

Dosing Approaches to Optimize Cost-Effective Care of Patients

A presentation for HealthTrust Members
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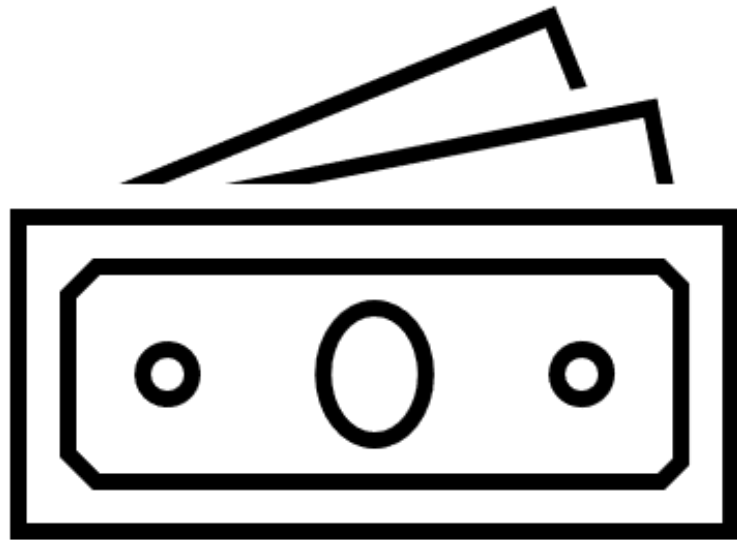
Objectives

Pharmacists & Nurses

- Identify a fixed-dose, cost-effective strategy for 4F-PCC
- Compare and contrast costs of different dosing strategies for IVIG
- Describe strategies to reduce costs associated with therapeutic drug monitoring for vancomycin

Technician

- State the indications for 4F-PCC, IVIG, & vancomycin
- Outline healthcare facility policy recommendations to reduce costs associated with 4F-PCC, IVIG, and vancomycin
- Identify appropriate preparation & handling of 4F-PCC, IVIG, & vancomycin to ensure cost minimization



Background

Medication costs make up a majority of pharmacy budgets & continue to grow faster than any other healthcare expenditure

Four primary factors that drive growth in drug expenditure:

Price → increase in the unit price of existing drug


Utilization → increased users, days of therapy, or doses per day of therapy

Mix → newer, expensive drugs take the place of older, equally effective drugs

Innovation → new drugs available to treat conditions previously untreatable

Background (cont.)

- Why do we need to control healthcare costs, including drug costs?
 - Allow limited healthcare resources to be used equitably & judiciously
 - Play a role in determining the nation's long-term fiscal condition
- Dosing strategies that lead to similar clinical outcomes can lead to cost-savings & proper resource allocation
 - Decreased inventory turnover
 - Lower backorder occurrences
- Previous examples that have led to decreased drug expenditure
 - Decreased duration of antibiotics in infections (e.g. pneumonia)
 - IV to PO conversions
 - Discontinuation of drugs without indication (e.g. PPI & probiotic use)



4-Factor Prothrombin Complex Concentrate (4F-PCC)

4F-PCC

- Hemostatic agent indicated for vitamin K antagonist (warfarin) reversal in life-threatening bleeds
 - Off-label use for non-vitamin K antagonist (e.g. DOACs) reversal
- Contains factors II, VII, IX, X, protein C, protein S, heparin, and albumin
- No dose adjustments for renal/hepatic impairment
- Contraindications: hypersensitivity, disseminated intravascular coagulation (DIC), and heparin-induced thrombocytopenia (HIT)

