University HOSPITAL Newark, NJ

Pharmacy News

Fourth Quarter 2022
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Special Points of Interest:

- New and Revised Requirements for Antibiotic Stewardship
- University Hospital Pharmacy and Therapeutics (P&T) Committee Artesunate Medication Use Evaluation (MUE)
- Discharge Anti-Infective Utilization in Patient with Listed Diagnoses of "Cellulitis", "UTI", and"Pyelonephritis"
- Biosimilars: The Biologics Price Competition and Innovation Act (BPCI Act)
- National Pharmacy Week
- Welcome New Pharmacy Technician

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P&T Update

Formulary Additions

1. *Lutetium Lu 177 Vipivotide Tetraxetan - Pluvicto®*
   Temporary approval with restrictions
   Use to be reviewed in 1 year – Approved

2. *Faricimab - Vabysmo®*
   Faricimab has longer durability compared to other intravitreal injection (ranibizumab and aflibercept). This would result in less injections needed (q12-16 weeks compared to q4-6 weeks). In addition, the mechanism of action differs slightly from ranibizumab and aflibercept – having both VEGF and angiopoetin inhibition. In addition, ranibizumab and aflibercept carry the indication for retinal vein occlusion, which faricimab does not have. In the future, if faricimab gets approval for RBO, can consider removal of ranibizimab. Motion to approve and revisit in a year

Formulary Deletions

N/A

Formulary Line Extensions

N/A

Policies and Procedures/Floorstocks

700-500-118 Titration
Update on having guidance on pausing and restarting of the titration drips. The policy update is highlighted, already approved at the combined critical care committee – Revisions Approved

707-400-103 Samples Policy
Updates are made to comply with the explicit TJC standards for samples as identified while performing the FSA. The updates are highlighted and other disciplines communicated such as the PCS for having a mechanism in place for first dose monitoring. – Revisions Approved

707-500-115 Standard Concentrations for IV Infusion Medications
Drips policy updates streamline procainamide to one strength. Remove theophylline drip, have aminophylline drip – both rare use. Specified neonatal standard concentrations for various drips to also facilitate syringe pump programming. – Revisions Approved

707-700-105A IV Medication Administration
Update to ketamine administration restriction, PCC-4, alteplase, tenectaplase can be administered in any setting but post dose monitoring to be in critical care setting.
– Revisions Approved

Naloxone Rescue Kit Policy
Update to the naloxone policy to comply with NJ Law to include sterile syringe exchange program and opioid use disorder information. Housewide roll out to follow after decision by inpatient services- Revisions Approved

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P&T Update

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707-900-102 ASP Policy
Update policy to define ambulatory care ASP. Defines difference in roles in inpatient and outpatient settings - Revisions Approved

707-500-121 Vincristine Policy
Policy updated to prevent inadvertent administration of medication intrathecally. To prevent accidental intrathecal administration, all IV infusions of vinca alkaloids to be administered via IV mini-bag -Revisions Approved

707-600-177 Hazardous Medication - Receiving and Handling
Update policy to further define PPE and cleaning requirements. List of hazardous medications updated - Revisions Approved

University Hospital Hazardous Drug List 2022
List of hazardous medications updated; it is a USP 800 requirement for the list to be updated yearly. The updated list include medications that were added to the hospital formulary last year, as well as newly approved medications being used in the cancer center that are not part of the NIOSH 2016 list - Revisions Approved

Medication Sample Addition Request

N/A

Medication/Clinical Guidelines and DUE/MUE

Pain management opioid stewardship committee
Methadone guidelines approved and naloxone medication usage evaluation presented.

ED Pediatric Empiric Antibiotic Guideline approved

Cefpodoxime MUE reviewed after 6 months of use– most common indication was for UTI. Level of use deemed appropriate and recommend to continue to keep on formulary, unrestricted to all services

Audit of compliance with ht/wt allergy prior to chemotherapy. Outpatient had no fall outs, but inpatient some fall outs. Reemphasized with inpatient staff that information needs to entered within 24 hours.

Updated policy on intrathecal chemotherapy
OB/GYN audited chart for missing pregnancy urine test prior to administration of chemotherapy, no positive pregnancy. Will include verbiage in consent that patient was counseled to avoid pregnancy

New and Revised Requirements for Antibiotic Stewardship

Effective January 1, 2023, new and revised antibiotic stewardship requirements will apply to all Joint Commission–accredited hospitals and critical access hospitals. The 12 elements of performance (EPs) are included in the "Medication Management" (MM) chapter (Standard MM.09.01.01) and expand upon the current expectations for antibiotic stewardship programs in the hospital setting.

