ESTATE OF DENNIS ALLEN, et al. v. UMMS, et al.

Circuit Court for Baltimore City

Case No.: 24-C-15-003384 MM

Hospitals cannot expose a patient to an unreasonable risk of injury. When a hospital's doctor chooses to expose a patient to an unreasonable risk of injury, the hospital is responsible for the harms and losses caused.

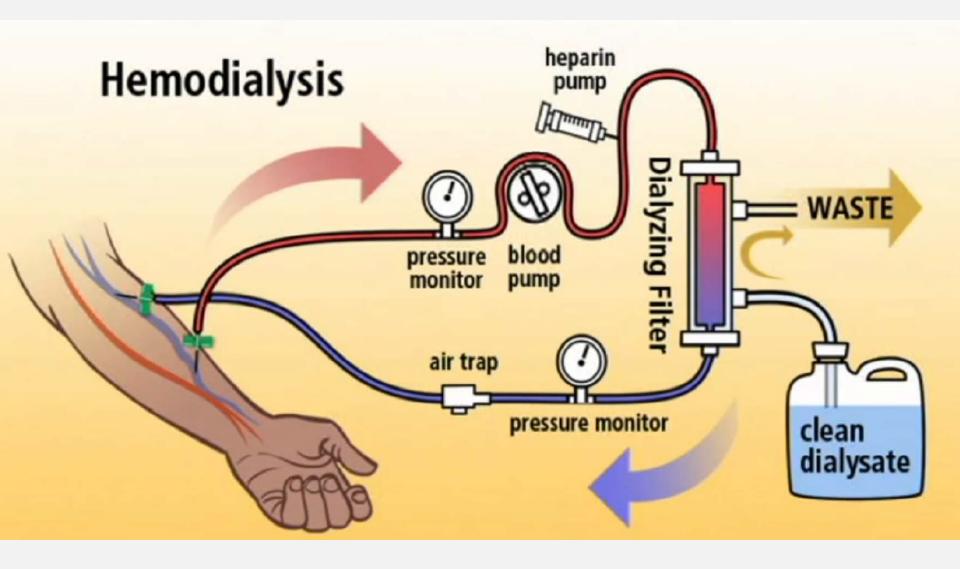
WHO WE ARE SUING AND WHY

We are here to hold the hospital and Dr. Burks responsible for giving Mr. Allen a drug which caused his suffering and death.

Medical Terms

- Hyperkalemia
- Dialysis



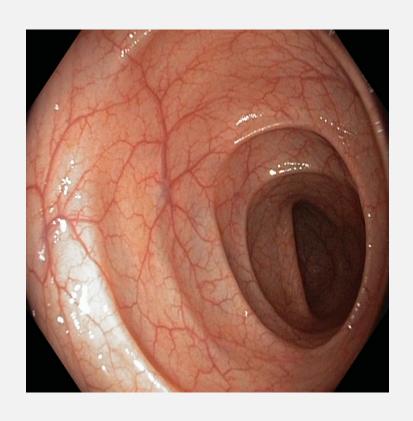


DIALYSIS IS SAFE

Medical Terms

- Hyperkalemia
- Dialysis
- Intestinal Necrosis (Tissue Death)