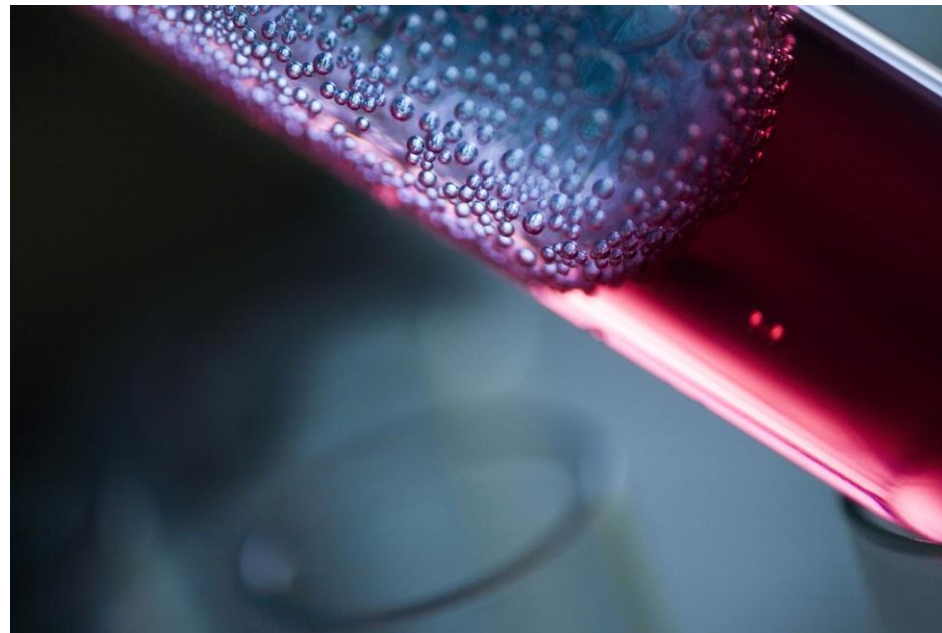


4F-PCC (cont.)

- Warning: fatal and nonfatal arterial/venous thromboembolic complications
- Monitoring: INR (baseline and 30 minutes after dose), clinical response after treatment, and signs of thromboembolism
- Pharmacodynamics/kinetics
 - Onset of action → rapid; significant decline in INR within 10 minutes
 - Duration → 6-8 hours
 - Half-life elimination → differs per the different components; protein C (1.5-6 hours) being the shortest and factor II (48-60 hours) being the longest
- Cost (AWP): \$3.14 per unit (e.g. 5000 units = \$15,700)

SBMC Policy

- Agent is restricted for use and must meet restriction criteria
 - Urgent reversal of warfarin therapy in patients with acute major bleeding
 - Acute major bleeding/life-threatening hemorrhage associated with non-vitamin K antagonist anticoagulation
 - Restricted to critical care units, emergency department, hematology attending physicians, cardiology attending physicians, and/or respective direct designee
- Should be ordered with vitamin K IV for warfarin-related major bleeds



Product & Preparation

- Available product
 - Intravenous kit (preservative-free): ~500 units
- Store at 2-25°C (do not freeze) & protect from light
- Follow manufacturer's directions for reconstitution/preparation
- Reconstituted product may be stored at 2-25°C & be used within 4 hours
- Label bag with total dose; dose is based on units of factor IX
- Dose is given as an IV infusion at 0.12 mL/kg/min (~3 units/kg/min); not to exceed 8.4 mL/min (~210 units/min)
- Do not allow blood to enter syringe due to fibrin clot formation



Dosing

- Acute major bleeding during vitamin K antagonist therapy

Pretreatment INR	Dose
2 to <4	25 units/kg (max = 2500 units)
4 to 6	35 units/kg (max = 3500 units)
>6	50 units/kg (max = 5000 units)

- Non-vitamin K antagonists
 - 50 units/kg
- **Fixed dosing (vitamin K antagonist)**
 - **1000 units for any major bleed or 1500 units for an intracerebral hemorrhage (ICH)**
- Dose is rounded to the nearest vial size to avoid unnecessary waste

