Peninsulas Emergency Medical Services Council, Inc.
Pharmacy Committee
Regular Session

AGENDA

Wednesday, February 06, 2019 at 15:00

Location in PEMS Office – (Dunston Room) or

* Please join my meeting from your computer, tablet or smartphone.

https://global.gotomeeting.com/join/781156677

1. Call to Order introductions:

2. Approval of Minutes:
   a. 11-07-2018

3. Membership Change:

4. Staff Report
   a. Contract Deliverables
   b. Medication box program

5. Old Business
   a. Drug shortages (Morphine, Haldol, Normal Saline, Calcium Chloride, Magnesium Sulfate, Lidocaine, Dextrose abboject, Epinephrine, Dopamine, Ativan, Morphine, Zofran, Benadryl, Ketamine, Amioderone, Atropine, Fentanyl).
   b. Expiration Ativan discussion. (See email)
   c. PPP Committee 2019 update:
      i. Add Zofran 4mg PO 4 tabs.
      ii. Add Toradol IM/IV 1 30mg/1mL vial.
      iii. Remove 100mcg Fentanyl.
   d.

6. New Business
   a. Morphine Sulfate/Ativan notice.
   b. Bi-annual Medication Box Incident Report review.
   c. November 14, 2014 VAOEMS Elimination of requirement to obtain practitioner signature.
   d. Epinephrine 30mg/30mL vial label with IM/SQ use only.
   e. Ativan Discussion. (60 day exp.?)

7. Good of the Order
   a. Next meeting: Wednesday, May 01, 2019, 1500-1630.
   b. Verify Attendance, check contact information.

8. Important Dates:
   a. VEMA Symposium March 26-29, 2019.
   b. PEMS Protocol update March 1, 2019.
   c. PEMS Annual Awards Ceremony at Busch Garden May 18, 2019.
   d.

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9. Adjournment

If you should have any questions feel free Contact Jeff Bendit via phone or email @ 804-693-6234 / jbendit@vaems.org

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PEMS Pharmacy Committee Meeting Minutes

A Subcommittee of the Board of Directors

Meeting Date: 02-06-19 **Meeting Location: PEMS** **Chaired By: S. Hopkins**

Begin Time: 3:06 PM **End Time: 4:00 PM** **Minutes Submitted By: S. Craig** **Draft Approved Date: 05-01-19**

Members Present:	Members Absent:	Staff:	Others:
Blake, Greg (TC)	Beam, Bradley	Craig, Seth	Olatunji, Kemi (TC)
Bridges, Wendy (TC)	Berry, Wayne		Samuels, Gary (TC)
Efremidis, Laurie (TC)	Eaker, Mary		Scott, Julie (TC)
Elzarian, Ed (TC)	Harmon, Mike		
Hopkins, Suzanne (Chair) (TC)	Horton, John		
Ryman, Kristy (TC)	Langley, Cindy		
Sim, Terri (TC)	Lawson, Cheryl		
St. George, Linda (TC)	Lyon, Sharon		
Harris, Sandra (TC)	Perkinson, Lindsay		
	Rizzo, Sarah		
	Rowls, Charles		
	Sledge, Tyler		

Item	Discussion	Action Required	By Whom/When
Call to Order	Meeting called to order at 3:06 pm. By S. Hopkins.		
Introductions and Membership Changes	Attendance as recorded above. Changes: Add Kristy Ryman Bon Secours MIH replacing Cindy Langley M. Eaker correct to Bon Secours MIH Lindsay Perkinson correct to Riverside Doctors Hospital (NOT Riverside Walter Reed). Add Sandy Harris from Tappahannock sandra.harris@rivhs.com Add Olatunji, Kemi from RRMC alternate Pharmacist. Motion made by G. Blake to make changes. Seconded by W. Bridges. Approved unanimously.	Update roster	P. Hoyle/ 02-17-19

Item	Discussion	Action Required	By Whom/When
Minutes	11-07-2018 Minutes approved as written. Motion to approve by G. Blake. 2nd K. Ryman. Approved unanimously.		
Staff Report	• Committee reviewed Contract Deliverables to ensure they are being met by Committee. No discrepancies found. • Medication Box program- March 1 new inventory sheets as restocked.	Correct Inventory Sheet	J. Bendit/03-01-19
Old Business	Review Pharmacy Contact list for Clearly Inventory Discussion regarding the current and growing list of drug shortages- • Morphine (10 mg vials has slightly improved since last meeting) • Haldol (has improved somewhat) (REMOVE) 11-07-2018 • Calcium Chloride • Ketamine (Shortage reported across the Committee) • Magnesium Sulfate • Lidocaine • Dextrose abboject • Epinephrine • Dopamine- anyone having to stock with norepinephrine? • Amioderone shown to have shortages recently. • Ativan • Atropine • Fentanyl (REMOVE) 11-07-2018 • 0.9 NaCL 100mL (REMOVE) 11-07-2018 • G. Blake reported shortage in Sodium Bicarb • G. Blake reported shortage in epi		
New Business	Motion made by G. Blake to state that Ativan Vials can be used up to 60 days after placing in PEMS Medication Box. Seconded by T. Sim. Discussion regarding studies and current practices followed. Motion approved unanimously. Attachment 1-Ativan/Morphine study 60-day expiration in EMS. G. Blake recommended adding a BUD 60 days out of frig on inventory list. Restocking list still states "OTD" needs to say "ODT." Attachment 2- PEMS Medication Box Inventory Sheet Version 3/2019. Concern about reports that VCU is sometimes stocking morphine in 5 mg instead of 10 mg. Bi-Annual Medication Box Incident Report: uncapped needles found in drug boxes. All are reported dealt with and closed. No Committee members had new concerns about any of the submitted Incident Reports. Attachment 3. Elimination of requirement to obtain practitioner signature for narcotics was discussed. G. Samuels brought up a current issue regarding the signature on the blue card for administration of narcotics. The Committee	Discuss with J. Bendit Change "OTD" to "ODT" Contact VCU Pharmacy	S. Craig J. Bendit/03-01-19 J. Bendit/G. Blakc

Item	Discussion	Action Required	By Whom/When
	unanimously agreed to continue requiring physicians' signature to help monitor prehospital administration of narcotics. Attachment 4- SBAR March 2015- EMS Standing Protocol Requiring prescriber signature. Attachment 5- Virginia Administrative Code Title 18 Professional and Occupational Licensing Agency 110. Board of Pharmacy Ch. 20 regs. governing practice of pharmacy. Attachment 6- 18VAC110-20-500 Licensed EMS Agency Program Code of Virginia 54.1-3408 Professional use by practitioners. G. Blake would like the Committee to look at improving tracking Prehospital usage of opioids. G. Samuels proposed that PI Committee look at opioid usage within the PEMS Region and provide a report. Clearly Inventory Update. No one was in person to verify contact information. No action on this item. Roster updated prior to this meeting in Attachment 7- Clearly Inventory Instruction for use by PEMS pharmacy Epinephrine 30 mg/30 mL IM/SQ use only was discussed. S. Hopkins stated Sentara has approved the IM/SQ bottle to make IV drips in the prehospital setting. They are currently stocking the PEMS box with the IM/SQ bottle and working on educating providers. G. Blake suggested looking at changing the concentration of epi provided to facilitate constituting epi drips and modifying PEMS Protocols.	Review PEMS usage of opioids Investigate alternatives to epi concentrations. Determine the standard concentration of epi in the hospitals	PI Committee? Pharmacy Committee/ G. Blake
Good of the Order	Important Dates: • State Holiday- Office Closed 2-18-19 for President's Day. • 10th Annual Central VA EMS Education Expo 2/28-3/3, 2019		
Next Meeting	Attendance verified as recorded above. The next meeting is scheduled for **Wednesday, May 1st, 2019.**		
Adjournment	Meeting adjourned at 4:00 p.m. Motion by L. Efremidis. 2nd by G. Blake. Unanimously approved to adjourn.		

PENINSULAS EMS COUNCIL, INC.

Peninsulas EMS Council, Inc.
Pharmacy Committee

FY2019

Please initial attendance under today's meeting date.

Member	Email	Organization	Position	08-01-18	11-07-18	02-06-19	05-01-19
Arneson, Rebecca 757-764-6758	rebecca.l.arneson.mil@mail.mil	Joint Base Langley-Fort Eustis	Licensed Pharmacist				
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Bendit, Jeff (NV) 804-695-7651	jbendit@vaems.org	Peninsulas Emergency Medical Services Council	Staff Facilitator		X		
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Bridges, Wendy 757-764-6758	wendy.bridges@us.af.mil	Joint Base Langley-Fort Eustis	At Large	TC	TC	TC	
Eaker, Mary 757-886-6467	mary_eaker@bshsi.org Bon Secours	Mary Immaculate Hospital	Licensed Pharmacist	TC			
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Harmon, Mike 804-519-1452	robert_harmon@bshsi.org	Memorial Regional Medical Center	At Large				
Harris, Sandra 540-847-0257	sandra.harris@rivhs.com	Riversde Tappahannock Hospital	Licensed Pharmacist				
Hopkins, Suzanne (C) 757-984-8653	sjhopkin@sentara.com	Sentara Williamsburg Regional Medical Center	Licensed Pharmacist	TC	TC	TC	
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~~Langley, Cindy~~ Ryman, Kristy 757-~~886-6498~~ 947-3561	cynthia_langley@bshsi.org Kristy_Ryman@	Bon Secours Mary Immaculate Hospital	Licensed Pharmacist	TC			
Lawson, Cheryl 757-594-2050	cheryllawson11@gmail.com	Medical Advisors Committee	At Large				
Lyon, Sharon 804-693-8800	sharon.lyon@rivhs.com	Riverside Walter Reed Hospital	Licensed Pharmacist				
Perkinson, Lindsay 757-585-2084	lindsay.perkinson@rivhs.com	Riverside ~~Walter Reed~~ Doctor's Hospital	Licensed Pharmacist		X		
Rizzo, Sarah 757-736-1015	serizzo1@sentara.com	Sentara Careplex Hospital	Licensed Pharmacist	TC	TC		
Rowles, Charles 757-388-2235	chrawlsi@sentara.com	Sentara Norfolk General Hospital	Licensed Pharmacist		TC		
Sim, Terri 757-984-8110	tasim@sentara.com	Sentara Williamsburg Regional Medical Center	Licensed Pharmacist			TC	
Sledge, Tyler 757-534-6007	tyler.sledge@rivhs.org	Riverside Regional Medical Center	Licensed Pharmacist	TC	TC	[illegible]	
St.George, Linda 804-435-8000	linda_st.george@bshsi.org	Bon Secours Rappannock General Hospital	Licensed Pharmacist			TC	

PENINSULAS EMS COUNCIL, INC.

Peninsulas EMS Council, Inc.
Pharmacy Committee

FY2019

Please initial attendance under today's meeting date.

Member	Email	Organization	Position	08-01-18	11-07-18	02-06-19	05-01-19
Amin, Rali N. 757-388-3296	rnamin@sentara.com	Sentara Norfolk General Hospital	Licensed Pharmacist				
Krempa, Cheryl 804-443-6059	cheryl.krempa@rivhs.com	Bon Secours Rappannock General Hospital	Licensed Pharmacist				
Guests							
CRAIG, SEAN		PEMS				SCC	
RYMAN, KRISTY						TC	
SAMUELS, GARY						TC	
Scott, Julie						TC	
Harris, Sandy	Sandra.harris@rivhs.com					TC	

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Published in final edited form as:
Prehosp Emerg Care. 2013 ; 17(1): 1–7. doi:10.3109/10903127.2012.722177.

The 60-Day Temperature-Dependent Degradation of Midazolam and Lorazepam in the Prehospital Environment

Jason T. McMullan, MD, **Ashley Pinnawin, BS**, **Elizabeth Jones, MD**, **Kurt Denninghoff, MD**, **Nicholas Siewart, BA**, **Daniel W. Spaite, MD**, **Erin Zaleski, MA**, and **Robert Silbergleit, MD on behalf of the Neurological Emergencies Treatment Trials investigators**
Department of Emergency Medicine, University of Cincinnati (JTM), Cincinnati, Ohio; Wayne State University, College of Medicine (AP), Detroit, Michigan; the Department of Emergency Medicine, University of Texas Health Science Center at Houston (EJ), Houston, Texas; the Department of Emergency Medicine, Arizona Emergency Medicine Research Center, University of Arizona (KD, DWS), Tucson, Arizona; and the Department of Emergency Medicine, University of Michigan (NS, EZ, RS), Ann Arbor, Michigan

Abstract

Background—The choice of the optimal benzodiazepine to treat prehospital status epilepticus is unclear. Lorazepam is preferred in the emergency department, but concerns about nonrefrigerated storage limits emergency medical services (EMS) use. Midazolam is increasingly popular, but its heat stability is undocumented.

Objective—This study evaluated temperature-dependent degradation of lorazepam and midazolam after 60 days in the EMS environment.

Methods—Lorazepam or midazolam samples were collected prior to (n = 139) or after (n = 229) 60 days of EMS deployment during spring–summer months in 14 metropolitan areas across the United States. Medications were stored in study boxes that logged temperature every minute and were stored in EMS units per local agency policy. Mean kinetic temperature (MKT) exposure was derived for each sample. Drug concentrations were determined in a central laboratory by high-performance liquid chromatography. Concentration as a function of MKT was analyzed by linear regression.