Intestinal Necrosis



Healthy Colon



Necrotic Colon

Medical Terms

- Hyperkalemia
- Dialysis
- Intestinal Necrosis (Tissue Death)
- Kayexalate

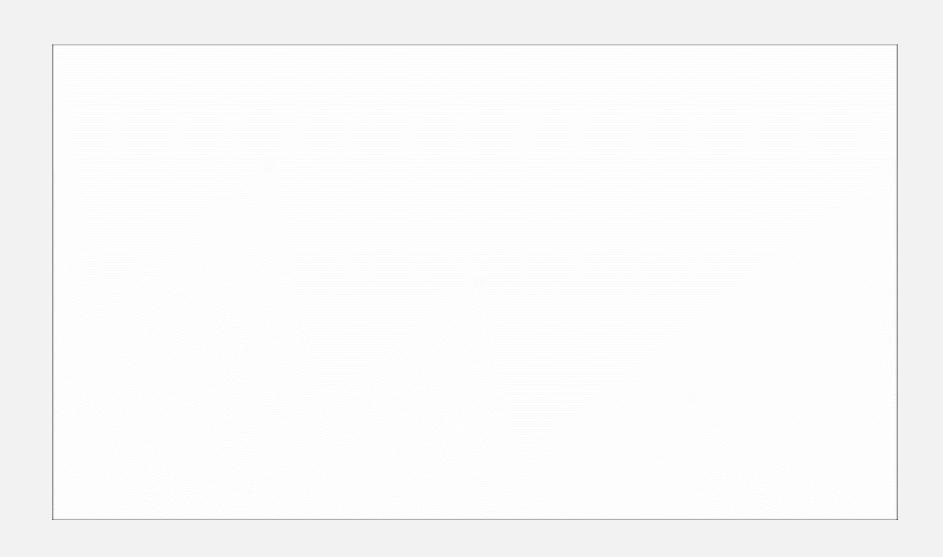
What is Kayexalate/Sorbitol

- Removes Potassium
- 2009 & 2011 FDA warned of:
 - Intestinal Necrosis (tissue death)
 - o Bowel Perforation
- Symptoms:
 - Abdominal pain
 - Bloody stool

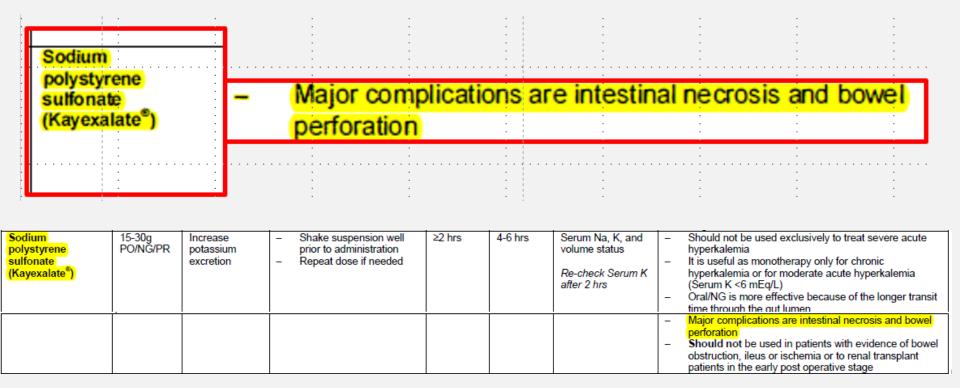


USE ONLY AS A LAST RESORT WHEN DIALYSIS IS NOT READILY AVAILABLE

Intestinal Necrosis from Kayexalate/Sorbitol Administration



What the Hospital Knew



March 2013

- March 2, 2013 Cholesterol medication changed
- March 10, 2013 NW Hospital with Rhabdomyolysis
- March 11, 2013 University of Maryland Hospital

University Hospital

- Dr. Burks is Mr. Allen's attending physician
- Mr. Allen has hemodialysis (13th, 14th, 15th, 16th)
- March 18, 2013 Dr. Burks arrives 7:00 am
- No blood drawn from Mr. Allen
- 12:00 noon Irregular heartbeat/hyperkalemia
- Dr. Burks fails to order calcium
- Hemodialysis ordered on urgent basis
- Dr. Burks orders Kayexalate/Sorbitol

What Happened Within 14 Hours After Kayexalate/Sorbitol

- The hospital and doctors were aware of:
 - o 2 bowel movements during dialysis
 - Abdominal pain
 - Bloody stools
 - o 8 more bowel movements after dialysis

ALL SIGNS AND SYMPTOMS OF INTESTINAL NECROSIS MR. ALLEN'S COLON IS DYING

What Mr. Allen Experienced

- March 18, 2013 through March 20, 2013:
 - Intestinal bleeding and bloody stools
 - o 10 bowel movements in 14 hours
 - Abdominal Pain crying out in pain
 - Rectal tube
 - Death of his colon
 - Transferred to ICU
 - First pain medication March 19th 2:00pm

March 19th, 2013 - AM

- Dr. Burks tells the family:
 - o I'm sorry. I made a mistake.
 - I gave your husband Kayexalate that caused injury to his colon.
 - We caught it in time.
 - He will have to go to surgery. He'll only be there for an hour or two.
 - He will be okay.

March 19, 2013 - PM

- Surgery takes 7 hours
- Entire colon is removed
- They left him open
- Told the family to pray

(Dr. Burks never saw the family again)

Mr. Allen dies on March 20th at 2:18 pm with his entire family by his side.