Efficacy Trial #1

- Design
 - Retrospective, single-center cohort study
 - Inclusion criteria: ≥ 18 years, received 4F-PCC for warfarin associated acute major bleeding reversal, & pre-4F-PCC infusion INR > 2
 - 60 patients requiring urgent warfarin reversal (30 patients/group)
- Groups
 - Fixed dosing \rightarrow 1500 units for ICH or 1000 units if another bleed type
 - Package insert dosing \rightarrow based on weight and pre-treatment INR
- Demographics
 - No significant differences in baseline characteristics (e.g. median initial INR, indication, & vitamin K use)
 - Age \rightarrow high 70s
 - Main indication was ICH; others included GI bleed & emergent surgery

Efficacy Trial #1 (cont.)

- Results (package insert dose vs fixed dose)
 - No differences in post-treatment INR
 - INR <1.6: 90% vs. 86.7% (p=0.68)
 - INR <1.4: 73.3% vs. 50% (p=0.06)
 - Median INR (IQR): 1.3 (1.1-1.9) vs. 1.35 (0.9-2.1) (p=0.16)
 - Mortality: 26.7% vs. 13.3% (p=0.19)
 - **In patients with intracranial hemorrhage: 45.5% vs. 9.1% (p=0.02)**
 - No difference in thrombotic events at 7 days post-infusion: 0% vs. 3.3% (p=1)
- PCC dose utilized
 - **Dose lower in fixed dose group (median [IQR]): 1521 (980-2099) vs. 2551 (1620-5210) units (p=0.004)**
 - Expected mean cost savings of \$3140 for difference of 1000 units

Efficacy Trial #2

- Design
 - Multicenter, noninferiority, interventional, quasi-experimental cohort study
 - Patients >18 years of age & administered 4F-PCC for rapid reversal of warfarin for severe bleeding or emergent invasive surgery/procedure
 - 24 subjects in the prospective cohort & 30 in the retrospective cohort
- Groups
 - Retrospective cohort → weight-based dose dependent on INR
 - Prospective cohort → fixed-dose of 1500 units (2000 units if >100 kg or INR >7.5)
- Demographics
 - No significant differences in baseline characteristics except in baseline INR (higher in fixed-dose) & bleeding type (more ICH in weight-based dose)
- Results
 - Primary outcome: post-infusion INR <2 was achieved in 96% (retrospective cohort) vs. 95% (prospective cohort) [p = 0.0035]
 - Secondary outcomes: post-infusion INR <1.5 in 90% (retrospective cohort) vs. 75% (prospective cohort) [p > 0.4]; no significant differences in 24-h post-infusion INRs, mortality, or venous thromboembolic events

Cost Trial

- Design
 - Retrospective, single-center study
 - Patients who received 4F-PCC for warfarin reversal using a fixed-dose protocol
 - 65 patients on warfarin were evaluated for this study
- Results
 - Total amount of 4F-PCC used during study was 102,883 units vs 140,031 units that would have been used with standard weight-/INR-based dosing
 - Institutional cost savings from the fixed-dose protocol implementation during the study period, based on average wholesale price, was \$107,729
 - This means the center saved, on average, \$1,657 per patient on 4F-PCC

Recommendation & Question 1 (Pharmacist/Nurse)

Recommendation

The use of a fixed-dose 4F-PCC protocol is safe and effective for the rapid reversal of VKA-associated anticoagulation and it comes with potential cost savings, which make it preferable to weight-/INR-based dosing

A patient with a life-threatening bleed (intracranial hemorrhage) comes into the ED. Provider wants to start 4F-PCC and calls pharmacy for recommendation. The patient is 120 kg and has an INR value of 4.1. What are the appropriate fixed dose or package-insert dose, respectively, that can be recommended?