Results—Prior to deployment, measured concentrations of both benzodiazepines were 1.0 relative to labeled concentration. After 60 days, midazolam showed no degradation (mean relative concentration 1.00, 95% confidence interval [CI] 1.00–1.00) and was stable across temperature exposures (adjusted R^2 –0.008). Lorazepam experienced little degradation (mean relative concentration 0.99, 95% CI 0.98–0.99), but degradation was correlated to increasing MKT

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The authors report no conflicts of interest.

Meetings: This work has not been presented at a scientific meeting.

Author Contributions: JM and RS conceived the study; JM, EJ, KD, DWS, EZ, and RS designed the trial; RS obtained funding; EJ, KD, DWS, AP, NS, and EZ managed sample collection and processing. JM drafted the manuscript and all authors contributed significantly to its revision. JM takes responsibility for the paper as a whole.

(adjusted R^2 0.278). The difference between the temperature dependence of degradation of midazolam and lorazepam was statistically significant ($T = -5.172$, $p < 0.001$).

Conclusions—Lorazepam experiences small but statistically significant temperature-dependent degradation after 60 days in the EMS environment. Additional study is needed to evaluate whether clinically significant deterioration occurs after 60 days. Midazolam shows no degradation over this duration, even in high-heat conditions.

Keywords

midazolam; lorazepam; temperature; emergency medical services

Introduction

Prolonged seizures frequently require treatment by emergency medical services (EMS) prior to hospital arrival, and benzodiazepines are the mainstay of initial therapy.[1,2] However, the optimal agent for use by paramedics in the prehospital setting is unclear. Lorazepam, considered the benzodiazepine of choice for seizure cessation in the hospital environment,[3] is generally thought to require replacement after 60 days unless it is refrigerated.[1] This need for refrigerated storage has prevented lorazepam's widespread adoption for prehospital use, despite demonstrated effectiveness in this setting.[1] Diazepam experiences degradation similar to lorazepam and is no better than midazolam in control of status epilepticus.[4,5] As such, midazolam is becoming more widely used by EMS because it is thought to be heat-stable and can be readily given intramuscularly or intranasally if needed. However, its use for seizures is an off-label indication that has not been approved by the Food and Drug Administration,[6] and its temperature stability has not yet been established.

Although product labeling for lorazepam calls for refrigerated storage, the rate of medication degradation without refrigerated storage, and the extent to which this degradation is temperature-dependent, is poorly documented. In a single-site EMS study with mild environmental temperatures and nonrefrigerated storage of the drug, lorazepam concentration did not substantially degrade over a 60-day period; lorazepam stored in an oven kept at 37°C experienced significant degradation, suggesting that lorazepam's stability is heat-sensitive.[4] Midazolam is thought to be stable at room temperature, but the heat stability and degradation at varying storage temperatures in the prehospital setting are poorly documented.

Storage conditions for EMS drugs are known to vary from the United States Pharmacopeia (USP) standard for storage at “controlled room temperature.”[7,8] However, the effect of typical EMS storage temperatures on drug degradation is poorly understood.[8] Determining the heat stability of benzodiazepines is an important step in ensuring clinical effectiveness and patient safety and will be helpful to EMS planners when choosing which medications to stock, rotate, retire, and replace.

The objective of this investigation was to provide empirical data on the magnitude and temperature dependency of degradation in concentrations of lorazepam and midazolam over 60 days of EMS storage at sites with large variations in ambient temperatures.

Methods

Study Design and Setting

This was an experimental in-field pharmacostability study conducted during a multicenter, randomized, controlled trial of paramedic treatment of status epilepticus with lorazepam or midazolam.[2]

As part of the multicenter trial, midazolam and lorazepam were distributed to EMS agencies in 14 cities across the United States. Midazolam (5 mg/mL) was packaged in a glass cartridge within an autoinjector (Meridian Medical Technologies, Columbia, MD) and lorazepam (2 mg/mL) was packaged in a prefilled disposable single-use glass syringe (Carpuject, Hospira, Lake Forest, IL). Study medications were stored in instrumented boxes that recorded temperature every minute for 60 days or until the medication was used, whichever came first. Unused study drugs were retired at 60 days.

For quality assurance and research purposes, two subsets of sample drug kits were randomly selected by a computerized drug-tracking system for analysis. A baseline subset was drawn from refrigerated new kits that were never placed in the field. The other was a subset of retired, unused study drugs collected after 60 spring or summer days in the field between April and August 2010. For the purpose of this investigation, the two participating study sites that are known to have the highest ambient temperatures were deliberately oversampled by a ratio of 3:1 to obtain a larger number of samples expected to experience high-heat conditions.

Generally, EMS agencies stored the medications in the study boxes alongside other routine medications and per individual agency policies. Use of temperature-control systems beyond normal vehicle air conditioning was not specified in the study protocol. The drugs were stored inside the cabs or external compartments of fire apparatus, ambulances, and other vehicles used for emergency medical response. Some vehicles were kept in environmentally controlled stations unless responding to an emergency call, while others were in constant exposure to ambient temperatures during work shifts.

Sample size was estimated to provide significance of 0.05 and power 0.8, assuming a mean difference of 2.5% for the aggregate comparison of midazolam and lorazepam groups and a within-group sample variability (standard deviation) of 5%.

Methods of Measurement

Temperature was measured every minute for 60 days by a microprocessor-controlled thermistor in each study box and recorded to a nonvolatile memory card (MicroSD, SanDisk, Milpitas, CA). This time-varying signal was analyzed and summarized by determination of mean kinetic temperature (MKT). MKT is a metric used to describe the overall effect of temperature fluctuations on heat-sensitive materials and is used widely in the pharmaceutical industry.[9] This measure is not simply a weighted average of temperature, but serves as a way to express the cumulative heat stress to which a product has been exposed over time. The MKT was calculated for each sample across 60 days of temperature

data (Stability System II software, Scien Tek Software, Tustin, CA). Daily ambient temperature data were gathered from online resources for each city.[10]

Samples were analyzed in a commercial laboratory (DynaLabs, St. Louis, MO) by high-performance liquid chromatography (HPLC) to determine concentration of the active drug. Samples were refrigerated (including shipping) before deployment in the field and after retirement prior to analysis to prevent further degradation.

Data Collection and Processing

Memory cards from the selected study boxes were sent to the study's clinical coordinating center (CCC), and drug samples were sent directly to the processing center for analysis. Results of the HPLC were returned to the CCC to be paired with temperature data. Data were managed using Microsoft Excel (Microsoft Corp., Redmond, WA) and analyzed via SPSS version 19 (International Business Machines, Armonk, NY).

Outcome Measures

The primary outcome was relative reduction in medication concentration from the labeled concentration.

Primary Data Analysis

Linear regression determined the dependence of each medication's degradation as a factor of MKT. The beta coefficient was calculated to compare the regression slopes, as a means to compare the differences in the relationship between MKT and degradation for midazolam and lorazepam.[11]

Results

Baseline

Prior to study drug deployment, 139 randomly selected samples were sent for baseline concentration determination by HPLC as part of the larger trial's quality assurance process. These samples were kept refrigerated, not exposed to prolonged periods of ambient temperature prior to testing, and confirmed to have baseline concentrations consistent with manufacturer labeling. The mean relative concentration (actual versus labeled) at baseline was 1.00 (95% confidence interval [CI] 0.99–1.00) for midazolam (n = 74) and 1.01 (95% CI 1.01–1.01) for lorazepam (n = 65).

Between April and August 2010, 122 midazolam and 107 lorazepam samples were randomly selected from unused study drugs of 14 cities and sent for HPLC analysis after 60 days of environmental exposure in EMS vehicles. The mean monthly ambient temperatures for the 14 cities ranged from 9.2°C to 35.9°C (Table 1).

The mean MKT was 22.1°C (95% CI 21.6°C–22.5°C) for all samples. There was no difference in the overall MKT for midazolam or lorazepam samples. Figure 1 shows relative drug concentrations over the range of individual MKT exposures. Midazolam showed no significant degradation over time (mean relative concentration 1.00, 95% CI 1.00–1.00);

degradation over time was not correlated with temperature (adjusted R^2 –0.008), demonstrating stability over a broad range of temperatures. Lorazepam experienced some degradation (mean relative concentration 0.99, 95% CI 0.98–0.99), and greater degradation was correlated with increasing MKT (adjusted R^2 0.278), suggesting that the degree of degradation is affected by the degree of exposure to higher temperatures.

The absolute difference in mean concentration of midazolam and lorazepam was small but statistically significant (1.4%, $p < 0.001$). However, increasing MKT had a much greater effect on lorazepam than midazolam ($T = -5.172$, $p < 0.001$), providing evidence that lorazepam is more heat-sensitive than midazolam.

Discussion

Both lorazepam and midazolam maintained clinically acceptable concentrations of active drug after 60 days of EMS deployment. Lorazepam demonstrated a small amount of temperature-dependent degradation over this interval, whereas midazolam did not.

There is evidence that not all medications used by EMS are affected by storage in uncontrolled environments.[12] However, understanding which drugs are affected, and to what degree, is essential to ensure that patients receive effective treatment. Prior to this study, the heat stability of midazolam in the EMS environment had not been reported. We demonstrated that after 60 days of environmental exposure, midazolam shows little degradation over a broad range of temperature exposures. Lorazepam, on the other hand, shows some temperature-dependent degradation. The stability of both medications over a longer period of exposure deserves investigation. The ambient temperatures encountered in this study were in the cool (8°C–15°C), room-temperature (15°C–30°C), and warm (30°C–40 °C) ranges as defined by the USP.[9] The effects of excessive heat (>40°C) require further study.

Our results build upon those previously reported,[4] since this investigation occurred in more diverse environments, thereby allowing further evaluation of the degree to which observed drug degradation was affected by MKT exposure. The median lorazepam degradation we observed was similar to that observed by Gottwald et al.,[4] and the amount of degradation is indeed tied to increasing MKT. The clinical implications of lorazepam's degradation are uncertain. However, it is notable that the concentrations in some lorazepam samples (5/106, 4.7%) were reduced by more than 5% when they came from high-heat environments. Thus, the deterioration of lorazepam may be rapid and considerable in areas that routinely experience extreme temperatures, such as the deep southern and southwestern regions of the United States.

The two cities with the highest ambient temperatures were purposely oversampled; however, ambient temperatures and sample MKT did not directly correlate (Table 1). This unexpected observation may be related to EMS system operational aspects, whereby medications kept in garaged fire department bays likely have better temperature controls than dynamically deployed third-service EMS agencies. When considering the potential impact of heat

exposure on medications, EMS agencies should sample the temperatures where drugs are stored (i.e., ambulance patient compartment) and not rely solely on ambient temperature.

Limitations and Future Research

Baseline and postexposure measurements were not taken from the same samples. Thus, it is possible that packaged concentrations were different and resulted in systemic bias. However, this is unlikely since deployed medications were packaged 1) by a commercial vendor with extensive product quality control, 2) according to USP recommendations, and 3) in the same manner as the samples used to determine baseline concentrations (which all had very small variability).

The use of advanced temperature-control systems by participating agencies was not captured as part of data collection; however, the temperatures recorded for samples do not suggest the use of refrigerators. Further investigation of drug-storage strategies used by agencies where the observed MKT is different from observed ambient temperatures could provide evidence in support of best practices.

Conclusion

These data confirm that lorazepam experiences small but statistically significant temperature-dependent degradation after exposure to 60 days in the EMS environment. Additional study is needed to evaluate whether clinically significant deterioration occurs after 60 days. Midazolam does not show any sign of degradation over this duration, even in high-heat conditions.

Acknowledgments

This work was conducted as part of the RAMPART trial, which was supported by awards from the National Institute of Neurological Disorders and Stroke (NINDS) (U01NS056975 and U01NS059041); the National Institutes of Health Office of the Director CounterACT Program; and the Biomedical Advanced Research and Development Authority of the Assistant Secretary for Preparedness and Response.