MEDICAL NEGLIGENCE

A health care provider is negligent if the health care provider does not use that degree of care and skill which a reasonably competent health care provider, engaged in a similar practice and acting in similar circumstances, would use.

MEDICAL NEGLIGENCE

- The hospital's doctor breached the standard of care by ordering and administering Kayexalate to Mr. Allen.
- The hospital's doctor also failed to obtain Mr. Allen's informed consent before administering Kayexalate/Sorbitol.

FIVE REQUIRED ELEMENTS OF **INFORMED CONSENT**

1.	Reveal the nature of the ailment	FAILED
2.	Reveal the nature of the proposed procedure	FAILED
3.	Reveal the probability of success	FAILED
4.	Reveal any alternatives	FAILED
5.	Reveal the material risks	FAILED

QUESTIONS WE ANSWERED

• Did the Kayexalate cause Mr. Allen's Intestinal Necrosis?

Dr. Burks' Discharge Summary

```
University of Maryland Medical System
Patient Name: ALLEN, DENNIS V
Medical Record Number: 240925
Account Number: 1002867761
Document Type: DISCHARGE SUMMARY
rule out SBP and the differential diagnosis for his blood values and
decompensation include intestinal ischemia due to hepatitis C related
vasculitizade xiteesexitat rechemia ade to nepatrets e rera
lactule intestinal ischemia due to concomitant Kayexalate
GI ble
conditions hepatic decompensation with coagulopathy and low
MEDICATIONS ON TRANSFER: As per Power chart, he was transferred on a
Levophed drip as well as a bicarb drip. He had also received a dose of
Flagyl 500 mg in addition to the aforementioned vancomycin 1.5 g and
Zosyn 3.375 q.
----[ Related Clinicians: Docnum#: 3975548 ]------
BURKS, ALLEN C ( DICT )
BURKS, ALLEN C (SIGN 19-MAR-13)
*******
                  End of Dictated Report ************
This document has been read and signed. Please contact the medical
records department for any questions regarding this document.
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1735

Patient Name:	AWAN, DANNIS	M	edical Record No	240925
Assessment/Plan	: 1) amount/complexity of dat	is 2) number of Dx and treatment op	tions 3) risk of complice	Sons
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Hospital's Critical Care Note 3/19/2013

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- VC-diff, peop. panel
USK: Phatodomorphisis, puntarphorphy stating-induced ANA/ mitigo neg.
- CMH all nights
- CAN'T FOR AN REMEMBER MOST
- ? Sala (muscle) ariging & breuse
- mind copic

HP11 (rev. 6/11)

episodic hypotension within the operating room. There was no evidence of SMA thrombosis or embolic disease. Given the patient's significant hematochezia and lactic acidosis, we elected to perform on-table EGTHrospital's Surgeon colonoscopy. The EGD revealed no evidence of esophageal varices or gastric ulceration. The colonoscopy revealed diffuse mucosal level 3/119/2013 ischemia of the transverse colon, splenic flexure, descending colon, 3/119/2013 sigmoid colon.

INDICATION FOR SURGERY: Dennis Allen is a 63-year-old male with a past medical history of chronic kidney disease with new-onset hemodialysis, hepatitis C cirrhosis, osteoarthritis, congestive heart failure, and gastroesophageal reflux disease, who presented to an outside hospital on March 10th with weakness and elevated CK and myoglobin. The patient was transferred to the University of Maryland Medical Center for further workup due to his proximal muscle weakness and myositis. The patient had been in his usual state of health when he developed the acute onset of abdominal pain overnight and early this

have significant abdominal pain with associated hypotension and pressor requirements. Given the constellation of symptomatology, we were concerned for mesenteric ischemia or ischemic colitis. The Medical Intensive Care Unit Team had pointed out that the patient had received Kayexalate the night before, and there were several case reports of