- A) 1000 units OR 3500 units
- B) 1000 units OR 4200 units
- C) 1500 units OR 3000 units
- D) 1500 units OR 3500 units
- E) 1500 units OR 4200 units



Recommendation & Question 1

– Correct Response

Recommendation

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- B) 1000 units OR 4200 units
- C) 1500 units OR 3000 units
- D) 1500 units OR 3500 units**
- E) 1500 units OR 4200 units





Intravenous Immunoglobulin (IVIg)



IVIG

- Gamunex-C & Gammagard available at SBMC
- Indications
 - B-cell chronic lymphocytic leukemia
 - Chronic inflammatory demyelinating polyneuropathy
 - Immune thrombocytopenia
 - Measles
 - Multifocal motor neuropathy
 - Primary humoral immunodeficiency disorders
- Transplant-specific: treatment of antibody-mediated rejection & induction therapy for positive match/positive donor specific antibodies
- Other off-label uses (e.g. Guillain-Barre syndrome & myasthenia gravis)

IVIIG (cont.)

- Renal impairment
 - Use with caution due to risk of immune globulin-induced renal dysfunction
 - Rate of infusion and concentration of solution should be minimized
 - Discontinue if renal function deteriorates during treatment
- No dose adjustment for hepatic impairment
- Contraindications: hypersensitivity

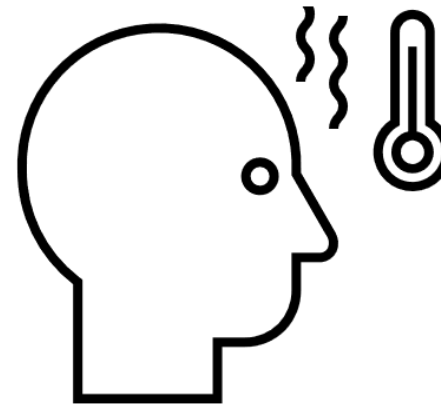


IVIg (cont.)

- Warnings: thrombosis, renal dysfunction, & acute renal failure
- Monitoring: renal function, signs of thrombosis, infusion reactions, & signs of hemolysis
 - High risk of hemolysis → monitor hemoglobin/hematocrit
- Pharmacodynamics/kinetics
 - Onset of action → provides immediate antibody levels
 - Duration → 3-4 weeks
 - Half-life elimination → 14-24 days
- Cost (AWP)
 - Gammagard = \$17.13 per mL (e.g. 10 g = 100 mL = \$1,713)
 - Gamunex-C = \$14.66 per mL (e.g. 10 g = 100 mL = \$1,466)

SBMC Policy

- Adverse reactions may occur within 30-60 minutes (flushing, chest tightness, fever, & chills)
 - Stop infusion & consult physician
- Pre-medications include acetaminophen & diphenhydramine; methylprednisolone used for indications that require high doses
- Monitor for hypersensitivity; monitor initially, then every half hour for 2 hours, then every 2 hours until end of the infusion
- Pediatric patients must be monitored per pediatric IVIG physician orders
- Can be administered by all registered nurses



Other Information

- Dose
 - Usually 100-400 mg/kg/dose (order expressed in grams, not mL)
 - **Mainly dosed using total body weight (TBW), but ideal (IBW) & adjusted body weights (AdjBW) are sometimes used in obese patients**
 - Doses for transplant can be up to 2000 mg/kg for a single dose
 - Doses are usually rounded to the nearest 5 g to reduce waste
- Rate
 - Initial rate → 0.5 mL/kg/hr
 - Maximum rate → 5 mL/kg/hr
 - Risk for renal dysfunction or thrombotic complications → <2 mL/kg/hr
- Prepared as a standard 10% solution
 - Gammagard: 10 g/100 mL, 20 g/200 mL, & 30 g/300 mL
 - Gamunex-C: 10 g/100 mL & 20 g/200 mL

Body Weight Calculations

TBW → actual body weight (kg)