Appendix

The Neurological Emergencies Treatment Trials investigators are: Clinical Coordinating Center

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National EMS Coordinator

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Statistical Data Management Center

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Robin Conwit, MD, Scott Janis, PhD, David Jett, PhD, Brandy Fureman, PhD

Hubs

Wayne State University

Hub Principal Investigator: Robert D. Welch, MD, MS

Primary Study Coordinators: Lynnmarie Mango, MPH, Valerie H. Mika, MS

EMS Director(s)/Coordinator: Jenny Atas, MD

Other Site Investigators: Robert Dunne, MD, Douglas Wheaton, MD, Phillip Levy, MD, MPH, Marc-Anthony Velilla, MD, Robert Sherwin, MD, Brian O'Neil, MD, Angela Groves, MD, Marc Rosenthal, DO, PhD

Participating EMS Service: Detroit EMS

University of Cincinnati

Hub Principal Investigator: Arthur Pancioli, MD

Primary Study Coordinators: Irene Ewing, RN, BSN, Peggy Waymeyer, RN

EMS Director(s)/Coordinator: M. Kay Vonderschmidt, MPA, MS-EM, NREMT-P, Jason McMullan, MD

Other Site Investigators: Hamilton Schwartz, MD, Brian Stettler, MD, William Knight, MD, Opeolu Adeoye, MD, Rhonda Cadena, MD, Jordan Bonomo, MD, Erin Grise, MD, Laura Heitsch, MD, George Shaw, MD, Nick Gagai, CCRP, Pamela Schmit, RN BSN, Sara Stark, Med, Traci Doellman, RN

Participating EMS Services: Cincinnati Fire Department, BlueAsh Fire Department, Forest Park Fire Department, Green Township Fire Department, Florence Fire Department, Independence Fire Department

University of California San Francisco

Hub Principal Investigator: J. Claude Hemphill, III, MD, MAS

Primary Study Coordinators: Michele Meeker, RN, BSN, Kelley Rosborough, BA

EMS Director(s)/Coordinator: Jeany Duncan EMT-P

Other Site Investigators: Karl Sporer, MD, FACEP, FACP, Alan Gelb, MD; Wade Smith, MD, PhD, Prasanthi Ramanujam, MD, Kazuma Nakagawa, MD, Asma Moheet, MD, Hooman Kamel, MD, Bharath Naravetla, MD, Mary Mercer, MD, Christine Wong, MD

Participating EMS Services: San Francisco Fire Department, EMS Division

University of Texas -Houston

Hub Principal Investigator: Elizabeth Jones, MD

Trial Principal Investigator: Truman J. Milling, MD

Primary Study Coordinators: Misty Ottman, RN, BSN, Ben King, Laura LaChance

EMS Directors/Coordinators: Jeff Brockman, RN, Pete Didonato, EMT-P

Other Site Investigator: Paul Hinchey, MD

Participating EMS Service: Austin-Travis County EMS

Emory University

Hub Principal Investigator: David W. Wright, MD

Trial Principal Investigators: Matthew D. Bitner, MD, Gerald W. Beltran, DO

Primary Study Coordinator: Harriet Nevarez, RN, CCRC

EMS Director/Coordinator: Rachel Barnhard, Andrea G. McDougal

Other Site Investigators: Jeffrey F. Linzer Sr, MD, Lisa H. Merck, MD MPH, Tamara Espinoza, MD

Participating EMS Service: Grady EMS

Henry Ford Health System

Hub Principal Investigator: Christopher A. Lewandowski, MD

Trial Principal Investigator: Taher T. Vohra, MD

Primary Study Coordinators: Paula L. Crouse, RN, BSN., MA., Anna E. Baker, RN, BSN

EMS Director/Coordinator: Dean R. Creech EMT-P, I/C

Other Site Investigator: Andrew N. Russman, DO, Joseph B. Miller, MD, Jumana Nagarwala, MD, Daniel J. Miller, MD, Raymond Fowkes, MD, Anne Marie Lundell, RN, BSN

Participating EMS Services: Detroit EMS, West Bloom-field Fire and EMS Services

Stanford University

Hub Principal Investigator: James V. Quinn, MD, MS

Primary Study Coordinators: Stephanie Casal. RN, CNS, Anke Hebig, Mark Liao

EMS Director/Coordinator: Peter D'Souza, MD

Participating EMS Services: Palo Alto Fire Department, San Jose Fire Department, Redwood City Fire Department, San Mateo Fire Department

University of Arizona

Hub Principal Investigator: Kurt R. Denninghoff, MD

Trial Principal Investigator: Daniel W. Spaite, MD

Primary Study Coordinator: Bruce Barnhart, RN, CEP

EMS Director(s)/Coordinator: Willie Haro, CEP

Other Site Investigator: Bentley J. Bobrow, MD

Participating EMS Service: Glendale Fire Department

Virginia Commonwealth University

Hub Principal Investigator: Joseph P. Ornato, MD

Primary Study Coordinator: Sallie L. Noe, RN

EMS Director/Coordinator: Alan D. Payne, CCEMTP

Other Site Investigators: Alan R. Towne, MD, Michael C. Kurz, MD, John T. Carmack, MD

Participating EMS Service: Richmond Ambulance Authority

University of Minnesota

Hub Principal Investigator: Michelle Biros, MD

Trial Principal Investigator: Brian Mahoney, MD

Primary Study Coordinators: Corey Sargent, Kathleen Miller, BSN, CCRC

Other Site Investigators: David Hildebrandt, Chris Kummer, Doug Gesme

Participating EMS Services: Hennepin County EMS

Medical College of Wisconsin

Hub Principal Investigator: Tom P. Aufderheide, MD

Primary Study Coordinator: Joseph T. Brandt Jr., BS, EMT-P

EMS Director/Coordinator: M. Riccardo Colella, DO

Other Site Investigators: Ron Pirrallo, MD, MHSA, Walter Bialkowski, MS, Benjamin Hermanson, BS, Christopher Sandoval, BS, EMT-P, Kevin Morrow, MFA, Kelly McCormick, BS, MBA, Katherine Burpee, BA, Geri Price, BS, Dawn Kawa, BA

Participating EMS Services: Milwaukee County EMS, Milwaukee Fire Department, Franklin Fire Department, Greenfield Fire Department, North Shore Fire Department, Oak Creek Fire Department, South Milwaukee Fire Department, Wauwatosa Fire Department, West Allis Fire Department

University of Kentucky

Hub Principal Investigator: Roger L. Humphries, MD

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EMS Director/Coordinator: Christofer Sweat

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Participating EMS Service: Lexington-Fayette Urban County Government Division of Fire & Emergency Services

University of Pennsylvania

Hub Principal Investigator: Jill M. Baren, MD, MBE Trial Principal Investigator: R. Daniel Bledsoe, MD

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Participating EMS Services: York Hospital Medic 97, White Rose Ambulance, Grantley Fire Company, Jacobus Lions Ambulance Club, West York Ambulance

Oregon Health & Science University

Hub Principal Investigators: Craig R. Warden, MD, MPH, Robert A. Lowe, MD, MPH

Primary Study Coordinator: Rachel N. Stone, CCRP

Participating EMS Service: Clackamas Fire District #1

New York Presbyterian Hospital

Hub Principal Investigator: Stephan Mayer, MD, FCCM

Trial Principal Investigator: Neal Flomenbaum, MD

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Participating EMS Services: New York Presbyterian

Temple University

Hub Principal Investigator: Nina T. Gentile, MD Trial

Principal Investigators: Alvin Wang, DO, Christopher Vates, MD, Ben Usatch, MD

Primary Study Coordinators: Brent B. Freeman, Stacey L. Cleary

Participating EMS Services: Volunteer Medical Services Corps of Lower Merion and Narberth (Narberth Ambulance), Life Lion EMS

University of Maryland

Hub Principal Investigator: Barney Stern, MD

Trial Principal Investigators: Tricia Ting, MD, Gregory Krauss, MD

Primary Study Coordinators: Virginia Ganley, RN, Susan Rice, RN, Jennifer Ronald

EMS Director/Coordinator: Michelle Stevens, RN

Other Site Investigators: Brian Browne, MD, Robert Rosenthal, MD, Peter Hill, MD

Participating EMS Services: Maryland Institute for Emergency Medical Services Systems (MIEMSS), Baltimore City EMS

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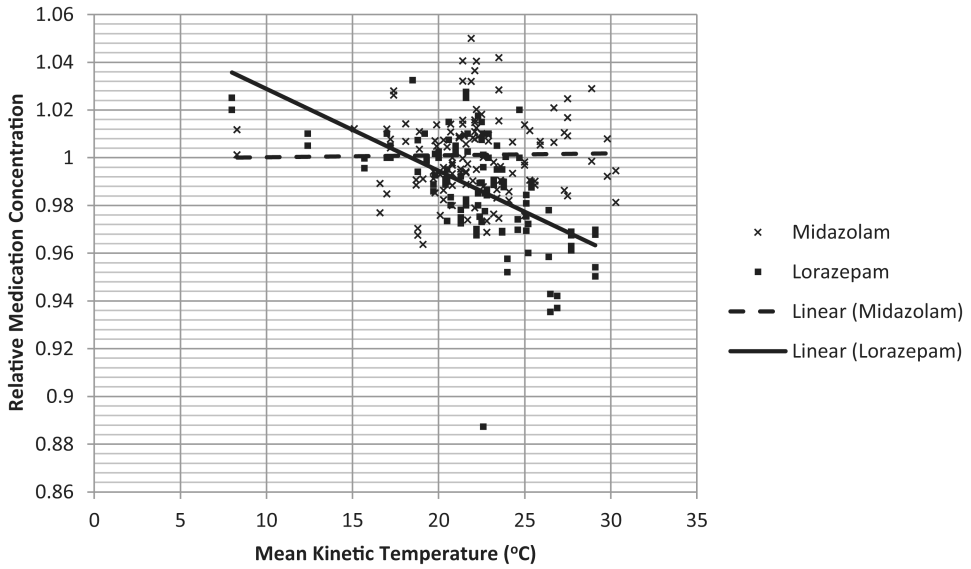


Figure 1.

Relative medication concentration versus mean kinetic temperature for midazolam and lorazepam after 60 days of heat exposure in active emergency medical services vehicles. Individual data points and the linear trend lines are displayed.

Prehosp Emerg Care. Author manuscript; available in PMC 2014 July 25.

Table 1

Mean Monthly and Aggregate Ambient Temperatures (°C) and Mean Kinetic Temperatures (°C) of Medication Samples for the 14 Cities During the Study Period

City	April	May	June	July	August	Aggregate	MKT	Samples
1	28.1	25.7	32.3	35.9	34.4	30.9	21.7	19
2	14.8	18.9	23.9	25.5	25.6	21.5	21.5	6
3	18.4	23	27.4	27.9	28.2	24.7	22.3	6
4	12.3	17.1	21.9	24.8	24	19.8	18.2	12
5	15.2	19.3	24.8	25.6	25.6	21.8	22.7	6
6	12.7	15.9	20.7	24.9	25	19.6	25.0	5
7	12.1	19.6	25.7	27.6	26.1	22.0	20.2	5
8	9.2	10.6	13.5	15.3	15.7	12.7	22.4	6
9	11.2	13.7	19.3	18.6	18.8	16.1	21.0	6
10	12.9	17.6	21.6	24.2	23.6	19.8	25.3	6
11	20.8	26.3	29.3	28.9	30.7	26.9	23.6	22
12	11.2	13.7	19.3	18.6	18.8	16.1	17.9	6
13	16.8	21.2	27.3	28.2	26.6	23.7	24.8	6
14	13.8	18.5	24.6	26.7	24.9	21.5	22.3	6

MKT = mean kinetic temperature.

PEMS Medication Box Inventory

Box # _____

Write Expiration Dates in Column with Pen - Pharmacist Checking Box Se

		1	2	3	4	5	6	7	8
	Date								
	Facility								
EXTERIOR SEAL	**SEAL #**								
TOP THOMAS PACK (RED)	**SEAL #**								
Albuterol (Proventil) 0.083% 3mL	1								
	2								
Aspirin unit dose package chewable 81 mg tablets	1								
	2								
	3								
	4								
	5								
	6								
Atrovent (Ipratropium) 0.02% 3 mL	1								
Diphenhydramine (Benadryl) 50 mg/1 mL vial/syringe	1								
	2								
Epinephrine 1:1,000 1 mg/ 1 mL syringe	1								
	2								
Nitrostat 0.4mg 25 Tabs (replace if opened)	1								
Methylprednisolone (Solu-Medrol) 125 mg/2 mL act-o-vial	1								
Ondansetron (Zofran) OTD 4mg tab	1								
	2								
Ondansetron (Zofran) 4 mg/2 mL	1								
	2								
Haloperidol (Haldol) 5 mg/1 mL vial	1								
	2								
Tubex syringe holder	1								
Ketorolac (Toradol) 30mg/1mL	1								
Saline Bullets for inhalation (0.9%)	1								
	2								
TOP THOMAS PACK POUCHE (RED)	**SEAL #**								
Fentanyl 100 mcg/2ml vial	1								
Lorazepam (Ativan) 2 mg/1 mL	1								
	2								
Midazolam (Versed) 5 mg/1 mL vial	1								
	2								
Morphine Sulfate 10 mg/1 mL syringe	1								
	2								
BOTTOM THOMAS PACK (RED)	**SEAL #**								
100 mL 0.9% Saline IV bag	1								
Glucagon 1 mg/ 1 mL emergency kit	1								
INT adapters (**rubber cap, for needled med filter and fill needles)**	1								
	2								
Naloxone (Narcan) 2mg/2mL preload	1								
	2								
Intranasal (IN) device	1								

January 2019 update revised

PEMS Medication Box Inventory

Box # _____

Write Expiration Dates in Column with Pen - Pharmacist Checking Box Write Name Below Bes

		1	2	3	4	5	6	7	8
	Date								
Bottom Section (UNDER CLEAR PLASTIC)	Facility								
	SEAL #								
Adenosine (Adenocard) 6 mg/2 mL	1								
	2								
	3								
Amiodarone (Cordarone) 150 mg/3 mL vial	1								
	2								
	3								
	4								
Atropine Sulfate 1 mg/10 mL preload	1								
	2								
	3								
Calcium Chloride 1gm / 10mL preload	1								
Dopamine 400 mg/10 mL	1								
Epinephrine 1:1,000 Vial 30 mg/30 mL	1								
Epinephrine 1:10,000 1 mg/10 mL preload	1								
	2								
	3								
	4								
	5								
	6								
	7								
	8								
Furosemide (Lasix) 100mg / 10mL preload	1								
Lidocaine 2% (Xylocaine) 100 mg/5 mL preload	1								
	2								
Magnesium Sulfate 5 gm/10 mL	1								
Sodium Bicarbonate 8.4% 50 mEq/50 mL preload	1								
	2								
Dextrose 50% 25 gm/50 mL preload	1								
	2								

Signature and Printed Name of Pharmacist:

1)	5)	9)
2)	6)	10)
3)	7)	11)
4)	8)	12)

