Addressing Community Pharmacy System-mediated Medication Safety Issues

American Public Health Association
Pharmacy Section Task Force on System-Mediated Medication Safety Issues

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This report represents the best thinking of the APHA Pharmacy Section Task Force on System-mediated Medication Safety Issues and does not represent APHA policy or any final position of the Association.
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Executive Summary

The Task Force on System-mediated Medication Safety Issues convened from 2020-2021 to study workplace issues that influence medication safety within community pharmacies. This report provides an overview of its findings and actions.

The key findings include:

- An estimated 54 million dispensing errors occur in US community pharmacies each year; 2.3 million hold the potential for patient harm.
- Workplace factors such as understaffing, work disruptions, inconsistent competency of support staff and consumer demand for fast prescription service are key drivers of these errors.
- Workplace conditions negatively affect pharmacy staff health and well-being.
- Strong advocacy for addressing system-mediated factors impacting medication safety within community pharmacies has been lacking, but signs of support from pharmacy professional associations, boards of pharmacy and organized labor are emerging.
- There is an urgent need for heightened public awareness of the risk of medication errors and increased public education about best medication safety practices.

Policy position recommendations for Pharmacy Section consideration:

- Medication safety interventions must be data-driven. A concerted national effort to establish a community pharmacy data reporting system with data items such as medication error rates, root causes of errors, and error impact on patient health must be undertaken. The system’s goal should be to facilitate the early adoption of policies and procedures that can prevent medication errors as well as identify needed remediation to promote safety.

- Medication safety database design processes must address data security issues, standardization of data elements, their definitions and collection processes. This effort should build upon the experiences of national institutional healthcare data systems designed to improve patient outcomes. Successful implementation requires collaboration among health professionals, pharmacy corporations, regulators, patient advocates and others who hold an interest in medication safety.

- Pharmacy metrics, their implementation processes and performance quotas must be designed to promote and protect patient and healthcare worker safety and health. Meeting this goal can only occur with input from frontline pharmacists and other interdisciplinary stakeholders. The effect of these indicators on medication safety, patient care, healthcare worker health and healthcare practices must be routinely assessed. Unintended negative effects of pharmacy metrics should be rapidly addressed to avoid patient and healthcare worker harm and healthcare practice disruptions.

- Pharmacy metrics should be designed to incentivize the use of clinical decision making, patient counseling and education and appropriate interdisciplinary communication and collaboration.
• Pharmacy performance metrics and quotas should be responsive to changes in healthcare practice, in general, and community pharmacy practice, specifically.

• Strong, actionable advocacy from government agencies and regulators, state and national pharmacy associations, organized labor, health professionals, the public and others interested in patient safety is needed to ensure community pharmacy work environments promote medication safety and protect healthcare worker health.

• Health professionals, state and national health professional associations, public health entities, governmental agencies, healthcare systems and others interested in patient safety increase public awareness about community pharmacy medication safety and advance public education on medication safety best practices.

The Task Force welcomes discussion of these proposed policy statements and stands ready to work with those who wish to protect public health by promoting medication safety within community pharmacies.
Medication Safety

Medication safety is essential given that medications are fundamental therapies for health promotion and treatment. It encompasses a wide range of processes including drug development, manufacturing and surveillance, product packaging and labelling, health system processes, health professional training and practices, patient counseling, drug therapy monitoring, patient decision-making about medication use and medication disposal. The responsibility for medication safety is broad and it is shared across healthcare systems and communities. It must be prioritized to create environments that protect patient safety, embrace continuous quality improvement and ensure adequate healthcare worker resources and support.

Medication Safety within Community Pharmacies

Within health professions, pharmacists are particularly focused on ensuring medication safety through responsibilities that range from product purchasing to patient counseling and interdisciplinary medication therapy management. Pharmacist involvement in drug therapy management and coordination of care has enhanced pharmacists’ ability to detect and resolve medication safety problems. Community pharmacy care is unique in that it is provided in convenient retail settings without an appointment, is free of charge and is available during extended hours of the day. Pharmacists are likely to be the most approachable healthcare practitioners for those with no or limited access to healthcare.

Community pharmacy medication safety practices affect a significant proportion of the U.S. population. In 2019, nearly 3.8 billion prescriptions were dispensed at retail pharmacies. Overall, 66% of US adults take at least one prescription; 75% of those age 50 to 64 use prescription drugs, while 91% of those age 80 and older use prescription medications.