According to the Centers for Disease Control and Prevention, there are at least 2.8 million antibiotic-resistant infections each year, and more than 35,000 people die as a result. When Clostridioides difficile (a bacterium that can cause deadly diarrhea and is associated with antibiotic use) is included in the analysis, there are more than 3 million infections and 48,000 deaths.[1] Optimizing the use of antibiotics is a patient safety priority, and antibiotic stewardship programs play a critical role in supporting appropriate antibiotic prescribing practices and reducing antibiotic resistance. As a result, The Joint Commission made several revisions to Standard MM.09.01.01, which include updates to align with federal regulations and current recommendations from scientific and professional organizations.

Engagement with stakeholders, customers, and experts

In addition to an extensive literature review and public field review, The Joint Commission obtained expert guidance from the following group:

- Technical Advisory Panel (TAP) of subject matter experts from various health care and academic organizations and professional associations.

The prepublication version of the antibiotic stewardship standards will be available online until December 31, 2022. After January 1, 2023, please access the new requirements in the E-dition or standards manual.

Medication Management

Requirements: There are 12 new and revised EPs that address antibiotic stewardship. The requirements marked as "new" introduce concepts and expectations that have not been addressed previously. Requirements marked as "revised" include a combination of editorial changes, additional notes to clarify expectations, and EPs that will now apply to all accredited hospitals (deeming lead-in statements have been deleted).

Standard MM.09.01.01: The hospital establishes antibiotic stewardship as an organizational priority through support of its antibiotic stewardship program.

EP 10 (new): The hospital allocates financial resources for staffing and information technology to support the antibiotic stewardship program. (See also LD.01.03.01, EP 5)

EP 11 (revised): The governing body appoints a physician and/or pharmacist who is qualified through education, training, or experience in infectious diseases and/or antibiotic stewardship as the leader(s) of the antibiotic stewardship program.
Note: The appointment(s) is based on recommendations of medical staff leadership and pharmacy leadership.

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New and Revised Requirements for Antibiotic Stewardship

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EP 12 (revised): The leader(s) of the antibiotic stewardship program is responsible for the following:

- Developing and implementing a hospitalwide antibiotic stewardship program that is based on nationally recognized guidelines to monitor and improve the use of antibiotics
- Documenting antibiotic stewardship activities, including any new or sustained improvements
- Communicating and collaborating with the medical staff, nursing leadership, and pharmacy leadership, as well as with the hospital's infection prevention and control and quality assessment and performance improvement programs on antibiotic use issues
- Providing competency-based training and education for staff, including medical staff, on the practical applications of antibiotic stewardship guidelines, policies, and procedures

EP 13 (revised): The hospital has a multidisciplinary committee that oversees the antibiotic stewardship program. Note 1: The committee may be composed of representation from the medical staff, pharmacy services, the infection prevention and control program, nursing services, microbiology, information technology, and the quality assessment and performance improvement program. *Note 2: The committee may include part-time or consultant staff. Participation may occur on site or remotely.*

EP 14 (revised): The antibiotic stewardship program demonstrates coordination among all components of the hospital responsible for antibiotic use and resistance, including, but not limited to, the infection prevention and control program, the quality assessment and performance improvement program, the medical staff, nursing services, and pharmacy services.

EP 15 (revised): The antibiotic stewardship program documents the evidence-based use of antibiotics in all departments and services of the hospital.

EP 16 (new): The antibiotic stewardship program monitors the hospital's antibiotic use by analyzing data on days of therapy per 1000 days present or 1000 patient days, or by reporting antibiotic use data to the National Healthcare Safety Network's Antimicrobial Use Option of the Antimicrobial Use and Resistance Module.

EP 17 (new): The antibiotic stewardship program implements one or both of the following strategies to optimize antibiotic prescribing:

- Preauthorization for specific antibiotics that includes an internal review and approval process prior to use
- Prospective review and feedback regarding antibiotic prescribing practices, including the treatment of positive blood cultures, by a member of the antibiotic stewardship program

EP 18 (new): The antibiotic stewardship program implements at least two evidence-based guidelines to improve antibiotic use for the most common indications.

Note 1: Examples include, but are not limited to, the following:

- *Community-acquired pneumonia*
- *Urinary tract infections*
- *Skin and soft tissue infections*
- *Clostridioides difficile colitis*
- *Asymptomatic bacteriuria*
- *Plan for parenteral to oral antibiotic conversion*
- *Use of surgical prophylactic antibiotics*

Note 2: Evidence-based guidelines must be based on national guidelines and also reflect local susceptibilities, formulary options, and the patients served, as needed.