January 2019 update revised

ee Page 2

9	10	11	12	
				Date
				Facility
				SEAL #
				SEAL #
				Albuterol
				Asprin
				Atrovent
				Benadryl
				Epinephrine
				Nitrostat
				Salu-Medral
				Zofran tab
				Zofran
				Haloperidol
				Tubex Holder
				Toradol
				Saline Bullets INH
				SEAL #
				Fentanyl
				Ativan
				Midazolam
				Morphine
				SEAL #
				100 ml. Saline
				Glucagon
				INT adapters
				Naloxone
				IN Device

side Corresponding Box Number

9	10	11	12	
				Date
				Facility
				SEAL #
				Adenosine
				Amiodarone
				Atropine
				Calcium
				Dopamine
				Epinephrine
				Epinephrine
				Furosemide
				Lidocaine
				Magnesium
				Bicarb
				Dextrose

PHYSICIAN SIGNATURES (Controlled substances)

EMS Standing Protocol Requiring Prescriber Signature March 2015

S	**Situation** Recent revisions to the Virginia Board of Pharmacy and EMS regulations have waived the requirement for obtaining a prescriber's signature on the record of administration for medications given via standing protocol.
B	**Background** In 2014, Regulation 18VAC110-20-500 was amended to conform to legislative changes in §54.1-3408 of the Drug Control Act to allow EMS personnel to administer drugs pursuant to an oral or written order or standing protocol. If a copy of the standing protocols signed by the EMS operational medical director is maintained by the pharmacy, regulation no longer requires that the record of administration be signed by a prescriber. The BOP cannot advise as to whether this complies with federal requirements for the administration of drugs in Schedules II-V.
A	**Assessment** Pharmacy personnel are unable to effectively determine whether a medication has been administered pursuant to a standing protocol with each medication box exchange. The Virginia Board of Pharmacy cannot advise as to whether the EMS or BOP regulations comply with federal requirements regarding the administration of Schedules II-V drugs. Furthermore, recent DEA correspondence promotes the practice of "one prescription per patient". This leads to non-compliance with the use of standing protocol orders. Neither State law nor Board regulation prohibits hospital pharmacies from requiring a prescriber signature on administration of drugs in Schedules II-V by EMS personnel.
R	**Recommendation** On Monday, March 23rd, Hampton Roads Sentara facilities will require EMS personnel to obtain "wet" prescribers' signatures on the administration record of all Schedules II-V drugs administered by EMS personnel.

12/4/2018

Virginia Administrative Code
Title 18. Professional and Occupational Licensing
Agency 110. Board of Pharmacy
Chapter 20. Regulations Governing the Practice of Pharmacy

18VAC110-20-500. Licensed Emergency Medical Services (EMS) Agencies Program.

A. The pharmacy may prepare a kit for a licensed EMS agency provided:

1. The PIC of the hospital pharmacy shall be responsible for all prescription drugs and Schedule VI controlled devices contained in this kit. A pharmacist shall check each kit after filling and initial the filling record certifying the accuracy and integrity of the contents of the kit.

2. The kit is sealed, secured, and stored in such a manner that it will deter theft or loss of drugs and devices and aid in detection of theft or loss.

a. The hospital pharmacy shall have a method of sealing the kits such that once the seal is broken, it cannot be reasonably resealed without the breach being detected.

b. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication or resealing. The pharmacy shall maintain a record of the seal identifiers when placed on a kit and maintain the record for a period of one year.

c. In lieu of a seal, a kit with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy may be used.

3. Drugs and devices may be administered by an EMS provider upon an oral or written order or standing protocol of an authorized medical practitioner in accordance with § 54.1-3408 of the Code of Virginia. Oral orders shall be reduced to writing by the EMS provider and shall be signed by a medical practitioner. Written standing protocols shall be signed by the operational medical director for the EMS agency. A current copy of the signed standing protocol shall be maintained by the pharmacy participating in the kit exchange. The EMS provider shall make a record of all drugs and devices administered to a patient.

4. When the drug kit has been opened, the kit shall be returned to the pharmacy and exchanged for an unopened kit. The record of the drugs administered shall accompany the opened kit when exchanged. An accurate record shall be maintained by the pharmacy on the exchange of the drug kit for a period of one year. A pharmacist, pharmacy technician, or nurse shall reconcile the Schedule II, III, IV, or V drugs in the kit at the time the opened kit is returned. A record of the reconciliation, to include any noted discrepancies, shall be maintained by the pharmacy for a period of two years from the time of exchange. The theft or any other unusual loss of any Schedule II, III, IV, or V controlled substance shall be reported in accordance with § 54.1-3404 of the Code of Virginia.

5. Accurate records of the following shall be maintained by the pharmacy on the exchange of the drug kit for a period of one year:

a. The record of filling and verifying the kit to include the drug contents of the kit, the initials of the

pharmacist verifying the contents, the date of verification, a record of an identifier if a seal is used, and the assigned expiration date for the kit, which shall be no later than the expiration date associated with the first drug or device scheduled to expire.

b. The record of the exchange of the kit to include the date of exchange and the name of EMS agency and EMS provider receiving the kit.

6. Destruction of partially used Schedules II, III, IV, and V drugs shall be accomplished by two persons, one of whom shall be the EMS provider and the other shall be a pharmacist, nurse, prescriber, pharmacy technician, or a second EMS provider. Documentation shall be maintained in the pharmacy for a period of two years from the date of destruction.

7. The record of the drugs and devices administered shall be maintained as a part of the pharmacy records pursuant to state and federal regulations for a period of not less than two years.

8. Intravenous and irrigation solutions provided by a hospital pharmacy to an emergency medical services agency may be stored separately outside the kit.

9. Any drug or device showing evidence of damage or tampering shall be immediately removed from the kit and replaced.

10. In lieu of exchange by the hospital pharmacy, the PIC of the hospital pharmacy may authorize the exchange of the kit by the emergency department. Exchange of the kit in the emergency department shall only be performed by a pharmacist, nurse, or prescriber if the kit contents include Schedule II, III, IV, or V drugs.

B. A licensed EMS agency may obtain a controlled substances registration pursuant to § 54.1-3423 D of the Code of Virginia for the purpose of performing a one-to-one exchange of Schedule VI drugs or devices.

1. The controlled substances registration may be issued to a single agency or to multiple agencies within a single jurisdiction.

2. The controlled substances registration issued solely for this intended purpose does not authorize the storage of drugs within the agency facility.

3. Pursuant to § 54.1-3434.02 of the Code of Virginia, the EMS provider may directly obtain Schedule VI drugs and devices from an automated drug dispensing device.

4. If such drugs or devices are obtained from a nurse, pharmacist, or prescriber, it shall be in accordance with the procedures established by the pharmacist-in-charge, which shall include a requirement to record the date of exchange, name of licensed person providing drug or device, name of the EMS agency and provider receiving the drug or device, and assigned expiration date. Such record shall be maintained by the pharmacy for one year from the date of exchange.

5. If an EMS agency is performing a one-to-one exchange of Schedule VI drugs or devices, Schedule II, III, IV, or V drugs shall remain in a separate, sealed container and shall only be exchanged in accordance with provisions of subsection A of this section.

Statutory Authority

§§ 54.1-2400 and 54.1-3307 of the Code of Virginia.

Historical Notes

Derived from VR530-01-1 § 10.8, eff. October 25, 1989; amended, Volume 09, Issue 04, eff. December 16, 1992; Volume 10, Issue 01, eff. November 4, 1993; Volume 11, Issue 21, eff. August 9, 1995; Volume 15, Issue 08, eff. February 3, 1999; Volume 20, Issue 23, eff. August 25, 2004; Volume 25, Issue 24, eff. September 2, 2009; Volume 29, Issue 26, eff. September 25, 2013; Volume 31, Issue 20, eff. July 16, 2015.

12/4/2018

Code of Virginia
Title 54.1. Professions and Occupations
Chapter 34. Drug Control Act

§ 54.1-3408. Professional use by practitioners.

A. A practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine or a licensed nurse practitioner pursuant to § 54.1-2957.01, a licensed physician assistant pursuant to § 54.1-2952.1, or a TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 shall only prescribe, dispense, or administer controlled substances in good faith for medicinal or therapeutic purposes within the course of his professional practice.

B. The prescribing practitioner's order may be on a written prescription or pursuant to an oral prescription as authorized by this chapter. The prescriber may administer drugs and devices, or he may cause drugs or devices to be administered by:

1. A nurse, physician assistant, or intern under his direction and supervision;

2. Persons trained to administer drugs and devices to patients in state-owned or state-operated hospitals or facilities licensed as hospitals by the Board of Health or psychiatric hospitals licensed by the Department of Behavioral Health and Developmental Services who administer drugs under the control and supervision of the prescriber or a pharmacist;

3. Emergency medical services personnel certified and authorized to administer drugs and devices pursuant to regulations of the Board of Health who act within the scope of such certification and pursuant to an oral or written order or standing protocol; or

4. A licensed respiratory therapist as defined in § 54.1-2954 who administers by inhalation controlled substances used in inhalation or respiratory therapy.

C. Pursuant to an oral or written order or standing protocol, the prescriber, who is authorized by state or federal law to possess and administer radiopharmaceuticals in the scope of his practice, may authorize a nuclear medicine technologist to administer, under his supervision, radiopharmaceuticals used in the diagnosis or treatment of disease.

D. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize registered nurses and licensed practical nurses to possess (i) epinephrine and oxygen for administration in treatment of emergency medical conditions and (ii) heparin and sterile normal saline to use for the maintenance of intravenous access lines.

Pursuant to the regulations of the Board of Health, certain emergency medical services technicians may possess and administer epinephrine in emergency cases of anaphylactic shock.

Pursuant to an order or standing protocol issued by the prescriber within the course of his professional practice, any school nurse, school board employee, employee of a local governing body, or employee of a local health department who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any employee of a school for students with disabilities, as defined in § 22.1-319 and licensed by the Board of Education, or any employee of a private school that is accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any employee of a public institution of higher education or a private institution of higher education who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any employee of an organization providing outdoor educational experiences or programs for youth who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order issued by the prescriber within the course of his professional practice, an employee of a provider licensed by the Department of Behavioral Health and Developmental Services or a person providing services pursuant to a contract with a provider licensed by the Department of Behavioral Health and Developmental Services may possess and administer epinephrine, provided such person is authorized and trained in the administration of epinephrine.

Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize pharmacists to possess epinephrine and oxygen for administration in treatment of emergency medical conditions.

E. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize licensed physical therapists to possess and administer topical corticosteroids, topical lidocaine, and any other Schedule VI topical drug.

F. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize licensed athletic trainers to possess and administer topical corticosteroids, topical lidocaine, or other Schedule VI topical drugs; oxygen for use in emergency situations; and epinephrine for use in emergency cases of anaphylactic shock.

G. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, and in accordance with policies and guidelines established by the Department of Health pursuant to § 32.1-50.2, such prescriber may authorize registered nurses or licensed practical nurses under the supervision of a registered nurse to possess and administer tuberculin purified protein derivative (PPD) in the absence of a prescriber. The Department of Health's policies and guidelines shall be consistent with applicable guidelines developed by the Centers for Disease Control and Prevention for preventing transmission of mycobacterium tuberculosis and shall be updated to incorporate any subsequently implemented standards of the Occupational Safety and Health Administration and the Department of Labor and Industry to the extent that they are inconsistent with the Department of Health's policies and guidelines. Such standing protocols shall explicitly describe the categories of persons to whom the tuberculin test is to be administered and shall provide for appropriate medical evaluation of those in whom the test is positive. The prescriber shall ensure that the nurse implementing such standing protocols has received adequate training in the practice and principles underlying tuberculin screening.

The Health Commissioner or his designee may authorize registered nurses, acting as agents of the

Department of Health, to possess and administer, at the nurse's discretion, tuberculin purified protein derivative (PPD) to those persons in whom tuberculin skin testing is indicated based on protocols and policies established by the Department of Health.

H. Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize, with the consent of the parents as defined in § 22.1-1, an employee of (i) a school board, (ii) a school for students with disabilities as defined in § 22.1-319 licensed by the Board of Education, or (iii) a private school accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education who is trained in the administration of insulin and glucagon to assist with the administration of insulin or administer glucagon to a student diagnosed as having diabetes and who requires insulin injections during the school day or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia. Such authorization shall only be effective when a licensed nurse, nurse practitioner, physician, or physician assistant is not present to perform the administration of the medication.

Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize an employee of a public institution of higher education or a private institution of higher education who is trained in the administration of insulin and glucagon to assist with the administration of insulin or administration of glucagon to a student diagnosed as having diabetes and who requires insulin injections or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia. Such authorization shall only be effective when a licensed nurse, nurse practitioner, physician, or physician assistant is not present to perform the administration of the medication.

Pursuant to a written order issued by the prescriber within the course of his professional practice, such prescriber may authorize an employee of a provider licensed by the Department of Behavioral Health and Developmental Services or a person providing services pursuant to a contract with a provider licensed by the Department of Behavioral Health and Developmental Services to assist with the administration of insulin or to administer glucagon to a person diagnosed as having diabetes and who requires insulin injections or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia, provided such employee or person providing services has been trained in the administration of insulin and glucagon.

I. A prescriber may authorize, pursuant to a protocol approved by the Board of Nursing, the administration of vaccines to adults for immunization, when a practitioner with prescriptive authority is not physically present, by (i) licensed pharmacists, (ii) registered nurses, or (iii) licensed practical nurses under the supervision of a registered nurse. A prescriber acting on behalf of and in accordance with established protocols of the Department of Health may authorize the administration of vaccines to any person by a pharmacist, nurse, or designated emergency medical services provider who holds an advanced life support certificate issued by the Commissioner of Health under the direction of an operational medical director when the prescriber is not physically present. The emergency medical services provider shall provide documentation of the vaccines to be recorded in the Virginia Immunization Information System.