Task Force on System-mediated Medication Safety Issues

In 2020, the New York Times published a series of articles highlighting a specific threat to medication safety: chaos within chain pharmacy workplaces. This series lead to the appointment of an American Public Health Association (APHA) Pharmacy Section Task Force on System-mediated Medication Safety Issues (Task Force) to recommend actions that could address system-mediated factors that impact medication safety in community pharmacies. Task Force members included pharmacy practitioners, educators, researchers and pharmacy students who had experience in community pharmacy and/or medication safety. Other APHA members and external experts contributed interdisciplinary expertise.

To meet its mission, the Task Force held a series of meetings throughout 2020 and 2021 during which practice experiences, research reports, professional statements and policies, medication safety programs, and legislation and regulations on medication safety were reviewed and debated. In October 2020, the Task Force recommended four actions for Pharmacy Section
consideration: interdisciplinary collaboration on the issue of healthcare worker moral injury within APHA, further review of the impact of performance metrics on medication safety, public engagement in medication safety initiatives and the development of APHA policy statements on system-mediated medication safety.

The specific work of the Task Force during 2021 to address these recommendations is described in the Appendix. The Task Force sponsored interdisciplinary webinars, created and disseminated public information about medication and vaccine safety and assembled a medication safety resource library for use by Pharmacy Section members. It also provided input and inspiration into scholarly activities related to system-mediated medication safety.

Tears in the Pharmacy Safety Net

Ensuring medication safety is a key priority for community pharmacists. Prescription verification processes, patient counseling and drug therapy management services all share a common goal of promoting safe medication use. Medication safety, however, can be thwarted by dispensing errors (e.g., wrong medication or vaccine given, prescription given to wrong patient, wrong directions on prescription label), and clinical errors, such as missed drug interactions or duplications and inadequate patient counseling.

The incidence of medication errors within community pharmacies is unknown. Reported rates vary dramatically across research studies due to differences in medication error definitions, study sample sizes, and methodologies. A 2009 literature review found that error rates ranged from 0.08% to 24%. A 2018 meta-analysis of medication error studies reported dispensing error rates ranging from 0.00003% to 55% with an overall estimated dispensing error rate of 0.015. The lowest error rate was reported from a claims database analysis of selected medications and the highest rate occurred from in-person observations related to selected prescriptions requiring patient consultation. Technological advances (e.g., computer alerts, prescription bar-coding, electronic prescribing), have decreased dispensing error rates, however, medication errors still occur. The frequency of medication errors resulting in patient harm also varies widely. Research findings ranging from 4% to 52% have been reported.

Using the average and conservative rates above, one can gain perspective to the immensity of the medication safety challenges within community pharmacy practice. Using the above mentioned error rate of 0.015 and a 2019 U.S. prescription volume of 3.8 billion prescriptions, an estimated 57 million dispensing errors occur each year. If 4% of these medication errors are clinically significant, then 2,280,000 prescriptions with the potential to cause patient harm are dispensed from U.S. community pharmacies each year. This translates into 6,247 clinically significant dispensing error occurring each day.

Why are these errors occurring? Research has consistently found that system-mediated factors such as high workload, inadequate staffing levels, inconsistencies in pharmacy technician training, and workplace disruptions increase error rates. Excessive workloads may interfere with patient counseling, an intervention known to prevent patient medication use
errors. Even customer demands for fast prescription service undermines medication safety.

Laying a Foundation for Prioritizing Medication Safety

Below is a summary of Task Force discussions and recommended policy positions related to system-mediated medication safety issues.

Data are critical

Given the millions of community pharmacy dispensing errors that occur each year and the estimated annual cost of preventable outpatient medications errors of $4.2 billion, data-driven interventions to improve medication safety are urgently needed. Quantitative data are needed about medication errors, the factors contributing to errors and the effectiveness of medication safety interventions to guide medication error prevention and remediation efforts. Current data suffer from some key deficiencies. Research studies and surveys capture error rates only at a given point in time. On-going medication error monitoring by entities such as the FDA MedWatch program, the Institute for Safe Medication Practices (ISMP) health provider and patient portals, and poison control centers is dependent upon voluntary reporting thereby yielding only a partial picture of error occurrence. Knowledge about medication errors occurring in large corporate pharmacies is lacking. These pharmacies, that dispensed about 75% of U.S. prescriptions, hold their medication error data internally. Their safety practices are mainly known through news reports, social media, blogs and findings from lawsuits and whistleblower cases.

