recognize the expectation that there is such a right for a pediatric patient and their guardian to learn of the event of an error—at the expense of a consequence for those who fail to abide. However, to support staff relinquishing this information, states should adopt a hierarchy of reporting wherein those events that are not severely harmful or fatal do not follow with punishment. Instead, there is an opportunity for management to record the frequency of minor

errors, such as timing errors, and reaffirm the importance of adhering to protocol and detail. For those that are severe, reporting is mandatory, and for those who either conceal or are knowledgeable about concealment, state law should provide for criminal or civil penalties. Within the area of accreditation, it's imperative healthcare practitioners understand and believe state procedure isn't premised on the accumulation of data to publicly embarrass staff; rather, the procedure is focused on delineating those errors which are a result of human nature, which need only reaffirmation and re-training, from those a consequence of negligence and indifference.

The second recommendation for states is to impose a requirement for prescribers to provide pharmacies with a minor's weight on a prescription—whether an E-scribe, written, or verbal. Sullivan and Buchino have already demonstrated the inherent relationship between pediatric weight and medication. Due to children's shifting metabolic processes and the infrequency of drug manufacturer's providing full pediatric assessment of adult drugs, it's imperative states at least provides pharmacists the opportunity to verify the dosage and frequency of use is accurate. The two authors also illustrated the positive impact pharmacists have in the clinical area; thus, it is only logical to extend such a relationship beyond the physical boundaries of a clinic or hospital to the pharmacy. One hypothetical demonstrates the case clearly. Suppose a 5-year-old boy is ill and taken to the doctor's office. After the child is weighed at 35 pounds and the doctor examines the child, he is prescribed an antibiotic. However, the nurse mistakenly confuses the wording and prepares a script twice the dosage and frequency—-a consequence of fatigue. There is no logical expectation for the pharmacist to recognize such a mistake, especially when the child is possibly not with the parent to receive the medication from the pharmacy. However, if the nurse or doctor were required to include the weight, there's a potential for the pharmacist to recognize the potential inconsistency and flag

such a high dose for a child that size. Previous studies in this report have confirmed the importance of weight in pediatrics, and it is sensible for state legislatures to ensure every prescriber includes a child's weight to both self-check one's work and provide a secondary reference source in pharmacists to verify the medical judgment.

Beyond state action, there is an opportunity for both state and federal governmental action to confront tort reform and employment contracts. For the former, federal and state civil systems should prohibit malpractice insurers from barring physicians from admitting guilt to patients at the risk of losing protection. According to Banja, the current system allows malpractice payors to include clauses that thwart practitioners under certain circumstances from admitting guilt; however, the implicit consequence is a reality wherein physicians are faced with a binary choice: avoid malpractice protection and risk financial exposure or limit their ability to disclose pertinent error-related information to pediatric patients and their guardian. Assuming the most important facet in a civil system is to ensure accountability and an avenue for justice, it's paradoxical for state systems to permit malpractice payor schemes including such a disclosure barrier. However, one major concern for payor companies rests in their financial exposure as physicians admit guilt. There are two remedies though to address the anxiety of an uncontained cash-grab system. The first option is to implement a tiered system with caps for each level of seriousness and neglect. For those errors which are a result of system failure or minor in nature, capped awards will ensure hospitals and staff members are not subject to the whim of jury opinion. However, as the level of offense increases, and especially accompanied with malfeasance or misfeasance, the capped amount will escalate. The debate of capped civil awards is not novel, but it's critical here because such an implementation can allow patient-plaintiffs the opportunity to seek justice while shielding insurance companies and hospitals from the shifting

tide of jury opinion. There is another option within the realm of caps to implement a no-fault system, discussed previously under Banja's section. If a state chose not to transition to such a system, it could still incorporate its piece of providing gradual payments to plaintiffs instead of lump-sum amounts. What this would do is de-incentivize those cases for plaintiffs seeking a windfall, but still enable true pediatric victims the opportunity to pursue their case; but while this recommendation examines tort reform, it doesn't address the context within the occupational environment.

Following this there are two recommendations crucial to the operations within any healthcare organization—necessary to both facilitate and manage the prevalence of PMEs. The two areas work in tandem as they require state health departments to define a medical error, and more importantly, formally disbar any employer from dismissing employees due to a non-fatal error—absent repeat offenses or critical interference with the organization's operation. There are some advocates for a national reporting system for medical errors, such as John Toussaint and Kenneth Segel in their article *4 Actions to Reduce Medical Errors in U.S. Hospitals* (2022), but there's a preliminary issue with the idea: states should decide what constitutes an error. While the Constitution's preamble calls for the federal government to provide for the general welfare, there is no indication or general practice in American society where the federal government is the sole author for medical error's definition. Instead, states should be responsible for adhering to their own practice and institute a formal definition which the state health department creates. Thus, instead of a national reporting system, each state should have its version of an official source for PME reporting, and from there, states should follow Toussaint and Segel's advice wherein the state reporting system is solely advisory and made of experts. What this will create is a trust relationship between staff and the reporting agency. It will allow some non-partisan,

evidenced-based group to collect incidents and find common practices, parsing them from rare occurrences. These series of disclosures will enable the expert body to issue advisory opinions and recommendations for healthcare institutions and legislatures to better understand what issues remain; moreover, states can achieve these reforms and shed light without penalizing staff for either their mistakes or system failure.

Within that discussion, however, is the need to ensure employees are protected from punishment when they do inevitably perform erroneously. This proposal doesn't suggest in any capacity the idea that employees should be shielded from responsibility or even a firing where errors are egregious, dangerous, or simply against protocol. However, systems are not entirely failproof, and even if they are, IOM makes clear in their research that humans will err. The federal and state health departments should therefore issue guidance prohibiting the ability for an employer to dismiss an employee based on a reasonable error or even minor ones—so long as the employee voluntarily discloses the mistake to both patient and employer. The state and federal government can also achieve this point through stipulating employment contracts that include information expressly recognizing the right of an employee to be free from harassment or termination if a minor error occurs or is the consequence of system failure.