J. A dentist may cause Schedule VI topical drugs to be administered under his direction and supervision by either a dental hygienist or by an authorized agent of the dentist.

Further, pursuant to a written order and in accordance with a standing protocol issued by the dentist in the course of his professional practice, a dentist may authorize a dental hygienist under his general supervision, as defined in § 54.1-2722, to possess and administer topical oral fluorides, topical oral

regulations relating to training, security and record keeping, when the drugs administered would be normally self-administered by a student of a Virginia public school. Training for such persons shall be accomplished through a program approved by the local school boards, in consultation with the local departments of health.

O. In addition, this section shall not prevent the administration of drugs by a person to (i) a child in a child day program as defined in § 63.2-100 and regulated by the State Board of Social Services or a local government pursuant to § 15.2-914, or (ii) a student of a private school that is accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education, provided such person (a) has satisfactorily completed a training program for this purpose approved by the Board of Nursing and taught by a registered nurse, licensed practical nurse, nurse practitioner, physician assistant, doctor of medicine or osteopathic medicine, or pharmacist; (b) has obtained written authorization from a parent or guardian; (c) administers drugs only to the child identified on the prescription label in accordance with the prescriber's instructions pertaining to dosage, frequency, and manner of administration; and (d) administers only those drugs that were dispensed from a pharmacy and maintained in the original, labeled container that would normally be self-administered by the child or student, or administered by a parent or guardian to the child or student.

P. In addition, this section shall not prevent the administration or dispensing of drugs and devices by persons if they are authorized by the State Health Commissioner in accordance with protocols established by the State Health Commissioner pursuant to § 32.1-42.1 when (i) the Governor has declared a disaster or a state of emergency or the United States Secretary of Health and Human Services has issued a declaration of an actual or potential bioterrorism incident or other actual or potential public health emergency; (ii) it is necessary to permit the provision of needed drugs or devices; and (iii) such persons have received the training necessary to safely administer or dispense the needed drugs or devices. Such persons shall administer or dispense all drugs or devices under the direction, control, and supervision of the State Health Commissioner.

Q. Nothing in this title shall prohibit the administration of normally self-administered drugs by unlicensed individuals to a person in his private residence.

R. This section shall not interfere with any prescriber issuing prescriptions in compliance with his authority and scope of practice and the provisions of this section to a Board agent for use pursuant to subsection G of § 18.2-258.1. Such prescriptions issued by such prescriber shall be deemed to be valid prescriptions.

S. Nothing in this title shall prevent or interfere with dialysis care technicians or dialysis patient care technicians who are certified by an organization approved by the Board of Health Professions or persons authorized for provisional practice pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.), in the ordinary course of their duties in a Medicare-certified renal dialysis facility, from administering heparin, topical needle site anesthetics, dialysis solutions, sterile normal saline solution, and blood volumizers, for the purpose of facilitating renal dialysis treatment, when such administration of medications occurs under the orders of a licensed physician, nurse practitioner, or physician assistant and under the immediate and direct supervision of a licensed registered nurse. Nothing in this chapter shall be construed to prohibit a patient care dialysis technician trainee from performing dialysis care as part of and within the scope of the clinical skills instruction segment of a supervised dialysis technician training program, provided such trainee is identified as a "trainee" while working in a renal dialysis facility.

The dialysis care technician or dialysis patient care technician administering the medications shall have

demonstrated competency as evidenced by holding current valid certification from an organization approved by the Board of Health Professions pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.).

T. Persons who are otherwise authorized to administer controlled substances in hospitals shall be authorized to administer influenza or pneumococcal vaccines pursuant to § 32.1-126.4.

U. Pursuant to a specific order for a patient and under his direct and immediate supervision, a prescriber may authorize the administration of controlled substances by personnel who have been properly trained to assist a doctor of medicine or osteopathic medicine, provided the method does not include intravenous, intrathecal, or epidural administration and the prescriber remains responsible for such administration.

V. A physician assistant, nurse or a dental hygienist may possess and administer topical fluoride varnish to the teeth of children aged six months to three years pursuant to an oral or written order or a standing protocol issued by a doctor of medicine, osteopathic medicine, or dentistry that conforms to standards adopted by the Department of Health.

W. A prescriber, acting in accordance with guidelines developed pursuant to § 32.1-46.02, may authorize the administration of influenza vaccine to minors by a licensed pharmacist, registered nurse, licensed practical nurse under the direction and immediate supervision of a registered nurse, or emergency medical services provider who holds an advanced life support certificate issued by the Commissioner of Health when the prescriber is not physically present.

X. Notwithstanding the provisions of § 54.1-3303, pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee authorizing the dispensing of naloxone or other opioid antagonist used for overdose reversal in the absence of an oral or written order for a specific patient issued by a prescriber, and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, a pharmacist may dispense naloxone or other opioid antagonist used for overdose reversal and a person may possess and administer naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose. Law-enforcement officers as defined in § 9.1-101, employees of the Department of Forensic Science, employees of the Office of the Chief Medical Examiner, employees of the Department of General Services Division of Consolidated Laboratory Services, employees of the Department of Corrections designated as probation and parole officers or as correctional officers as defined in § 53.1-1, and firefighters who have completed a training program may also possess and administer naloxone in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.

Y. Notwithstanding any other law or regulation to the contrary, a person who is authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone for use in opioid overdose reversal and who is acting on behalf of an organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone for overdose reversal and that has obtained a controlled substances registration from the Board of Pharmacy pursuant to § 54.1-3423 may dispense naloxone to a person who has completed a training program on the administration of naloxone for opioid overdose reversal approved by the Department of Behavioral Health and Developmental Services, provided that such dispensing is (i) pursuant to a standing order issued by a prescriber, (ii) in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, and (iii) without charge or compensation. The dispensing may occur at a site other than that of the controlled substance registration provided the entity possessing the controlled substances registration maintains records in accordance with

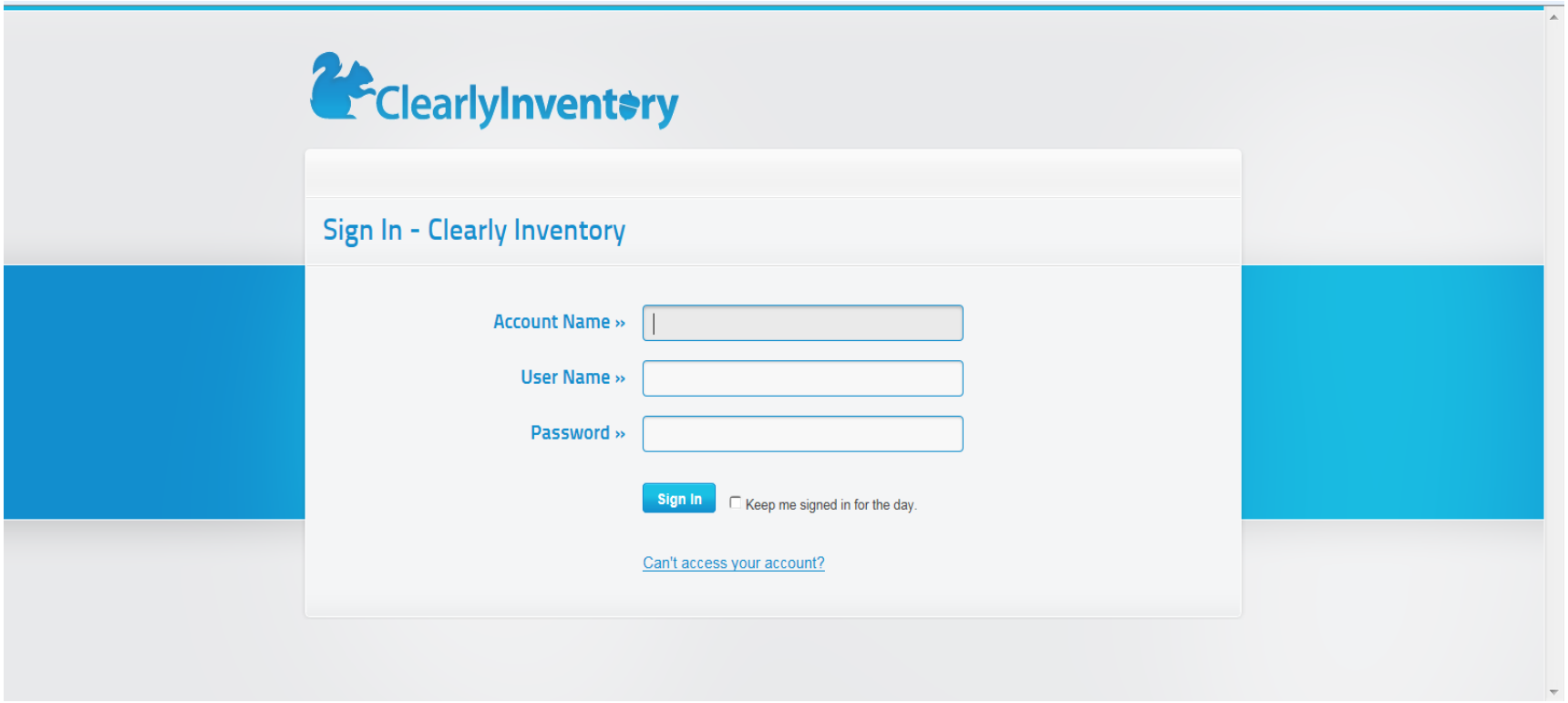
regulations of the Board of Pharmacy. A person to whom naloxone has been dispensed pursuant to this subsection may possess naloxone and may administer naloxone to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose.

Z. Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize, with the consent of the parents as defined in § 22.1-1, an employee of (i) a school board, (ii) a school for students with disabilities as defined in § 22.1-319 licensed by the Board of Education, or (iii) a private school accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education who is trained in the administration of injected medications for the treatment of adrenal crisis resulting from a condition causing adrenal insufficiency to administer such medication to a student diagnosed with a condition causing adrenal insufficiency when the student is believed to be experiencing or about to experience an adrenal crisis. Such authorization shall be effective only when a licensed nurse, nurse practitioner, physician, or physician assistant is not present to perform the administration of the medication.

Code 1950, § 54-497; 1956, c. 225; 1970, c. 650, § 54-524.65; 1973, c. 468; 1976, cc. 358, 614; 1977, c. 302; 1978, c. 224; 1980, cc. 270, 287; 1983, cc. 456, 528; 1984, cc. 141, 555; 1986, c. 81; 1987, c. 226; 1988, c. 765; 1990, c. 309; 1991, cc. 141, 519, 524, 532; 1992, cc. 610, 760, 793; 1993, cc. 15, 810, 957, 993; 1994, c. 53; 1995, cc. 88, 529; 1996, cc. 152, 158, 183, 406, 408, 490; 1997, cc. 272, 566, 806, 906; 1998, c. 112; 1999, c. 570; 2000, cc. 135, 498, 861, 881, 935; 2003, cc. 465, 497, 515, 794, 995, 1020; 2005, cc. 113, 610, 924; 2006, cc. 75, 432, 686, 858; 2007, cc. 17, 699, 702, 783; 2008, cc. 85, 694; 2009, cc. 48, 110, 506, 813, 840; 2010, cc. 179, 245, 252; 2011, c. 292; 2012, cc. 787, 803, 833, 835; 2013, cc. 114, 132, 183, 191, 252, 267, 328, 336, 359, 617; 2014, cc. 88, 491; 2015, cc. 302, 387, 502, 503, 514, 725, 732, 752; 2016, c. 144; 2017, cc. 3, 55, 107, 168, 174, 182, 294, 304, 713; 2018, cc. 62, 247.