that exploratory laparotomy was warranted. Risks, benefits, and alternatives were discussed with the patient's family, and appropriate consent was obtained.

The patient was transferred to the operating room PROCEDURE: critically ill on multiple vasopressors despite resuscitation. HE placed on the table in the supine position. General anesthesia was administered through his existing endotracheal tube. His abdomen was then prepped and draped in a sterile fashion. A midline incision was made and deepened through the level of the subcutaneous tissue to the level of the fascia. There were multiple abdominal wall varices that were controlled with electrocautery and suture ligation. The fascia was then entered in the midline. The abdominal cavity was entered. There was no significant ascites. We then placed a retractor and immediately evaluated the small bowel. It all appeared viable, and there was a palpable pulse in the SMA. During this evaluation, the patient did develop episodic hypotension to SBP in the 60's with some associated low-flow state of the bowel that improved with improved blood pressure. Externally, the colon appeared normal. There appeared to be some slight evidence of potential ischemia within the transverse colon. As there was no clear evidence of a full-thickness ischemia, we elected to perform on-table esophagogastroducdenoscopy and colonoscopy given the patient's hematochezia and mucosal current jelly-type stools.

University of Maryland Medical System

Hospital's Surgeon 3/19/2013

Patient Name: ALLEN, DENNIS V Medical Record Number: 240925 Account Number: 1002867761 Document Type: OPERATIVE REPORT

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Intensive Care Unit Team had pointed out that the patient had received Kayexalate the night before, and there were several case reports of mucosal level ischemia. Given his overall lability and state, we felt that exploratory laparotomy was warranted. Risks, benefits, and alternatives were discussed with the patient's family, and appropriate consent was obtained.

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Dr. Buchanan performed an esophagogastroduodenoscopy. There was no evidence of gastric ulceration, esophageal varices, or duodenal bulb Reviewed and Electronically Signed Out By: Rupal 1 Mehta, Attending Physician - Pathologist Report Verified 05/17/2013

Hospital's Autopsy 3/22/2013

Discussion

The decedent was a 63-year-old African-American man with a complicated past medical history notable for hepatitis C with cirrhosis (awaiting transplant), chronic kidney disease (stage IV), osteoarthritis, obesity, hypertension, and congestive heart failure. He was recently admitted with rhabdomyolysis and was treated with fluids and hemodialysis for acute renal failure. On 3/18/2013, the patient was noted to be bradycardic with peaked T waves seen on EKG; He was treated with an albuterol nebulizer, insulin, bicarbonate, and Kayexalate. Subsequently, he developed renal failure and lower intestinal bleed. His condition rapidly deteriorated and he developed hypotension resistant to fluids and albumin therapy. On 03/19/2013, colectomy was performed. Shortly thereafter, the patient went into pulseless electrical activity arrest and died at 2:18 pm on 03/20/2013.

residual small intestine, with scattered basophilic crystals, consistent with recent kayexalate use. The findings may be suggestive of kayexalate colitis, which could have exacerbated the patient's underlying medical disease. Additional findings in this case include pulmonary congestion, mild to moderate coronary artery

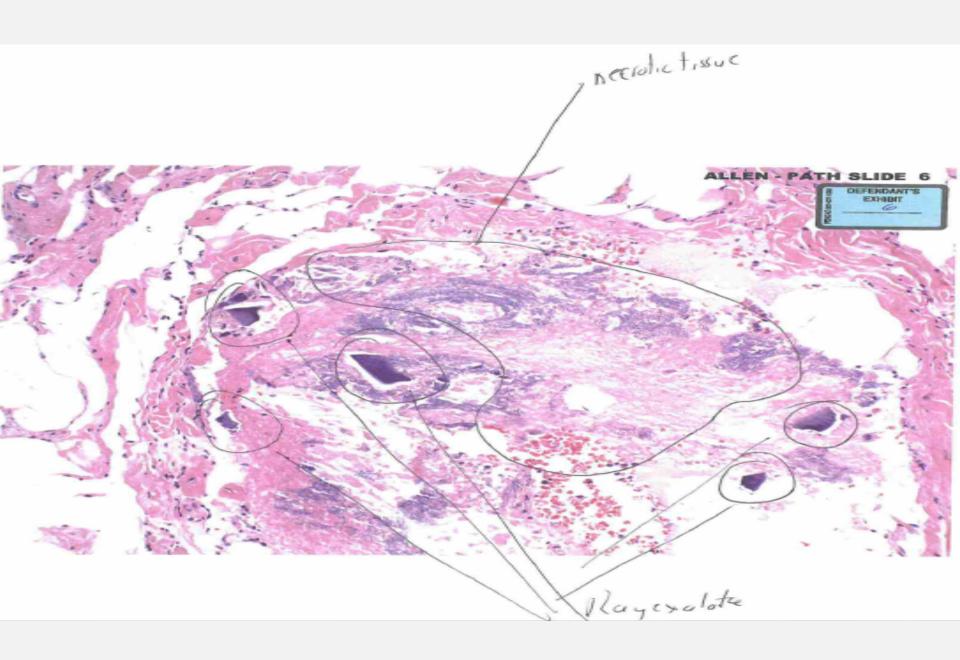