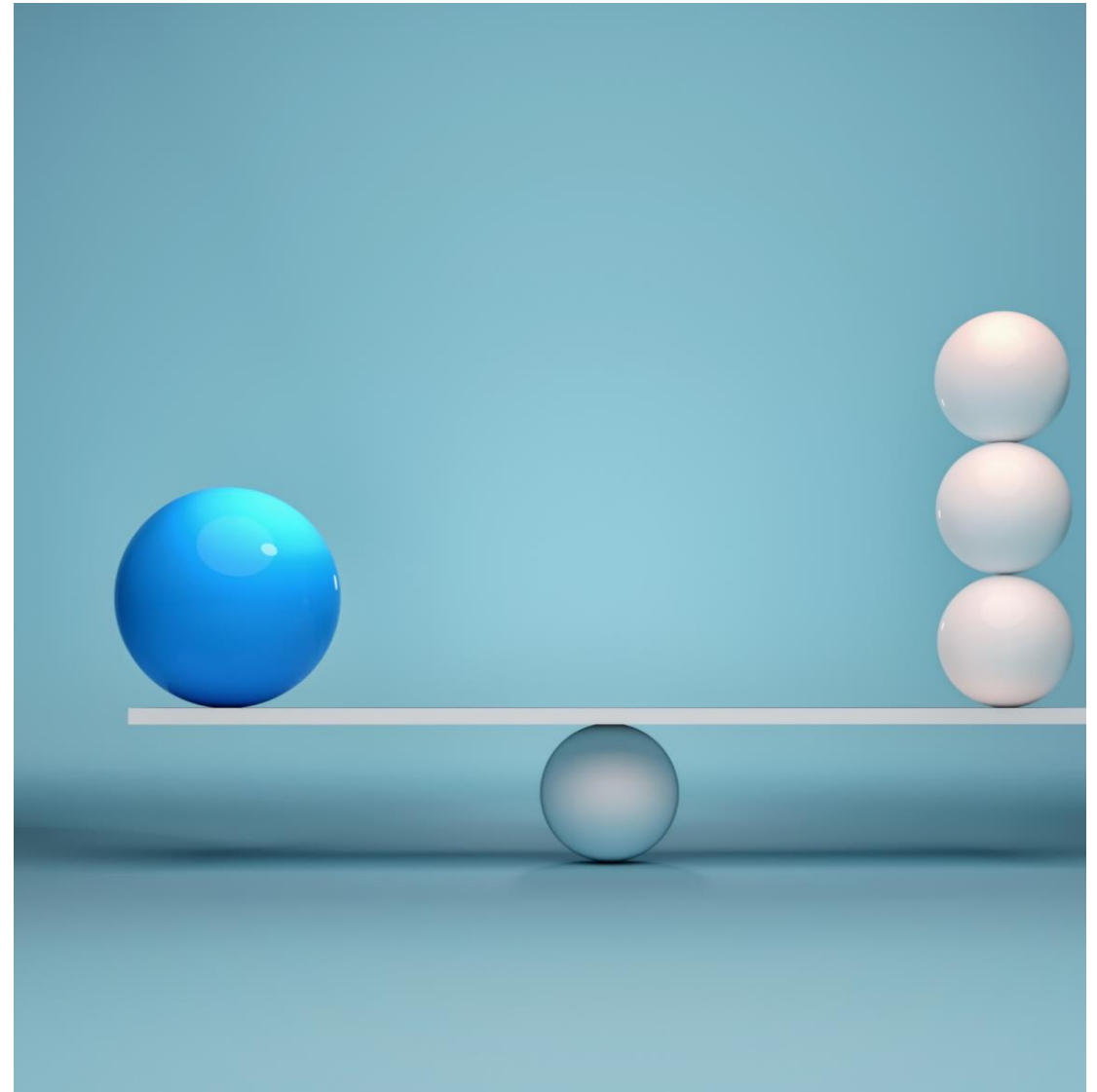
IBW

Males: $IBW (kg) = 50 + 2.3 (\text{inches over } 5 \text{ feet})$

Females: $IBW (kg) = 45.5 + 2.3 (\text{inches over } 5 \text{ feet})$

AdjBW → used in obese patients

$AdjBW (kg) = IBW + 0.4 (TBW - IBW)$



Efficacy Trial

- Design
 - Retrospective cohort study at an academic medical center
 - 209 IVIG encounters; 125 (traditional-dosing) & 84 (precision-dosing)
- Groups
 - Traditional-dosing → dosed using TBW
 - Precision-dosing → dosed using IBW or AdjBW, TBW if less than IBW, or TBW equaled IBW
- Results (traditional vs precision)
 - Primary outcome → infection rate within 30 days of IVIG administration
 - 16% vs 15.5%, $p=0.823$
 - Secondary outcomes → 60-day infection rate, immunoglobulin G (IgG)-level response (IgG >400 mg/dL), & realized/potential IVIG savings
 - 60-day infection rate → 19.8% vs 23.2%, $p=0.568$
 - IgG levels obtained after IVIG showed a response rate of 86% in both groups
 - Precision-dosing achieved \$2600/month in savings; potential for additional \$4600/month in savings with complete adherence

Cost Trial

- Design
 - Single-center retrospective review of IVIG use in a cancer center
 - Total of 2564 patients & 9918 IVIG doses included over 5 years
 - Did not evaluate potential clinical significance of doses
- Groups
 - Method 1 → AdjBW if TBW >1.2x IBW
 - Method 2 → AdjBW for all patients
 - Method 3 → IBW for all patients
 - Traditional → TBW for all patients
- Demographics
 - About 60% of the patients were male with a mean age of ~56 years
 - Main indications for use were for stem cell transplant & leukemia

Cost Trial (cont.)

Outcome	Traditional (TBW)	Method 1 (AdjBW if TBW >1.2x IBW)	Method 2 (AdjBW)	Method 3 (IBW)
Total IVIG use (g/yr)	75,994	59,336	57,623	48,742
Use averted (g/yr)	-	16,658	18,371	27,252
% reduction	-	21.9	24.2	35.9