STEP 1:

- Let's begin with the basic steps of accessing the Clearly Inventory web site and logging into the training program.
- The website address is: https://app.clearlyinventory.com/Login.aspx
- Once accessed, your screen should show the following:



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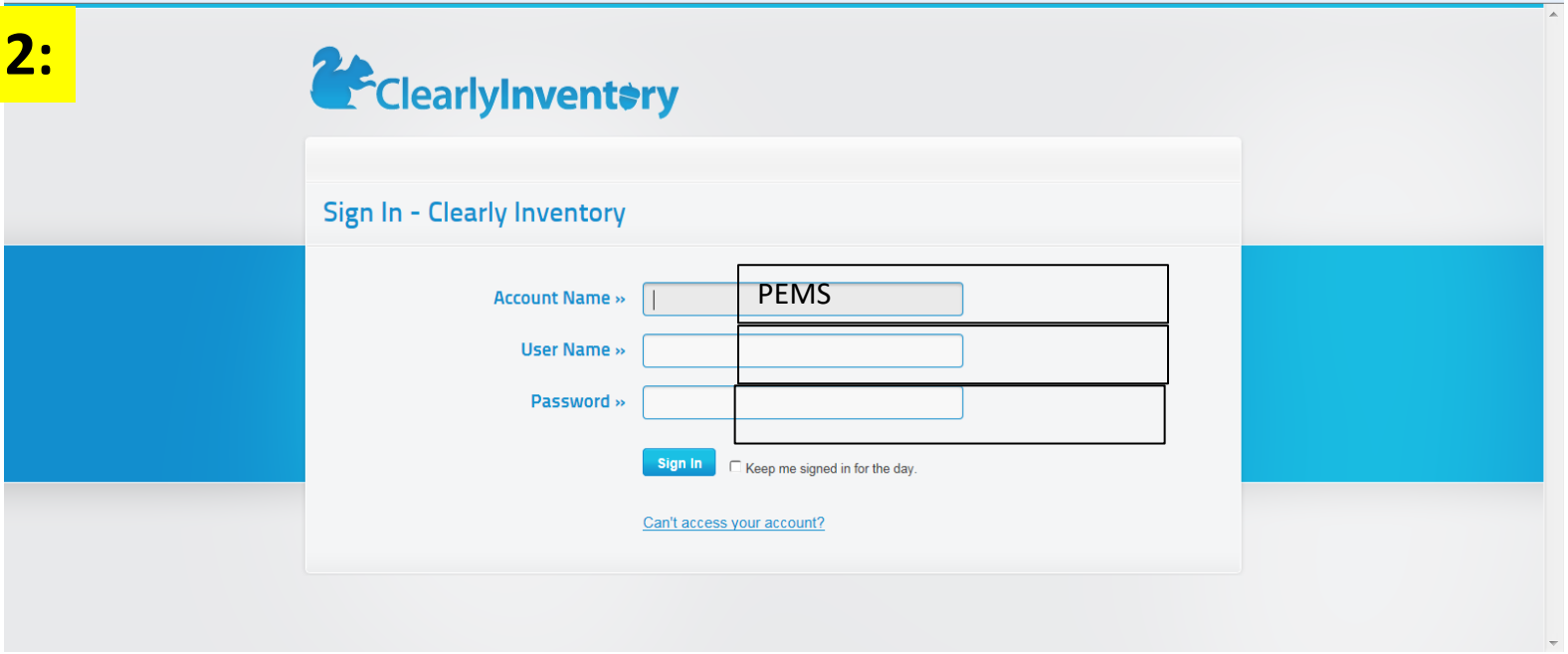
STEP 2:



- You are now at the Sign-In screen. To access the Trainer, enter the:

Under **Account Name>>**, enter PEMS.
Under **User Name>>** , enter Your Hospital Username.
Under **Password>>**, enter pemsva.

To have access all day without continuously signing in, check the box next to the Sign In button "☑ Keep me signed in for the day". Then click on the Sign In button.

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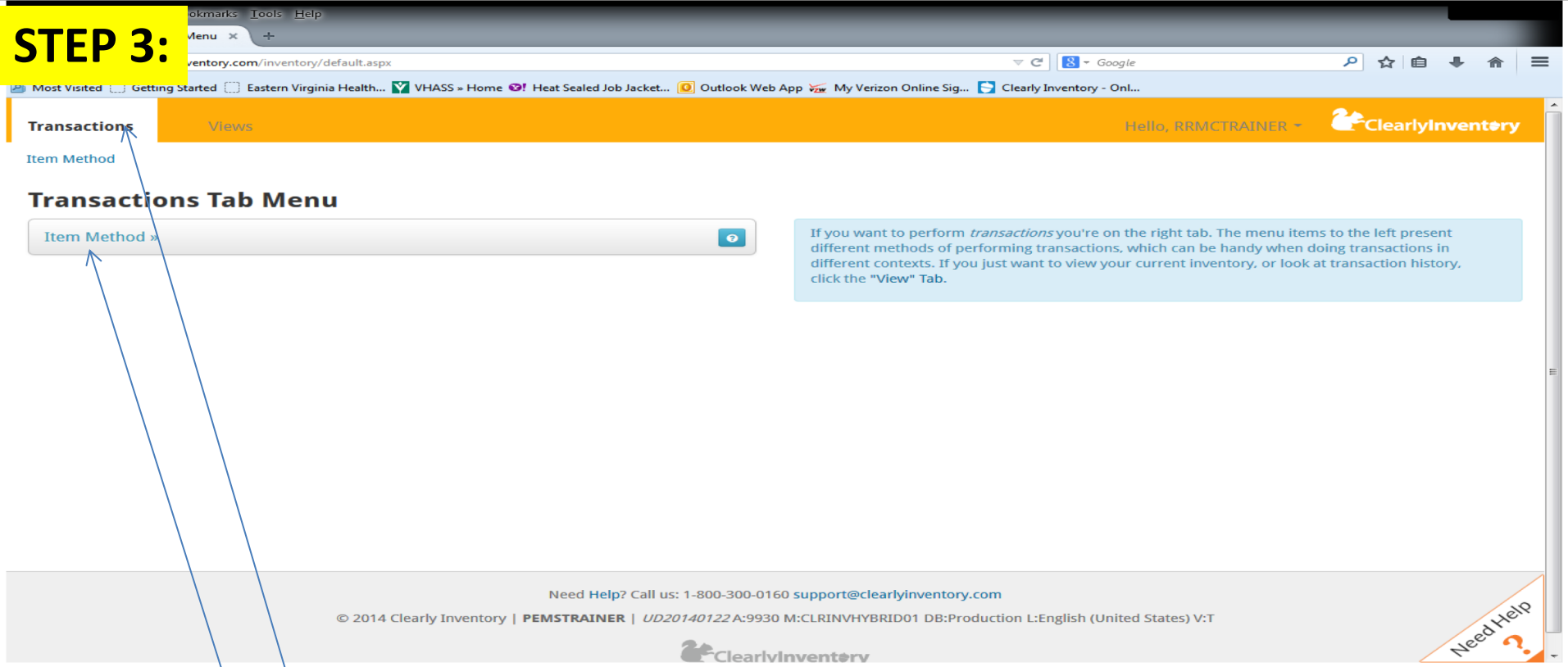
STEP 3:



*** At the upper left, you will see two tabs:**
> TRANSACTIONS and > VIEWS
If not already at the above screen, click on the "Transactions: tab.

*** Then Click the "Item Method" button.**

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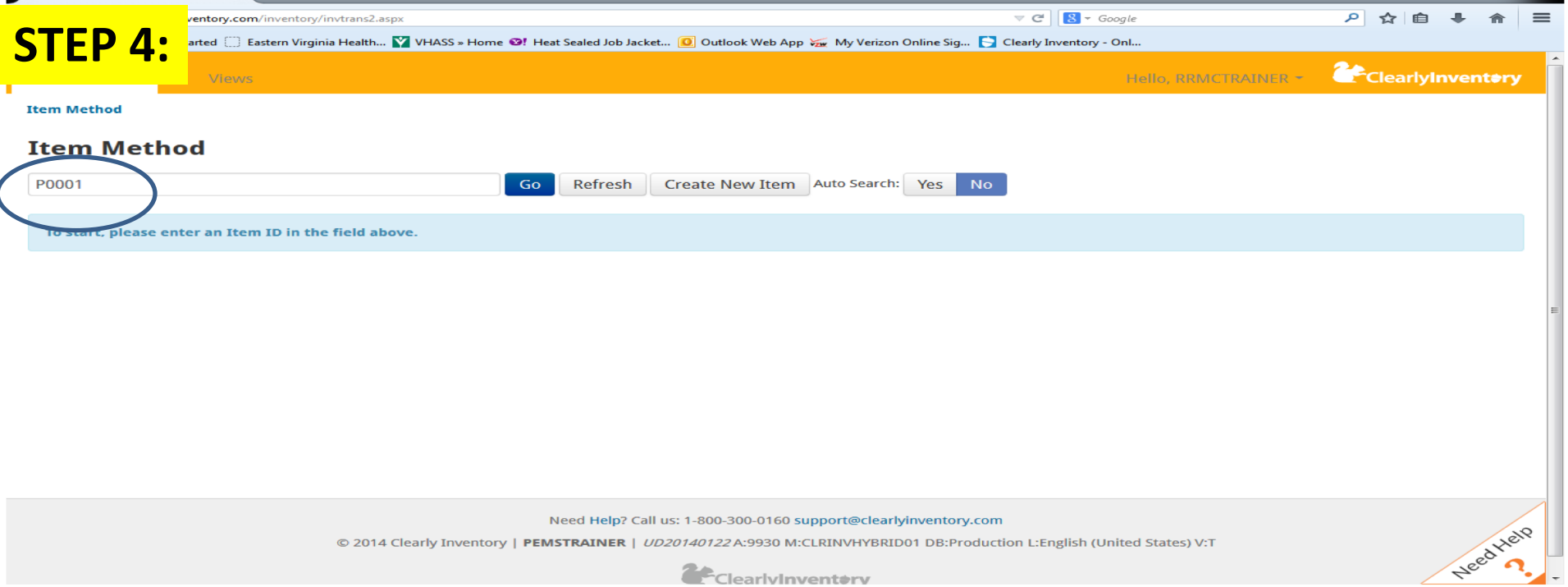
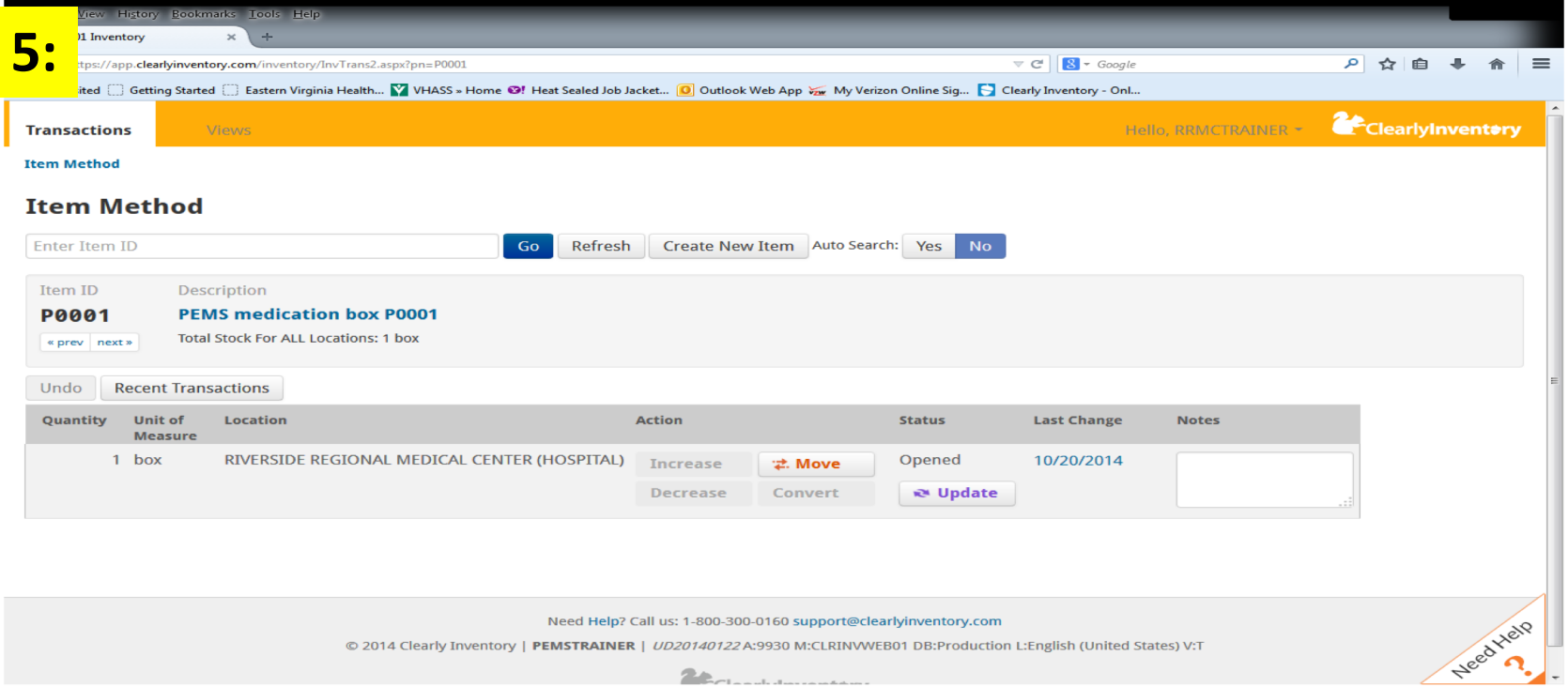
STEP 4:



*** As a member of the Pharmacy Medication Box Exchange team, you will need to locate the medication box being exchanged.**

*** Under Item Method, enter the medication box number you are trying to locate, then click the Go button. For example, enter P0001. Then click on the "Go" box. The following screen will appear…..**

STEP 5:



*** A screen will appear showing the location, (either an EMS Agency or Hospital), of the medication box number just entered. Assuming the medication box is being exchanged, it will need a "STATUS" update**