EP 19 (new): The antibiotic stewardship program evaluates adherence (including antibiotic selection and duration of therapy, where applicable) to at least one of the evidence-based guidelines the hospital implements.

Note 1: The hospital may measure adherence at the group level (that is, departmental, unit, clinician subgroup) or at the individual prescriber level.

Note 2: The hospital may obtain adherence data for a sample of patients from relevant clinical areas by analyzing electronic health records or by conducting chart reviews.

EP 20 (revised): The antibiotic stewardship program collects, analyzes, and reports data to hospital leadership and prescribers. *Note: Examples of antibiotic stewardship program data include antibiotic resistance patterns, antibiotic prescribing practices, or an evaluation of antibiotic stewardship activities.*

EP 21 (revised): The hospital takes action on improvement opportunities identified by the antibiotic stewardship program.

Rationale

Antibiotic stewardship programs promote appropriate antibiotic prescribing practices and play a critical role in reducing antibiotic resistance.[2,3] These new and revised requirements expand upon The Joint Commission's existing antibiotic stewardship requirements for hospitals and critical access hospitals and identify several key components that a successful program should have in place. For example, dedicating the resources necessary to support the antibiotic stewardship program is essential to demonstrate the hospital leadership's commitment to antibiotic stewardship as a patient safety priority.[2-4] Identifying qualified individuals to lead (or co-lead) the antibiotic stewardship program ensures that those responsible for the program have the necessary expertise to implement hospitalwide strategies and practices to improve the use of antibiotics.[5,6] As multiple departments and programs are responsible for antibiotic use, it is also important that the antibiotic stewardship program has a multidisciplinary antibiotic stewardship program team with representation from departments across the organization that provides guidance, support, and oversight for the program's activities.[2,3,7]

The goal of the antibiotic stewardship program is to optimize antibiotic prescribing practices. Measuring the hospital's antibiotic use is a critical first step to identifying improvement opportunities for antibiotic prescribing and can also help an organization determine whether its antibiotic stewardship activities are effective. Hospitals are encouraged to electronically submit antibiotic use data to the National Healthcare Safety Network Antimicrobial Use Option so they can benchmark their rates compared to national data.[2,3,8] Strategies such as preauthorization for specific antibiotics and prospective review and feedback are effective interventions to improve antibiotic use. These strategies can be adapted to the level of expertise of the antibiotic stewardship program team and to the complexity of the organization.[2,3,9,10] In addition, developing and implementing evidence-based guidelines for the diagnosis and treatment of the hospital's most common indications for antibiotic use can improve prescribing practices by providing recommendations for antibiotic selection and duration of therapy.[2-4,9,11] However, the use of evidence-based guidelines has limited effect on practice unless organizations measure adherence to the recommendations and provide feedback to clinicians.[2-4,9] Reporting antibiotic stewardship program data to hospital leadership and prescribers allows organizations to review the program's activities and its impact on prescribing practices and identify opportunities for improvement.[2,3]

Citations:

1. Centers for Disease Control and Prevention. (2021, December). About Antibiotic Resistance. U.S. Department of Health and Human Services. https://www.cdc.gov/drugresistance/about.html.
2. Centers for Disease Control and Prevention (2019). *Core elements of hospital antibiotic stewardship programs.* U.S. Department of Health and Human Services. https://www.cdc.gov/antibiotic-use/core-elements/hospital.html.
3. Centers for Disease Control and Prevention (2020b). *Implementation of antibiotic stewardship core elements at small and critical access hospitals.* U.S. Department of Health and Human Services. https://www.cdc.gov/antibiotic-use/core-elements/small-critical.html.
4. Baker, D. W., Hyun, D., Neuhauser, M. M., Bhatt, J., & Srinivasan, A. (2019). Leading Practices in Antimicrobial Stewardship: Conference Summary. *Joint Commission Journal on Quality and Patient Safety*, 45(7), 517–523. https://doi.org/10.1016/j.jcjq.2019.04.006
5. Centers for Medicare and Medicaid Services, Conditions of Participation for Hospitals, Infection Prevention and Control and Antibiotic Stewardship Programs, 42 C.F.R §482.42 (2019).
6. Centers for Medicare and Medicaid Services, Conditions of Participation for Critical Access Hospitals, Infection Prevention and Control and Antibiotic Stewardship Programs, 42 C.F.R §485.640 (2019).