may be suggestive of kayexalate colitis, which could have exacerbated the patient's underlying medical disease. Additional findings in this case include pulmonary congestion, mild to moderate coronary artery disease, mild interstitial fibrosis and myocyte hypertrophy, consistent with hypertensive disease.

Gross Description

An autopsy is performed at the University of Maryland Medical Center, Baltimore, MD on the body of Allen, Dennis on 3/22/2013. The body is identified by toe tag, which corresponds to the name and MRN/DOB on the accompanying chart and autopsy authorization form. An autopsy is authorized by Mrs. Cynthia Allen, the decedent's wife, who is contacted by telephone prior to the start of the autopsy for clarification of autopsy restrictions. Per request, autopsy is restricted to chest and abdomen only, with return of organs to the cavity.

EXTERNAL AND INTEGUMENT:

The deceased is a well-developed, well-nourished African-American man. The body weighs 303 lb; is 180 cm in height, and appears compatible with the stated age of 63 years. The body is cold, and rigor is present and fixed to an equal degree in all extremities. Lividity is present and fixed on the posterior surface of the body, except in areas exposed to pressure. Irides are brown. Each pupil measures 5 mm in diameter. Scleral interrus is present. The teeth are intact. The hair is black/brown. The thorax is symmetrical. A healing abdominal wound is present along the midline abdomen and measures 35 cm in length. The wound shows a partial staple line (intact) and is partially open with packed surgical sponges and overlying wound vac (intact). The adjacent skin



Medical Doctors

• Robert D. Odze, M.D.

Dr. Odze

have seen over the years, 12 to 23 of them, you don't know if Sorbitol was administered with the

- Q So you've said before, you teach about pathologic manifestation of ischemic bowel in association with Kayexalate?
 - A Yes.
- Q Can you explain what you teach about that?
- A I mean, could I explain what the findings are?
- Q Yes. I mean, what would you tell your students, the fellows, or the residents, about how to make the diagnosis of ischemic colitis caused by or in association with Kayexalate; what do you look for specifically; and what evidence --
- A Actually, I would show them this case 'cause it's a classic example.
 - 2 -- what you would see.

Dr. Odze

A Well, that's not exactly what I said, and so let me clarify.

Q Okay.

bowel necrosis and ischemia.

A It is well known amongst physicians and pathologists that Kayexalate, with Sorbitol, causes

bowel necrosis and ischemia. That's well known.

A It is well known amongst physicians and pathologists that Kayexalate, with Sorbitol, causes

is it's related to the hyperosmotic effect of the sorbitol.

worked out and known. I said one of the hypotheses

That's not negating the fact that

Kayexalate causes bowel necrosis. That's just

asking me what is out there with regard to thoughts
on how it does it. And what I also told you is

that I don't know if there's animal studies. There

may be animal studies, but I don't know of any. I

can -- I can certainly find out by doing a

literature search, but as I sit here right now, I

don't know if that's the case.

Q And you've told me you don't plan to do a literature search, and you're not gonna rely on any

Medical Doctors

• Robert D. Odze, M.D.

• Richard Goldstein, M.D.

Dr. Goldstein

standard of care. So he did not die as a result of calcium deficiency, whether in the form of chloride or gluconate.

Q So Mr. Allen did not die as a result of not receiving

Q So can you describe for me the basis for your opinion that Mr. Allen's death was caused by the Kayexalate causing bowel ischemia?

A The Kayexalate led to bowel necrosis which led to
emergency surgery which led to a lot of bleeding because of
his portal hypertension, his liver disease, which resulted