*** In order to do this, click on the blue "Update". You will see the following window……**

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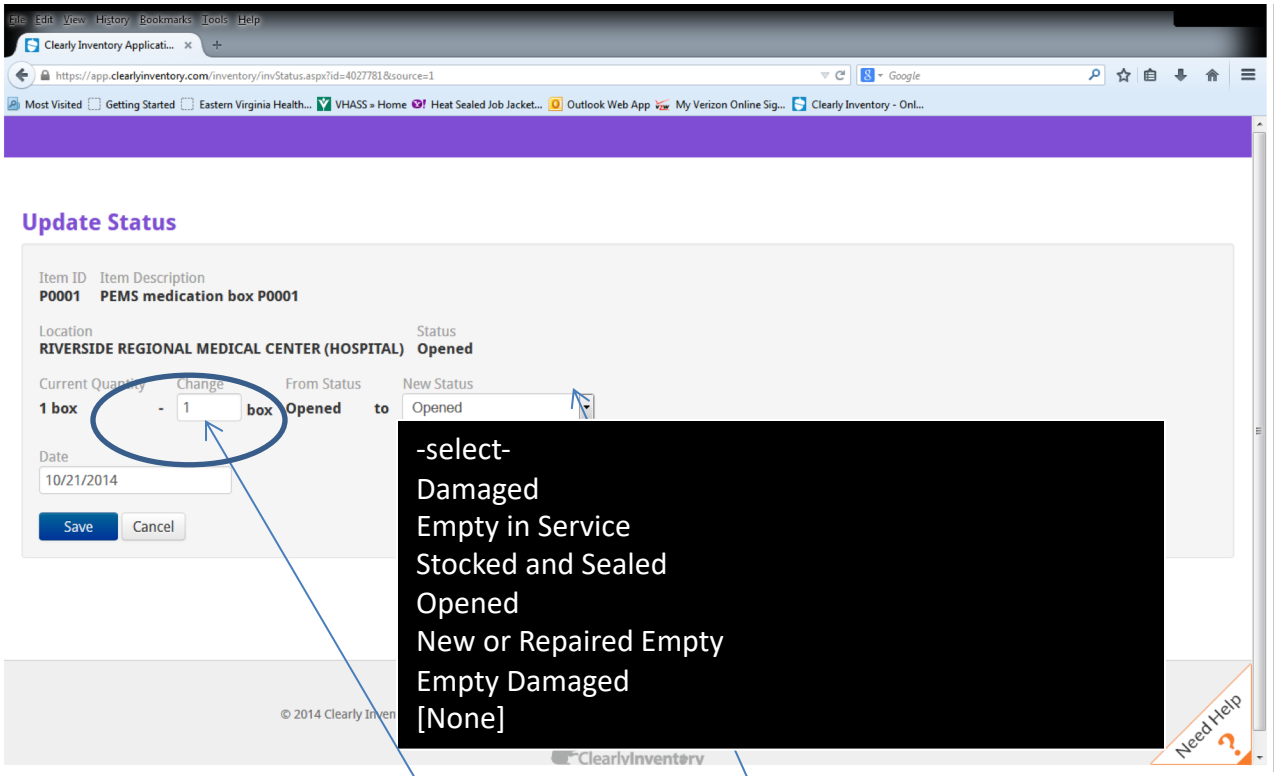
STEP 6:



* Ensure that the Change number is “1” box.

* New Status is then updated clicking on the drop arrow and selecting the new status

* Click on “SAVE”

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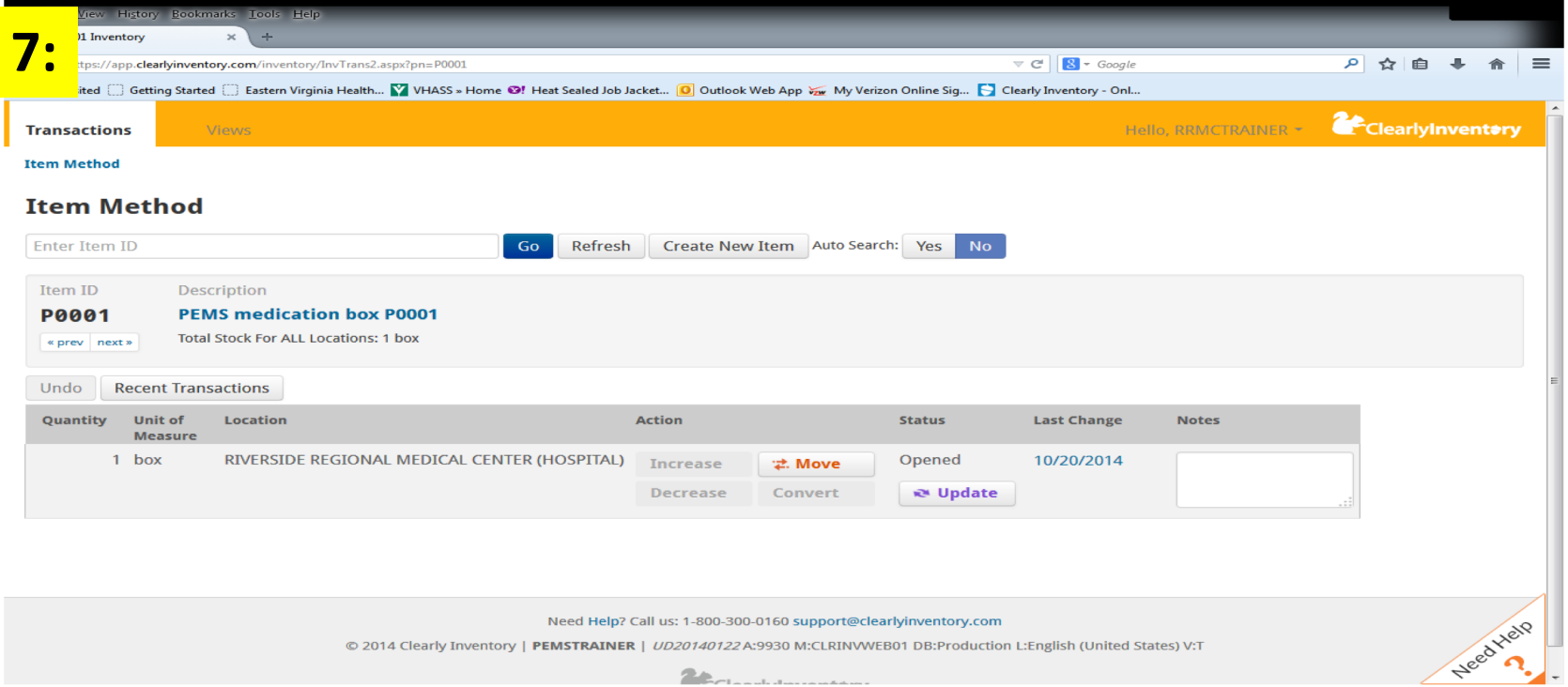
STEP 7:



*** A screen will appear showing the location, (either an EMS Agency or Hospital), of the medication box number just entered. Assuming the medication box is being exchanged, it will need to be moved in the tracking system from the agency turning it in, to your pharmacy.**

*** In order to do this, click on the orange "Move". You will see the following window……**

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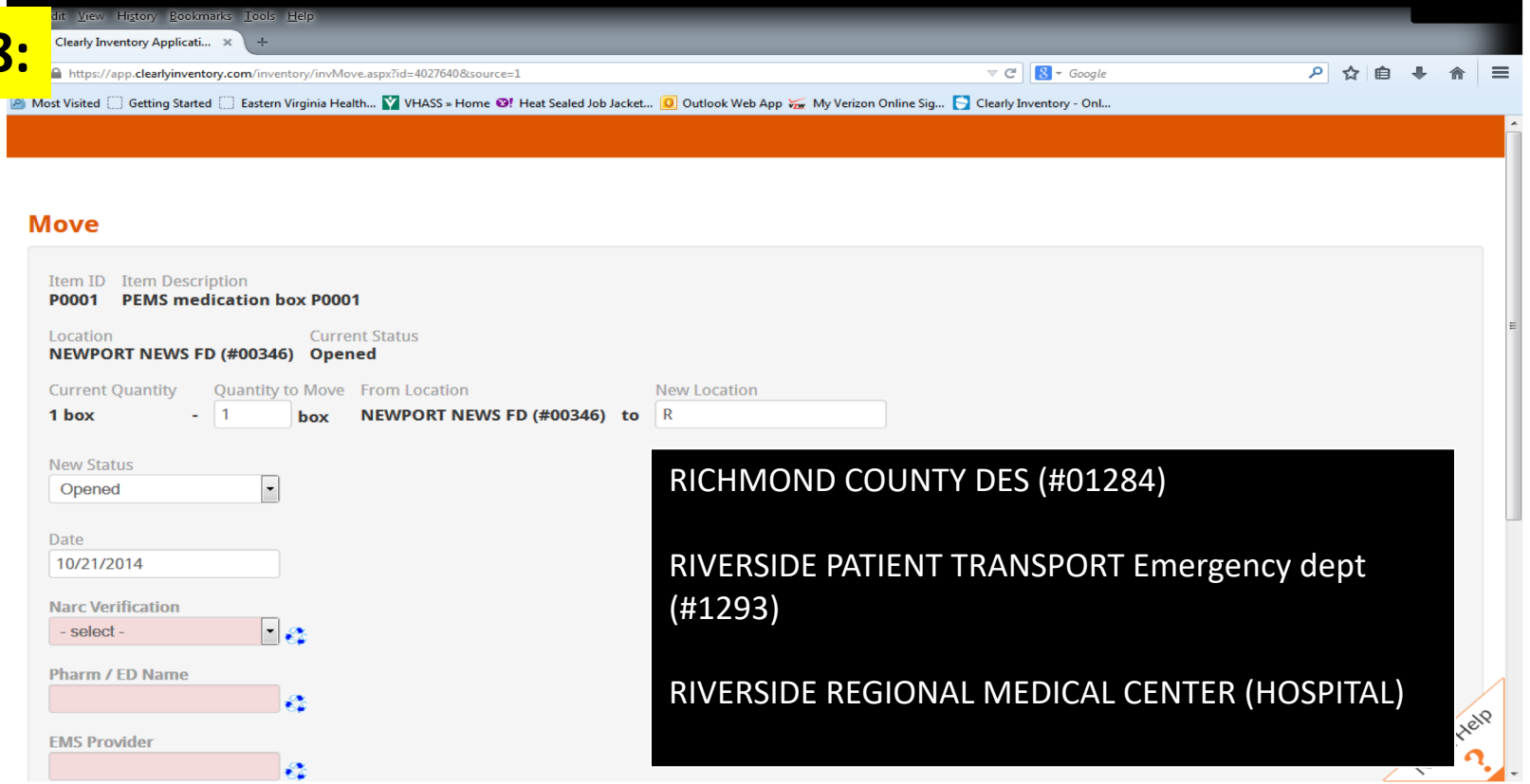
STEP 8:



*** The "Move" window is where you will record the actual exchange of medication box.**

*** First, ensure quantity "1" is pre-entered and the name of your location in the "New Location" Field. As you type, you may see your location appear. If so, make sure you click the name from the drop down list.**

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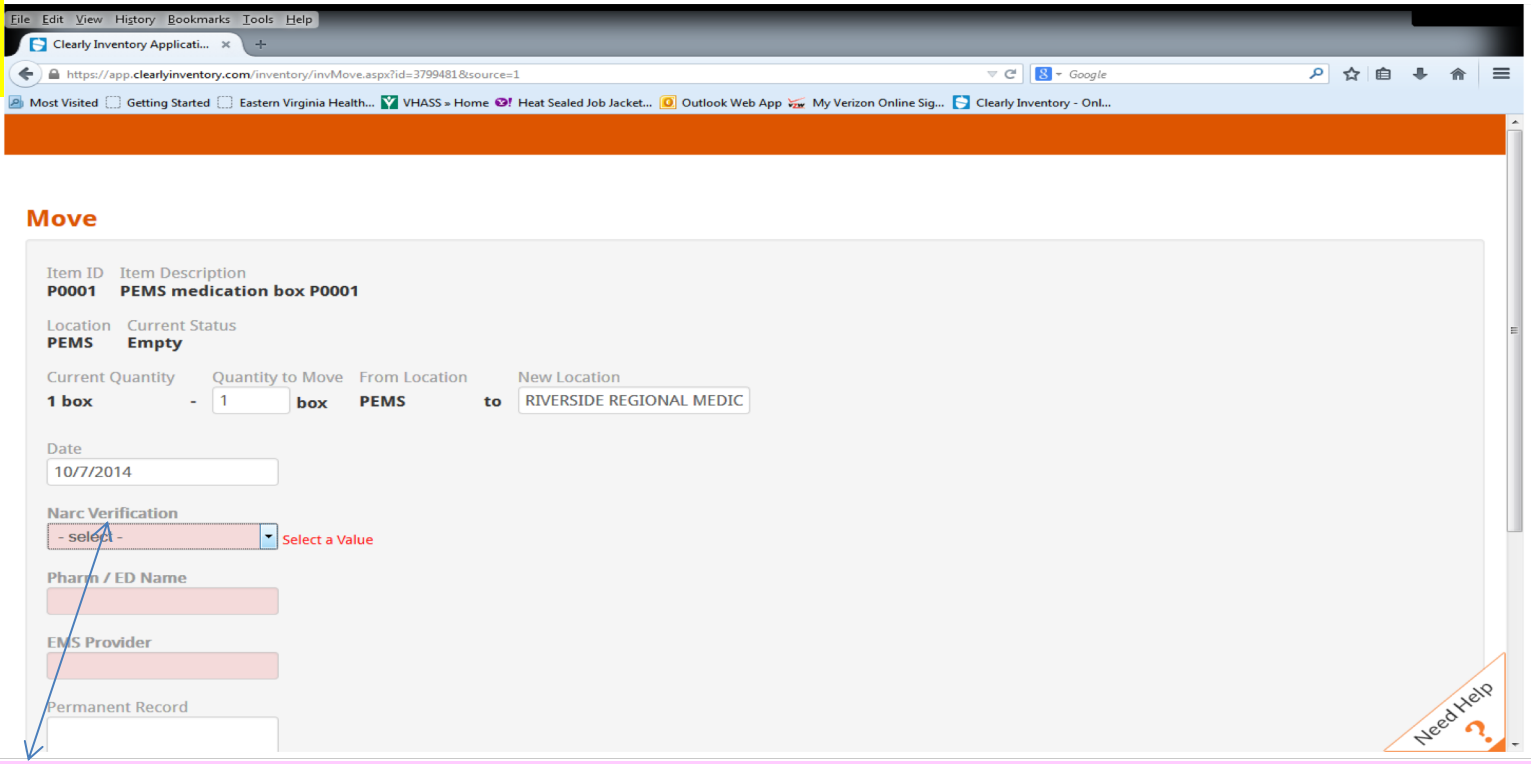
STEP 9:



- **Click the drop down for "Narc Verification" and select the appropriate option.**
- **2 Versed, 1 Fentanyl, 2 morphine sulfate, and 2 Ativan (This is the expected amount)**
- **Narcotics missing and unaccounted for. (if chosen enter note in "Permanent Record")**
- **Other (if chosen enter the quantity found in the "Permanent Record" field below, along with any other notes.)**
- **Outgoing drug kit- kit sealed**

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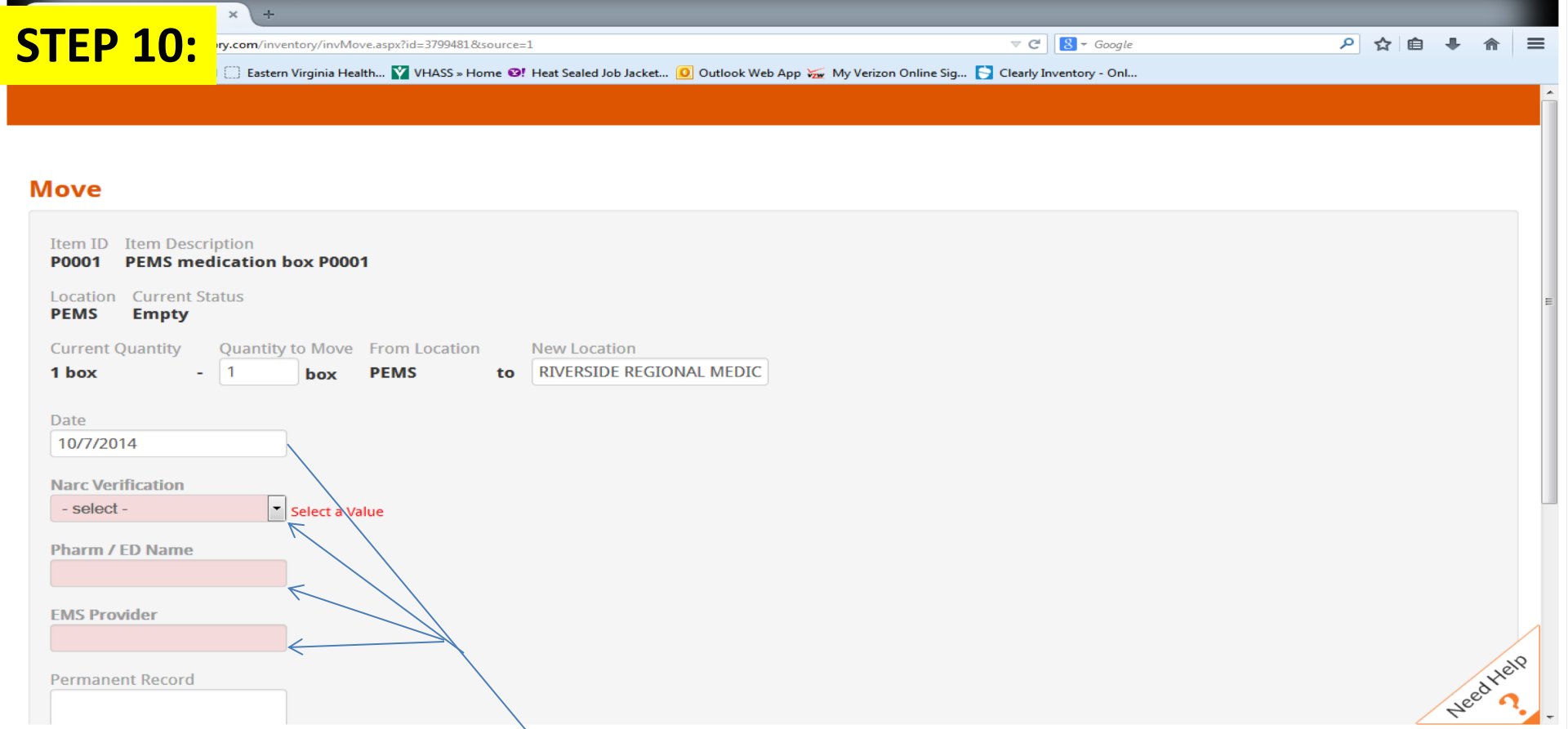
STEP 10:



- **Type the name of the Pharmacist or Tech moving the box (usually your name) in the "Pharm/ED Name" box.**
- **Type the name of the EMS Provider in the "EMS Provider" box.**
- **Please <u>double check your entries for accuracy</u> before you click the "Save" button.**

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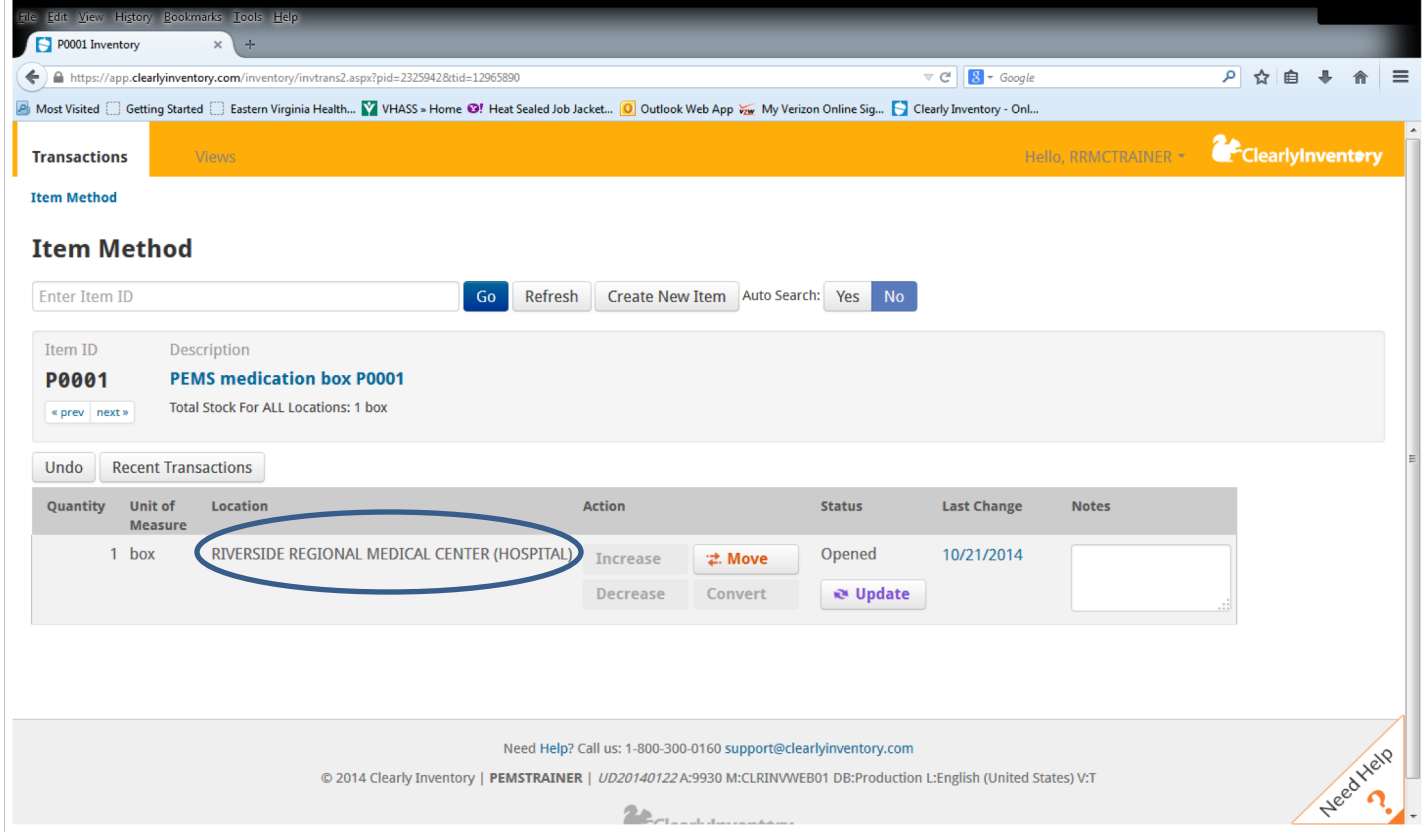
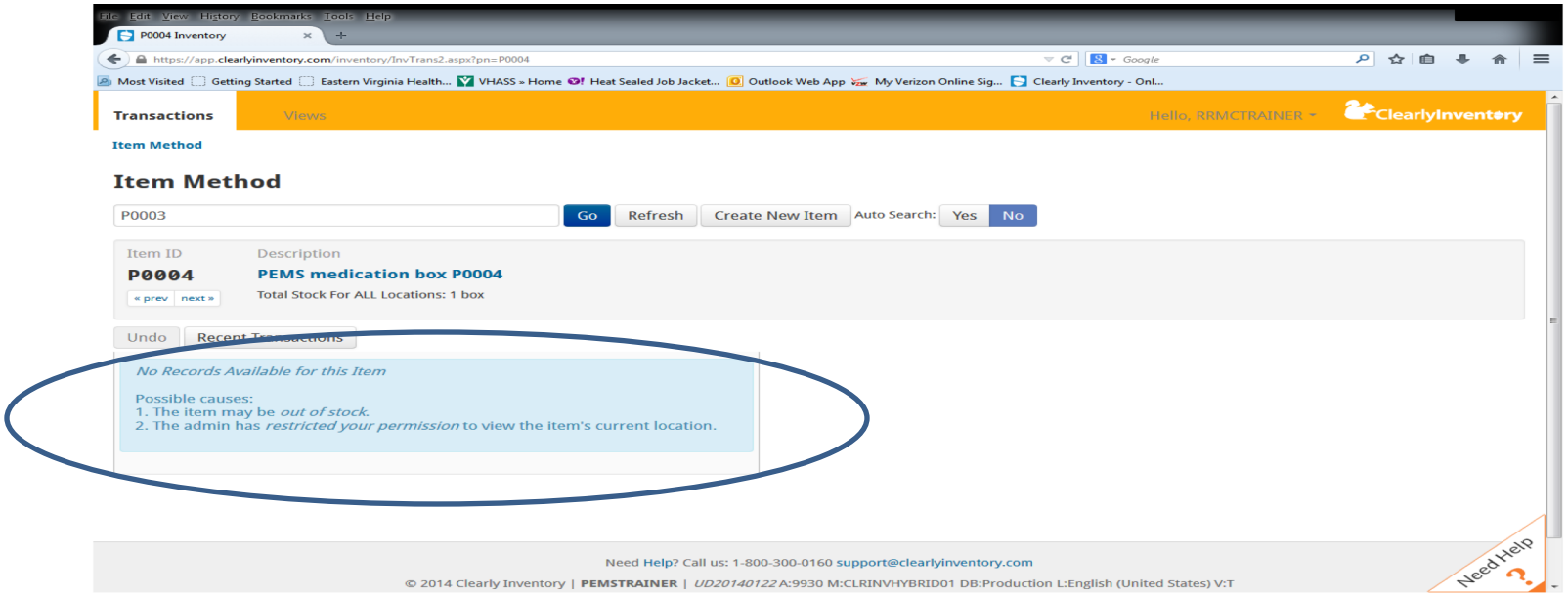
STEP 11:



Once you have saved your entries, the above screen will confirm the exchanges just made. You will see the medication box number that you moved and the new location name.



*** If you search for a box, and you see the above message in the blue box, it is due to one of two circumstances.**

1. You did not enter the box number correctly

2. The box was not moved to the provider by the previous pharmacy

*** In the first case, all you need to do is re-enter the number correctly.**

*** In the second case, you need to locate the box and either have the offending pharmacy move it to the provider, so you can move it, or you need to contact an PEMS administrator to correct the situation.**

CONTACTS

• PEMS		804-693-6234
• RRMC	PHARMACY	757-534-6010
• RRMC	EMERGENCY DEPT.	757-594-2983
• RWRH	PHARMACY	804-693-8829
• RWRH	EMERGENCY DEPT.	804-693-8899
• RDHW	PHARMACY	757-594-2080
• RDHW	EMERGENCY DEPT.	757-585-2254
• RTH	PHARMACY	804-443-6059
• RTH	EMERGENCY DEPT.	804-443-6297
• RGH	PHARMACY	804-435-8318
• RGH	EMERGENCY DEPT.	804-436-5314
• SCPH	PHARMACY	757-736-1220
• SCPH	EMERGENCY DEPT.	757-810-3208
• SWRMC	PHARMACY	757-984-8110
• SWRMC	EMERGENCY DEPT.	757-984-7159
• MIH	PHARMACY	757-886-6466
• MIH	EMERGENCY DEPT.	757-477-9089
• LAFB	PHARMACY	757-764-6758
• LAFB	EMERGENCY DEPT.	757-764-6800

* CHKD PHARMACY		804-123-1234
* SNGH PHARMACY		757-388-3455
* MRMC PHARMACY		804-764-6919
* VCU/MCV PHARMACY		804-828-6719