Meaningful medication safety data require a consistent use of standardized definitions and reporting processes. Currently a mix of definitions are used that include: errors reaching the patient, errors prevented prior to reaching the patient, dispensing errors and/or clinical errors. Error information is gathered from claim database analysis, health professional or patient reporting or observations by a third party. These definition and process variations can point to different root causes of errors that require different interventions for error prevention. Consistent adoption of a broad definition of medication errors may give the most accurate and comprehensive data. Use of overlapping data collection processes that measure both dispensing and clinical errors are likely to lead to an accurate account of error root causes and provide meaningful information to inform the implementation of effective and efficient means to improve medication safety.

Comprehensive data collection requires the existence of a “culture of safety” in which errors can be reported without the fear of retribution from boards of pharmacy or employers. A culture of safety rails against the notion that medication errors are the result of one individual’s actions and recognizes that multiple, overlapping environmental factors contribute to errors. It also embraces the corollary position that one individual’s actions cannot prevent medication errors, rather prevention requires a system-based multi-faceted approach to system change.
Tools for assessing, reporting and preventing medication errors within community pharmacies do exist.\textsuperscript{27,28} These tools encourage continuous quality improvement (CQI) processes to identify root causes of errors through on-going, transparent systematic evaluations of work processes. Data-driven interventions are recommended to improve outcomes with re-assessment of processes done to continue the cycle of safety measurement.\textsuperscript{29} The extent to which CQI processes have been adopted by U.S. community pharmacies is unknown. However, as of 2020, 16 state boards of pharmacy have mandated community pharmacies to implement some component of CQI.\textsuperscript{29} However, only 3 states require complete audits related to medication safety and only one requires documentation of quality improvements made. Whether such weak CQI regulations can result in system change is questionable.

The collection and sharing of comparable medication safety data across pharmacies have been shown to facilitate the early adoption of medication error prevention interventions.\textsuperscript{30} Given the costs associated with medication errors, healthcare purchasers and payors may welcome pharmacy participation in data-driven initiatives that seek to lower medication error rates. Public reports on medication safety processes that share key data points, but provide pharmacy confidentiality to encourage reporting, could increase consumer awareness about the value and need for medication safety measures and encourage them to become active partners in protecting their own safety.

\textit{Recommended policy positions}

Medication safety interventions must be data-driven. A concerted national effort to establish a community pharmacy data reporting system with data items such as medication error rates, root causes of errors, and error impact on patient health must be undertaken. The system’s goal should be to facilitate the early adoption of policies and procedures that can prevent medication errors as well as identify needed remediation to promote safety.

Medication safety database design processes must address data security issues, standardization of data elements, their definitions and collection processes. This effort should build upon the experiences of national institutional healthcare data systems designed to improve patient outcomes. Successful implementation requires collaboration among health professionals, pharmacy corporations, regulators, patient advocates and others who hold an interest in medication safety.

\textit{Addressing the unintended consequences of performance metrics}

Widespread pharmacist reports that performance metrics and quotas are leading to increased medication errors are of great concern. Examples of corporate pharmacy metrics are measures of prescriptions prepared and immunizations administered, and providing completed prescriptions by a promised time. An example of quality organizations' pharmacy performance metrics is medication adherence measured as the days of medication received during a specified time period as reported within claims data.\textsuperscript{31} These latter metrics spawned corporate pharmacy metrics for patient enrollment in auto-refill and 90-day supply programs and
pharmacy-initiated requests for prescription renewals. Because of the significant impact meeting these metrics has on revenues, corporate pharmacies set metric quotas. The degree to which pharmacists meet these quotas influences their performance reviews.