in irreversible shock and his ultimate demise. The
instigating agent, the instigating event was the
administration of the Kayexalate which lead to the ischemic
necrosis of the colon.

- Q So Mr. Allen experienced shock. Was the shock from sepsis, or was it from the bleeding, or do you know?
- A It was probably from a combination of both. This is

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Medical Doctors

• Robert D. Odze, M.D.

• Richard Goldstein, M.D.

• James D. Leo, M.D.

Dr. Leo

Leo, M.D. Cvathia Allen vs. Allen Burks, M.D.

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trier of fact. My opinion will be that the standard of care required that it be ordered and administered.

I will opine that if, in fact, Dr. Burks -well, let me back up. If, in fact, the trier of fact

D. Leo, M.D. Cynthia Allen vs. Allen Burks, M.D.

of the patient's ischemic colitis; and that ischemic colitis was the cause of the patient's death.

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I will be further testifying that Dr. Burks did have a duty to inform Mr. Allen of the potential

I will be testifying that to a reasonable

degree of medical probability Kayexalate was the cause of the patient's ischemic colitis; and that ischemic colitis was the cause of the patient's death.

I will be testifying that the lack of any documentation in the medical record in terms of continued alarming of the cardiac monitor regarding bradycardia suggests that, in fact, the initial treatment rendered to Mr. Allen in the form of glucose insulin, sodium bicarbonate and Albuterol was effective in reversing temporarily the adverse effects of the hyperkalemia, giving adequate time for dialysis to be undertaken.

I will be testifying that to a reasonable degree of medical probability Kayexalate was the cause designation.

Q. So let's get a list of all of your global opinions right now since we started down that road. So under the expert witness designation that you referred to, there's a statement that Dr. Burks breached the applicable standard of care by ordering and administering Kayexalate when dialysis was readily available. That's similar to the opinion you just gave, that there was no reasonable basis to give Kayexalate given the known or thought to be availability of the dialysis?

QUESTIONS WE ANSWERED

- Did the Kayexalate cause Mr. Allen's Intestinal Necrosis? **YES**
- Was Kayexalate urgently needed, or even necessary?

Orders

Order Date/Time 3/18/2013 12:43:04 PM

Mnemonic Insulin Regular (Adult Hyperkalemia Kit) inj 100 units/mL 3 mL	Order Status Completed	
Ordering Physician	Order Placed By	
Burks, Allen C MD	Sarg, Mohamed T, Pharmacist	

Mnemonic

Sodium Polystyrene Sulfonate oral susp udcup 15 gm/60 mL

•	Order Date/Time 3/18/2013	12:37:59 PM		
Mnemonic	:	Order Status	: :	ı
Potassium		Discontinued		l
Ordering Physician		Order Placed B	y	l
		C 1 12 12 12 12 1		L

Order Details

30 gm PO, once, dispense as: oral susp, Do not use if patient has ileus., --Start 03/18/13 12:37:00, Routine priority, --Order ends 03/18/13 12:37:00

Sodium Polystyrene Suffonate oral susp udcup 15 gm/60 mL	Соприска			
Ordering Physician	Order Placed By			
Burks, Allen C MD	Burks, Allen C MD			
Review Information				
Nurse Review, Accepted - Frock, Michele, RN, 3/18/2013 1:42:50 PM				
Pharmacist Verify, Accepted - Sarg, Mohamed T, Pharmacist, 3/18/2013 12:43:05 PM				
Order Details				
an man or described the state of the state o	- 11 Ct+ 02/19/12 12:27:00 Position priority - Order ands			

30 gm PO, once, dispense as: oral susp, Do not use if patient has ileus., -Start 03/18/13 12:37:00, Routine priority, -Order ends 03/18/13 12:37:00

Order Date/Time 3/18/2013 12:37:58 PM

Mnemonic	Order Status
Sedium Bicarbonate inj 50 mEq/50 mL	Completed
Ordering Physician	Order Placed By
Burks, Allen C MD	Burks, Allen C MD