Annual cost averted (\$/yr)	-	2,373,617	2,618,332	3,889,355
Average dose (g)	38	30	29	25
Average infusion time (hr/dose)	3.8	3	2.9	2.5
Average outpatient infusion time saved (hr/yr)	-	841	920	1,366
Infusion time saved (min/patient)	-	48	54	78

Recommendation & Question 2 (Pharmacist/Nurse)

Recommendation

Using IBW or AdjBW to dose IVIG can decrease the amount of IVIG required per dose, which has associated cost savings, when compared to dosing IVIG via TBW and the dosing methods show similar efficacy, but further studies are required to assess clinical utility

Patient is to receive IVIG for leukemia and the provider wants to give the least amount possible as they are very conscious of rising healthcare costs. Provider wants to know what weight to use for a male patient who is 70 kg and 5'5" to minimize dose & cost (100 mg/kg)?

- A) actual body weight
- B) total body weight
- C) adjusted body weight
- D) ideal body weight



Recommendation & Question 2 – Correct Response

Recommendation

Using IBW or AdjBW to dose IVIG can decrease the amount of IVIG required per dose, which has associated cost savings, when compared to dosing IVIG via TBW and the dosing methods show similar efficacy, but further studies are required to assess clinical utility

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- A) actual body weight
- B) total body weight
- C) adjusted body weight
- D) ideal body weight**





Vancomycin



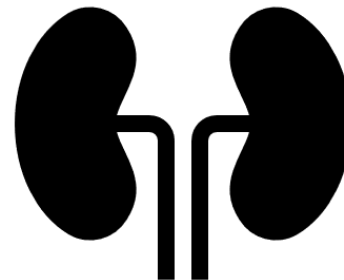
Vancomycin

- Antibiotic used to treat infections caused by Gram-positive organisms, including methicillin-resistant *Staphylococcus aureus* (MRSA)
 - Inhibits bacterial cell wall synthesis by blocking glycopeptide polymerization
- Loading doses are used in the critically ill and/or in obese patients
- No dose adjustment for hepatic impairment
- Renal impairment