The final opportunity for reform is for the FDA to institute a stricter policy regarding drug approval. Because of the work which has demonstrated a lax attitude toward complying with pediatric timeline assessments, in conjunction with the research confirming pediatric medications come from adult doses, the FDA should begin delaying drug approvals that omit a full pediatric assessment—provided there are exceptions for life-saving medications. Borrowing from the field of economics, this is a classic negative, producer externality in the sense that pediatric patients are exposed to the harms of off-label use because drug manufacturers don't

want to incur the marginal costs for complying with the FDA-imposed timeline. However, the costs to society and patients exceed the benefits. Thus, either the federal government must instruct the FDA if it is unwilling to act on its own volition and wholly prevent any medical drug's confirmation to the public market where it lacks a full pediatric assessment. The benefit from such a change is found in the increased transparency and evidence-based findings to support physicians prescribing adult-based drugs. There is no questioning of a medical expert's opinion; however, to sustain a practice wherein children's doses and medications are not studied prior to their dispensation is unnecessarily dangerous and irresponsible, especially when it is not a matter of practicality but business decisions.

II. Further Research and Conclusion Remarks

The character of PMEs is amorphous in nature due to its contemporary fluctuating status, incorporating a distinct definition based on the individual rather than fixed in time. However, based on the operational meanings used in the studies provided throughout this work, it's clear from several authors such as D'Errico et al., and Stratton et al., that PMEs are a common phenomenon. Whether the healthcare environment be an outpatient, inpatient, or pharmaceutical one, it's clear there are opportunities for medical errors. Moreover, while it may be through language, fatigue, or pure blunder, the reality is social science and logic have confirmed PMEs can occur at any place, but more importantly, as drugs continue to enter the market without pediatric assessments, it's evident the dependence for pediatric prescriptions upon weight for their dosage only compounds the exposure to risk. What common practice has revealed is a tendency to designate children as the most vulnerable and precious of all subgroups; yet they're left susceptible to the harms of taking an off-label medication that likely has no pediatric

assessment. Even when medications are provided and studied, there is currently no mandate for prescribers to provide a weight on the prescription to allow any pharmacist the opportunity to verify the correct weight-to-dose ratio, despite the positive impact clinical pharmacists have had in detecting errors. PMEs though are inevitable, yet too often practitioners either face the unrelenting fear of a malpractice suit premised on their contractual obligation to not admit fault or succumb to narcissist behavior and overzealous administrative staff. Now fearful of both the possibility of termination and legal action, there's no surprise when staff remain silent at the news of a PME, especially when there is no clear statewide definition for error or state source solely responsible for the collection of error reports and expert-guided recommendations.

What the research here presents are opportunities for states, agencies, and the federal government to closely examine the previous years' worth of research into the area of PMEs, finding an opportunity to realize what gains are present, but also, what work remains. It is critical states seize the role of creator and enforcer when it comes to accreditation processes as they mandate future healthcare professionals acknowledge their recognition of the importance of error reporting. Moreover, states should require every pediatric prescription to include the weight of a child given their demonstrated dependence upon adult drugs and fluctuating metabolic systems, impacting absorption rates. Beyond this, tort reform is necessary to accommodate both the right for a patient to vindicate a wrong experience but protect insurance companies and hospitals from the volatile and unpredictable nature of sensationalized trials. Patient-plaintiffs should not be indirectly punished because malpractice insurance companies include gag-clauses preventing physicians from admitting guilt where there is clear fault; however, states should also consider gradual payments or tiered capped amounts to ensure the civil process in PMEs doesn't become a form of income rather than vindication. However, all these reforms are premised on the

assumption the state creates a clear and understood definition of error because if not, subjectivity will dictate whether one reports an event as an error, harm, coincidence, or consequence of fate.

As for the FDA and federal government, it's clear there is ample room for their involvement too. First, the FDA should discontinue its current practice of approving adult drugs unless there is a full pediatric assessment when it does not retain an exemption from PREA. It's clear drug manufacturers may not be in the pediatric business, or they may experience a substantial increase in costs to comply with the FDA timelines; however, it's also understood physicians will continue to use off-label medications. Thus, it becomes critical for society and prescribers to truly understand whether these drugs are safe for children, and if so, what drug regimen is appropriate for which age group. The federal government on the other hand has a hand in civil tort reform where cases reach the federal courts; but the federal government can also assist states in mirroring the aforementioned efforts. Where states are unable or unwilling to act, the federal government should have the opportunity to act through interstate commerce and implement broad, but foundational, measures, such as the requirement of weight on prescriptions where patients and providers cross state boundaries.

Despite these recommendations though, there is still an opportunity for future research and action to combat the existence of PMEs. The research here is limited to what legislative action can achieve; however, it doesn't dwell into the role for non-governmental organizations (NGO) or other grassroot organizations. There is an incredible importance for public education, and NGOs have the capacity to expand their resources into alarming the public of the risks of error. Finally, the recommendations here limit the scope to states, agencies, and the federal government; but, as errors may be regionalized due to political, social, or economic factors, it's recommended future academic studies examine the role local governments have in their ability to

thwart the prevalence of PMEs. There are political trade-offs for all levels of government, and implementation analysis is crucial is the development of policy. But if political considerations hinder policy development, local actors may have the chance to consider their own implementation and impact analysis, assuming the responsibility of state and federal governments to ensure pediatric patient safety.

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