Daries Ve	formation

Review Information

Nurse Review, Accepted - Frock, Michele, RN, 3/18/2013 1:42:50 PM Pharmacist Verify, Accepted - Sarg, Mohamed T, Pharmacist, 3/18/2013 12:43:04 PM

Order Details

50 mEq IV Push, once, Binds Calcium; do not administer with IV Calcium, --Start 03/18/13 12:37:00, STAT priority, --Order ends 03/18/13 12:37:00

UNIVERSITY # MARYLAND	POLICY AND PROCEDURE MANUAL	PAGE: 4 OF 7	POLICY NO: MM-005	
MEDICAL CENTER		EFFECTIVE DATE: 10/78	LAST REVISION DATE: 04/13	
SUBJECT: MEDICATION MANAGEMENT		FUNCTION: MEDICATION MANAGEMENT		

- v. Name of patient
- vi. Date of dispensing
- vii. Expiration date
- viii. Medication name, strength, amount
- ix. Directions for use
- Cautionary statements for handling and storage
- b) The muse compares the discharge prescriptions and orders to the medication label on the multiple-dose product. The nume gives the patient the multiple-dose medications that are ordered to continue after discharge. If there is any discrepancy with the order and the label, the muse does not give the medication to the patient.
- c) Some multiple-dose medications are not eligible for take home. These include, but may not be limited to: controlled substances and medications that require a Risk Evaluation and Mitigation Strategy (REMS) per the FDA. These medications are labeled "Not eligible for take home."
- d) Pharmacist counseling is available upon request. If a patient requests medication counseling by a

7. Priedreadono ordered do 170% are to de administered within two nodro of the time the order to placed.

8. The goal for medications ordered as "Routine" (not ordered as "STAT") is to be administered at the next standard administration time unless otherwise indicated on the order. The dose will be available in the patient care area within two hours of the order being received by the pharmacy.

Orders are scheduled using the Standard Administration Times and/or the Medication Specific Schedule. Then

- 5. The goal for medications ordered as "Routine" (not ordered as "STAT") is to be administered at the next standard administration time unless otherwise indicated on the order. The dose will be available in the patient care area within two hours of the order being received by the pharmacy.
- Orders are scheduled using the Standard Administration Times and/or the Medication Specific Schedule. There
 are medications that are administered with set, specific administration times secondary to drug efficacy and/or
 interactions (See Attachment D and Attachment E, and refer to COP-003 Patient Care Orders in the hospital
 policy and procedure manual for more information).
- The following "Time Critical" scheduled medications must be administered within 30 minutes before or after the scheduled administration time.
 - Rapid, short, and ultra short acting insulins
 - b) Oral hypoglycemics
- Scheduled analysis (opioids and non-opioids with the exception of topical and transformal products)
- 11. "Non-Time Critical" scheduled medications are administered as follows:
 - a) Daily, weekly, or monthly medications are administered two hours before or after the scheduled administration from
 - b) Medications that are administered more frequently than daily, but no more frequently than every four hours are administered within one hour before or after the scheduled administration time.
- 12. One time doses are administered within two hours of the order.
- 13. On-call doses are administered within 60 minutes of identification of indicated need.
- As needed or PRN medications are administered within 60 minutes of identification of indicated need.
- Two licensed health care professionals perform an independent double-check for the following medications:

WAS KAYEXALATE EVEN NECESSARY

- Heart condition was under control