Pharmacists consistently report that metrics quotas are the most significant driver of work overload, work-related stress and moral injury and thus, contribute to the occurrence of medication errors.5,6,32,33 The American Pharmacists Association, the National Coordinating Council for Medication Error Reporting and Prevention and the National Association of State Boards of Pharmacy have adopted policies opposing metrics due to their negative impact on pharmacy practice environments since the 1970’s.34,35,36 While pharmacists’ scope of practice has significantly changed over these years, the focus of corporate metrics on prescription number and speed has not. As pharmacists began to provide immunizations, metric quotas were added to prescription volume metrics. Quotas for these metrics showed little consideration given to the work disruptions caused as pharmacists moved between prescription dispensing and vaccine administration areas.

The widespread impact of metrics on pharmacy workplaces was revealed by the Pharmacy Workforce Center’s 2019 National Pharmacist Workforce Study32 that captured responses from over 5,000 practicing pharmacists. It found that 91% of community pharmacists reported their practice workload to be “high” or “excessively high”. The majority of community pharmacist respondents reported decreases in pharmacy technician support. About half reported that they “felt a high degree of stress because they have so much work to do that everything cannot be done well and they fear a patient will be harmed by a medication error.”

The National Pharmacist Workforce Study highlighted that work conditions that increase the risk of medication errors create conflicts with patient care priorities. This conflict impacts pharmacist health and well-being which over time can lead to moral injury, a deep-seated feeling that can occur when clinical decisions must be altered to prioritize corporate objectives of increasing market share and profits.37,38 Current efforts to study pharmacist well-being should measure the degree to which this conflict is occurring.

Pharmacy metrics can also create patient risk. Metrics that drive the dispensing of 90-day quantities of antidepressants medications are opposed by psychiatrists and mental health professionals who cite the potential risk for intentional suicide.39,40 Persistent pharmacy-initiated refill requests harm interdisciplinary relationships and have resulted in the granting of unnecessary refills.37 Furthermore, the accuracy of metrics based on claims data analysis has been debated, calling into question the clinical value of these metrics.41,42

Others have noted that 90-day prescriptions can increase prescription costs if the medication is discontinued early.38 Unused medications in homes pose a direct threat to patient safety as they can lead to unintentional poisonings and substance abuse. The 420 tons of medications collected on the April 24, 2020, DEA Prescription Take-Back Day indicates the potential for such harm is significant.43
**Recommended policy positions**

Pharmacy metrics, their implementation processes and performance quotas must be designed to promote and protect patient and healthcare worker safety and health. Meeting this goal can only occur with input from frontline pharmacists and other interdisciplinary stakeholders. The effect of these indicators on medication safety, patient care, healthcare worker health and healthcare practices must be routinely assessed. Unintended negative effects of pharmacy metrics should be rapidly addressed to avoid patient and healthcare worker harm and healthcare practice disruptions.

Pharmacy metrics should be designed to incentivize the use of clinical decision making, patient counseling and education and appropriate interdisciplinary communication and collaboration.

Pharmacy performance metrics and quotas should be responsive to changes in healthcare practice, in general, and community pharmacy practice, specifically.

**Advocacy for system-based medication safety**

Broad-based advocacy is needed to combat the risk of patient harm due to medication errors caused by system-mediated factors. This advocacy should arise from worker rights agencies and organizations, professional pharmacy and health associations, boards of pharmacy, community-based advocates and the public. While pharmacists may try to “go it alone” through employee-employer grievance processes, the uneven balance of power between pharmacists and employers has shown this process to be ineffective.4,5

Federal law gives pharmacy staff the right to workplaces that protect them from harm and are free from discrimination.44,45 In addition, federal laws prevent employer retaliation because of job-related complaints or assistance with job discrimination proceedings such as an investigation or lawsuit.45 Reports of successful lawsuits against corporate pharmacies for workplace discrimination should encourage pharmacists to pursue their own legal remedies, when appropriate.24 Recent state expansions of whistleblower protections for healthcare workers may signal a strengthening of regulatory support.46 Pharmacy professional statements should recognize the legal basis for healthcare worker rights. In addition, documents, such as the Pharmacist’s Code of Ethics, should include statements that the duty to protect one’s own health is equal to the responsibility to protect patient health.47 These statements could free pharmacists from the belief that “ethical” pharmacists must sacrifice their own health to care for patients.