CrCl (mL/min)	Loading dose	Maintenance dose	Dosing interval
91-130	25-30 mg/kg	15-20 mg/kg	8-12 hours
50-90	20-25 mg/kg	15-20 mg/kg	12 hours
15-49	20-25 mg/kg	10-15 mg/kg	24 hours
<15	20-25 mg/kg	10-15 mg/kg	48-72 hours

Vancomycin (cont.)

- Contraindication: hypersensitivity
- Warnings: extravasation, **red-man syndrome**, **nephrotoxicity**, neutropenia, ototoxicity, & superinfection
- Monitoring: renal function, CBC, & serum trough concentrations
- Pharmacokinetics/dynamics
 - Distribution → widely distributes in body tissues/fluids (except CSF)
 - Protein binding → ~55%
 - Metabolism → no apparent metabolism
 - Half-life → 4-6 hours; prolonged with renal impairment
 - Excretion → primarily through the kidneys; 75% unchanged in urine
- Cost (AWP): \$0.18 per mL (e.g. 1000 mg = 200 mL = \$36)



SBMC Policy & Other Information

- Dosing (maximum 2 g/dose for adults)
 - Usual → 2-3 g/day in 2-3 divided doses (20-45 mg/kg/day)
 - Bacteremia, endocarditis, meningitis, osteomyelitis, or pneumonia → 15-20 mg/kg every 8-12 hours
 - Cellulitis or skin/soft tissue infections → 15 mg/kg every 12 hours
- Rate (important to reduce incidence of red-man syndrome)
 - Administer each gram over 1 hour
- Adult doses may be rounded to the nearest 250 mg; standard concentrations are present in IV medication manual
- Rotate injection site every 2-3 days to avoid extravasation

Therapeutic Drug Monitoring (TDM)

- Traditional monitoring
 - Trough levels prior to the 4th dose
 - Severe infections → 15-20 mg/L
 - Non-severe infections → 10-15 mg/L
- Updated vancomycin guidelines
 - Focus is reaching an AUC target versus reaching a trough level target
 - Dose calculated using Bayesian methods (trough levels & renal function)
 - AUC target → 400-600 mg*hr/L
 - Calculated based on earlier trough levels (24-48 hours)
- Benefits
 - Lower risk of nephrotoxicity
 - Individualized dosing
 - Potential cost savings



Efficacy Trial

- Design
 - Observational cohort study of Bayesian-guided vancomycin dosing (via DoseMe-Rx) in vascular surgery patients over 9 months
- Groups
 - Bayesian-guided dosed group → prospectively done
 - Dosed using standard algorithmic approach → retrospective control
- Demographics
 - 139 patients (control) & 104 patients (DoseMe-Rx)
 - ~80% of patients were elderly men; main indication was diabetic foot infection
- Results
 - Significantly higher proportion of DoseMe-Rx patients achieved mean AUC₂₄ values in the acceptable range; 71/104 (68.3%) vs 58/139 (41.7%), $p < 0.005$
 - Median percentage time in acceptable range was greater in DoseMe-Rx patients; 57.1 vs 30%, $p < 0.00001$
 - No difference was observed in incidence of AKI, amputation rates, & mortality

Cost Trial

- Objective
 - Compared therapeutic range attainment across 5 hospitals using trough-based dosing vs. 5 hospitals using Bayesian-supported AUC₂₄ dosing
- Methods
 - Data available from 5 hospitals across the United States, EU, & Australia that used a trough-based dosing method (375 adult patients, 13,024 doses, 4,654 drug levels) & from 5 hospitals that implemented Bayesian-based AUC₂₄ dosing (370 patients, 13,080 doses, 3,520 drug levels) using commercially available software (DoseMeRx)
 - Proportion of doses in the therapeutic target range was determined for each hospital, and the number & cost of therapeutic drug monitoring (TDM) levels required were compared

Cost Trial (cont.)