- No immediate effect on potassium levels

Hospital Hyperkalemia Guidelines

		· · · ·			
Agent	Mechanism	Onset of Action	Duration of Action	Comments	Major Complications
Calcium: Calcium gluconate OR Calcium chloride	Stabilizes cardiac membrane	2 – 3 mins	30 – 60 mins	Requires administration of other agents to shift Potassium into cells and remove Potassium	
'	' '	'	'	Potassisii iii reikii ranore patients	'
Sodium polystyrene sulfonate (Kayexalate)	Increase potassium excretion	≥2 <u>hrs.</u>	4 – 6 <u>hrs</u>	Should not be used in patients with evidence of bowel obstruction, ileus or ischemia or to renal transplant patients in the early post operative stage	Intestinal Necrosis and Bowel Perforation
Hemodialysis	potassium from the body			Potassium It can lower Serum Potassium by 1 mEq/L in the first hr and another 1 mEq/L over the second hr Gold standard in eliminating potassium in renal failure patients	
Sodium polystyrene sulfonate (Kayexalate)	Increase potassium excretion	≥2 hrs	4 – 6 hrs	Should not be used in patients with evidence of bowel obstruction, ileus or ischemia or to renal transplant patients in the early post operative stage	Intestinal Necrosis and Bowel Perforation

WAS KAYEXALATE EVEN NECESSARY

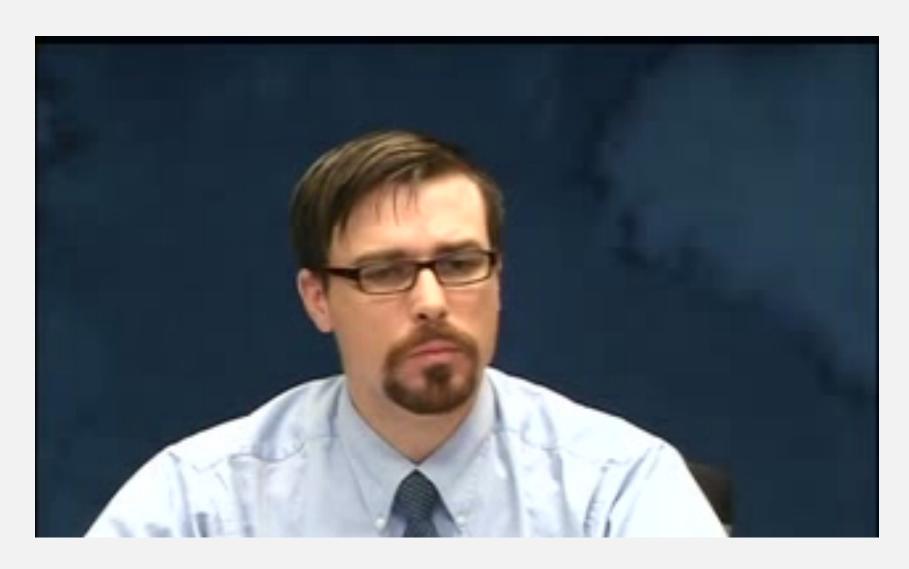
- Heart condition was under control
- No immediate effect on potassium levels
- Kidneys were already weak At risk/FDA
- Dialysis was on the way
- Dialysis works immediately without harm

NO NEED FOR KAYEXALATE ONLY GIVEN AS A LAST RESORT

QUESTIONS WE ANSWERED

- Did the Kayexalate cause Mr. Allen's Intestinal Necrosis? **YES**
- Was Kayexalate urgently needed, or even necessary? NO
- Was Mr. Allen going to die anyway?

"Before March 19th he did not have an indication for a critical care physician" – Page 28, Lines 16-28



- Q (By Mr. Gaston) Well, were you Mr. Allen's
 attending physician?
 A Yes, sir.
 Q Did you serve the role as his critical care
 physician?
 A No, sir.
- A Before March 19th he did not have an

indication for a critical care physician.

- 14 believe it was on March 19th --
- 15 Q We're talking about before March 19th.
- 16 A Before March 19th he did not have an
- 17 indication for a critical care physician.
- 18 0 So --
- 19 A Therefore, no.
- 20 Q Would it be fair to say that the person who
- 21 was in charge for managing his overall condition and
- 22 course of treatment from the time you first saw him up
- 23 until March 19th would be you?
- MR. SHAW: Objection. He's already talked
- 25 about the times that he was working or not working.

Dr. Robert Odze, M.D. - Pathologist

So how and what actually happened in this patient, I couldn't tell you. I don't think

Q You can't rule out that other comorbidities in Mr. Allen's case contributed to his death, including his -- his cirrhosis of the liver and his stage four kidney disease, his --

A Well, they did not cause the death --

Q -- hypotension --

THE STENOGRAPHER: Wait.

Q I'm sorry.

A But they did not cause the death of this patient at that time on that day. What caused the death of this patient on that time on that day was ischemic colitis secondary to Kayexalate.

Q Have you looked at his lab studies from

March 18, March 19, March 20?

A No.

Q Have you looked at his clinical course

Odze Depo – Pg. 61

QUESTIONS WE ANSWERED

- Did the Kayexalate cause Mr. Allen's Intestinal Necrosis? YES
- Was Kayexalate urgently needed, or even necessary? NO
- Was Mr. Allen going to die anyway? NO

DENNIS ALLEN

Pain, Suffering, and Mental Anguish

- March 18, 2013 through March 20, 2013:
 - Intestinal bleeding and bloody stools
 - o 10 bowel movements in 14 hours
 - Abdominal pain crying out in pain
 - o Rectal tube
 - Death of his colon
 - o Transferred to ICU
 - First pain medication March 19th 2:00pm

"Get me out of here,"
"They are trying to kill me"