The pharmacy profession advocacy for addressing system-mediated medication safety issues has included pharmacist well-being educational programs,48 professional statements outlining pharmacists’ responsibilities and rights55 and pharmacist surveys to collect workplace data on national and state levels.32,49 National survey data will be used for educational purposes and to develop best practices and recommendations for improving pharmacy workplaces.50 Given the lack of a clear connection between these efforts and the on-the-ground need for direct
advocacy, the degree to which these efforts will assist pharmacy staff and protect patient safety is questionable.

Boards of pharmacy have a duty to protect public safety. The National Association of Boards of Pharmacy (NABP) has issued a number of policy statements over the years that address workplace conditions that compromise medication safety. However, state boards of pharmacy have not consistently adopted model language related to these policies. Board of pharmacy efforts to promote safety, such as setting technician to pharmacist ratios, have yielded mixed results. However, boards may now be stepping up to protect the public from system mediated medication safety barriers. The NABP has announced the formation of a task force on workplace issues. One state board of pharmacy has publicly released pharmacist survey data on workplace issues and its state pharmacy association has vowed to discuss the results with regulators, legislators and the press. Another state board of pharmacy has taken the rare action of fining a corporate pharmacy because of system-mediated medication errors.

Pharmacists are increasingly seeking advocacy through participation in organized labor. Health professions, such as nursing have pursued worker rights through organized labor efforts. These efforts are often done in collaboration with state nursing associations to advance both patient care and worker rights. In Chicago, a union stood up for pharmacists who were blamed for high rates of medication errors by bringing attention to workplace conditions contributing to those errors. In California, a union representing pharmacists successfully advocated for two legislative bills designed to improve workplace conditions. While pharmacy associations shun involvement in organized labor efforts, within California, organized labor and the state pharmacy association have partnered to support needed legislation.

Interdisciplinary communication and collaboration must be cornerstones for advocating for system changes to promote medication safety. The safety of the pharmacy dispensing system affects all healthcare providers involved in prescribing, drug therapy management and health education. Coalescing interdisciplinary advocacy for medication safety and community pharmacy staff health and well-being fits with the mission of APHA making this association a logical launching point for interdisciplinary conversations, debate and action.

External pressure from the healthcare regulators and private and public payors is needed to hold community pharmacies accountable for medication safety. In To Err is Human: Building a Safer Health System, the authors wrote, “the best strategy for improving safety is to exert external pressure on the health care industry to make errors so costly in terms of maintaining market share and reputation that organizations would be compelled to take action and invest appropriate resources to improve safety.” Within healthcare institutions such pressures come from Joint Commission accreditation status, CMS provider status, CMS star ratings, and public disclosure of medical error-related lawsuits and whistleblower cases. But such external review mechanisms do not exist for community pharmacies.

Public scrutiny of community pharmacy safety practices has been effective in spurring advocacy to address community pharmacy system-mediated medication safety practices. However, the
public remains generally unaware of the magnitude of medication errors that occur and the potential harm that can result from them. Without such information, the public can be led to believe that the speed at which they receive prescriptions is the paramount measure of a good pharmacy.

Raising public awareness and interest in medication errors and their prevention will require innovative tactics to change public interest from prescription dispensing speed to medication safety. Partnerships among health disciplines and community advocacy groups may assist in public messaging. The use of unique educational forums such as theatre, art and music should be employed to actively engage the public in receiving, understanding and using safety best practices for medications and vaccines. Social media sources should be leveraged to hone in on groups that are at high risk for experiencing harm from medication errors (e.g., young children, the elderly and those with complex medication regimens).

**Recommended policy positions**

Strong, actionable advocacy from government agencies and regulators, state and national pharmacy associations, organized labor, health professionals, the public and others interested in patient safety is needed to ensure community pharmacy work environments promote medication safety and protect healthcare worker health.

Health professionals, state and national health professional associations, public health entities, governmental agencies, healthcare systems and others interested in patient safety must increase public awareness about community pharmacy medication safety and advance public education on medication safety best practices.