- Results
 - In the trough-based dosing hospitals, 49.1% of doses achieved the therapeutic target of 10–20 mg/L with significant variance per-hospital in the proportion of sub-/supra-therapeutic doses (range 11–35% & 14–41% respectively)
 - Hospitals that implemented Bayesian-based AUC₂₄ dosing successfully attained the target AUC₂₄ (400–700 mg*hr/L) for 73.5% of doses
 - Number of TDM levels used for trough-based dosing was 1 per 1.34 days compared with 1 per 2.14 days in the AUC₂₄ group (37.4% fewer levels)
 - Bayesian-based AUC₂₄ dosing hospitals avoided increased TDM costs & had decreased cost relative to the trough-based group
 - At \$35 per level, for a 500-bed hospital, this equals to savings of \$60,305/year

Recommendation & Question 3 (Pharmacist/Nurse)

Recommendation

The use of AUC-based dosing for vancomycin rather than trough level-based dosing will lead to more individualized treatment, less nephrotoxicity, potential less treatment failure, and potential cost savings via lower doses and less frequent blood draws

After inputting the trough levels and serum creatinine values into DoseMe-Rx for a patient on vancomycin, a predicted AUC value appears on the screen. Which one of the following AUC values would indicate that we are effectively treating a patient (e.g. avoiding undertreatment & nephrotoxicity) & reducing costs?

- A) 300
- B) 380
- C) 460
- D) 615
- E) 640



Recommendation & Question 3 – Correct Response

Recommendation

The use of AUC-based dosing for vancomycin rather than trough level-based dosing will lead to more individualized treatment, less nephrotoxicity, potential less treatment failure, and potential cost savings via lower doses and less frequent blood draws

After inputting the trough levels and serum creatinine values into DoseMe-Rx for a patient on vancomycin, a predicted AUC value appears on the screen. Which one of the following AUC values would indicate that we are effectively treating a patient (e.g. avoiding undertreatment & nephrotoxicity) & reducing costs?

- A) 300
- B) 380
- C) 460**
- D) 615
- E) 640



Conclusion

- It is important for all healthcare professionals to understand all the impacts of medication usage: efficacy, safety, and cost
- 4F-PCC, IVIG, and vancomycin all have dosing strategies that achieve either similar clinical outcomes and/or are safer for our patients, all while reducing costs for both health-systems and patients
- Pharmacists and pharmacy technicians are the main drug information resources in the hospital, who can assist other providers when they want to use one of with these novel dosing strategies
- With more of these strategies being researched, they can potentially be implemented as policies in different health-systems

Question 4 (Technician)

What type of infections are treated by vancomycin?

- A) Fungal
- B) Bacterial
- C) Viral
- D) Protozoal



Question 4 – Correct Response

What type of infections are treated by vancomycin?

- A) Fungal
- B) Bacterial**
- C) Viral
- D) Protozoal



Question 5 (Technician)

Which medication requires pre-medication to avoid infusion reactions

- A) 4-Factor prothrombin complex concentrate
- B) IV immune globulin
- C) Vancomycin



Question 5 – Correct Response

Which medication requires pre-medication to avoid infusion reactions

- A) 4-Factor prothrombin complex concentrate
- B) IV immune globulin**
- C) Vancomycin



Question 6 (Technician)

Which of the following are correct ways to handle/prepare $^4\text{F-PCC}$?

- A) Do not freeze
- B) Protect from light
- C) Use within 12 hours
- D) A & B
- E) All of the above



Question 6 – Correct Response

Which of the following are correct ways to handle/prepare 4F-PCC?

- A) Do not freeze
- B) Protect from light
- C) Use within 12 hours
- D) A & B**
- E) All of the above



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Thank you!

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