**Summary**

Medication safety is a critical public health issue that demands further research, interdisciplinary efforts for improvement and strong advocacy for community pharmacy workplaces that promote medication safety and healthcare worker health and well-being. Creating a comprehensive system for collecting medication safety data across pharmacies is needed to identify system-mediated medication safety barriers and advance the adoption of safety initiatives. Pharmacy performance metrics and associated workplace processes must be reassessed and modified to prevent unintended patient and healthcare worker harm. These actions will require strong advocacy from all those interested in medication safety and healthcare worker safety and well-being. Consumer awareness about medication error risks must be heightened and consumer education about best medication safety practices must be provided.
Appendix I: Task Force Activities and Products

Webinars

Through the Looking Glass: Incorporating the Humanities and Arts into Public Health Education
Sponsor: APHA Pharmacy Section
Moderator: Randi Wright, Pharmacy Student, University of Maryland-Eastern Shore
Speaker: Paul Ranelli, PhD, Professor, University of Minnesota College of Pharmacy Duluth
Date of offering: Monday, October 26, 2020

The session objective was to inspire participants to use new approaches to create health education initiatives that increase awareness, interest, and knowledge about public health issues. Dr. Ranelli shared his expertise in exploring patient perspectives in medication use through the use of art and theatre. A play containing scenarios in which patients, health providers and caregivers discussed medication use experiences was described. Following the play, an audience discussion highlighted key points and received audience feedback. The second initiative was an exhibit in which patients with mental health conditions expressed their views/emotions related to medication use through art. This zoom program shared lessons learned about the creative and funding processes involved in these educational endeavors and the need for close researcher-community ties to create successful, meaningful programs.

Changing the Blame Game: Moving from Burnout Shame to Moral Injury and Systemic Change
Sponsor: APHA Pharmacy Section  Co-sponsors: Ethics, Occupational Health and Safety and Public Health Nursing Sections
Moderator: Soosmita Sinha, Founder and President, Health Law Institute, Geneva, Switzerland
Panelists:
Wendy Dean MD, President and Co-founder of the Moral Injury of Healthcare
Andrea Fox RN, Associate Director of the Division of Labor Action, Massachusetts Nurses Association
Date of offering: June 23, 2021

The program objective was to give participants insight into system changes that could address healthcare worker moral injury, the factors driving moral injury and its impact on healthcare workers. The interdisciplinary nature of moral injury was discussed. The loss of professional autonomy and the prioritization of corporate goals were viewed as the drivers for moral injury. Effective means of seeking improved work environments through employee-employer conversations, interdisciplinary collaboration and advocacy from professions, organized labor and patients were discussed.
COVID-19 Fact Sheet
The COVID-19 fact sheet 12 Steps to Getting a Pharmacy Vaccine Shot was designed to assist the public in navigating the vaccination process and create efficiencies in pharmacy processes to lower pharmacy staff stress. Beginning in March, 2021 the fact sheet was shared via Task Force member social contacts and community outreach efforts. The Pharmacy Section shared the fact sheet on its Facebook page and through its social media channels. APHA staff shared the document through Leadership e-mails and the APHA COVID-19 resource page. The Fact sheet was incorporated into COVID-19 outreach efforts by public health and community health organizations, professional organizations and healthcare providers throughout the U.S. It was translated into Bengali for use in the New York area and Metro Detroit.

Consumer Medication Safety Postcard
A Halloween-themed card that informs individuals about the steps they can take to prevent prescription drug and vaccine administration errors was designed in October, 2021. The card will be distributed during the 2021 APHA Annual Meeting in Denver.

Medication Safety Online Resource Library
To encourage scholarly activity on medication safety issues, a Pharmacy Section Google folder containing articles on issues such as medication error rates, pharmacy metrics, moral injury and professional statements related to responsibilities and rights. It is accessible at: https://drive.google.com/drive/folders/1cOOiHTDscu5kKkKUnEEY6-RdTcHUQBic.

Task Force-inspired Publications
The following publications incorporated themes discussed within the Task Force meetings.


Marwitz, KK. The pharmacist's active role in combating COVID-19 medication misinformation. JAPhA. 2020;61:e71-e74.

Submitted Commentary
In response to a call for comments from the American Pharmacists Association, comments were submitted regarding the document, The Pharmacist’s Fundamental Responsibilities and Rights.

Research Advisory Support Given
To Ana Hincapie, PhD, University of Cincinnati, regarding her work on continuous quality improvement regulations mandated by state boards of pharmacy

To Soosmita Sinha, RPh, JD, Health Law Institute, regarding the Institute’s survey of state Boards of Pharmacy member composition

To Randi Wright, University of Maryland-Eastern Shore regarding her work to develop a program that educates pharmacists about mental health first-aid
References

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