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New and Revised Requirements for Antibiotic Stewardship

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7. MacDougall, C., & Polk, R. E. (2005). Antimicrobial stewardship programs in health care systems. *Clinical Microbiology Reviews*, 18(4), 638–656. https://doi.org/10.1128/CMR.18.4.638-656.2005
8. Jenkins, T. C., Knepper, B. C., Shihadeh, K., Haas, M. K., Sabel, A. L., Steele, A. W., Wilson, M. L., Price, C. S., Burman, W. J., & Mehler, P. S. (2015). Long-term outcomes of an antimicrobial stewardship program implemented in a hospital with low baseline antibiotic use. *Infection Control and Hospital Epidemiology*, 36(6), 664–672. https://doi.org/10.1017/ice.2015.41
9. Barlam, T. F., Cosgrove, S. E., Abbo, L. M., MacDougall, C., Schuetz, A. N., Septimus, E. J., Srinivasan, A., Dellit, T. H., Falck-Ytter, Y. T., Fishman, N. O., Hamilton, C. W., Jenkins, T. C., Lipsett, P. A., Malani, P. N., May, L. S., Moran, G. J., Neuhauser, M. M., Newland, J. G., Ohl, C. A., Samore, M. H., … Trivedi, K. K. (2016). Implementing an Antibiotic Stewardship Program: Guidelines by the Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America. *Clinical Infectious Diseases*, 62(10), e51–e77. https://doi.org/10.1093/cid/ciw118
10. Hamilton, K. W., Gerber, J. S., Moehring, R., Anderson, D. J., Calderwood, M. S., Han, J. H., Mehta, J. M., Pollack, L. A., Zaoutis, T., Srinivasan, A., Camins, B. C., Schwartz, D. N., Lautenbach, E., & Centers for Disease Control and Prevention Epicenters Program (2015). Point-of-prescription interventions to improve antimicrobial stewardship. *Clinical Infectious Diseases*, 60(8), 1252–1258. https://doi.org/10.1093/cid/civ018
11. Magill, S. S., O'Leary, E., Ray, S. M., Kainer, M. A., Evans, C., Bamberg, W. M., Johnston, H., Janelle, S. J., Oyewumi, T., Lynfield, R., Rainbow, J., Warnke, L., Nadle, J., Thompson, D. L., Sharmin, S., Pierce, R., Zhang, A. Y., Ocampo, V., Maloney, M., Greissman, S., … Emerging Infections Program Hospital Prevalence Survey Team (2021). Antimicrobial Use in US Hospitals: Comparison of Results From Emerging Infections Program Prevalence Surveys (2021). *Clinical Infectious Diseases*, 72(10), 1784–1792. https://doi.org/10.1093/cid/ciaa373

*Not a complete literature review.

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Artesunate Medication Use Evaluation (MUE)

1. Background

Severe malaria is a life-threatening illness that requires prompt parenteral treatment to mitigate morbidity and mortality. Both CDC Guidelines for Treatment of Malaria in the US (2020) and WHO Guidelines for the Treatment of Malaria (2015) recommend IV artesunate for all patients with severe malaria. Artesunate IV is the only guideline-recommended parenteral treatment option for severe malaria available in the US. University Hospital added artesunate to formulary on October 2021. This a post-formulary addition medication use evaluation.

2. Product information

Artesunate is an antimalarial indicated for the initial treatment of severe malaria in adult and pediatric patients.

a. Treatment of severe malaria with artesunate should always be followed by a complete treatment course of an appropriate oral antimalarial regimene oral antimalarial therapy.

The indications for intravenous artesunate include the following:

- Malaria confirmation by microscopy. In exceptional cases and after discussion with a CDC Malaria Branch clinician, microscopic diagnosis might be waived. Those include a patient with strong clinical suspicion of malaria for whom a timely, reliable microscopic diagnosis is not available.

AND

- Severe malaria based on at least one of the following:
  - High parasite density (≥5%)
  - Impaired consciousness
  - Seizures
  - Circulatory collapse/shock
  - Pulmonary edema or acute respiratory distress syndrome (ARDS)
  - Acidosis
  - Acute kidney injury
  - Abnormal bleeding or disseminated intravascular coagulation (DIC)
  - Jaundice (must be accompanied by at least one other sign)
  - Severe anemia (Hb <7 g/dL)

OR

- Inability to take oral medications despite attempt after an oral antiemetic

Artesunate for Injection is supplied as follows:

- Supplied as 110 mg of artesunate single-dose vial as sterile powder for constitution for intravenous (IV) injection
- Constituted with the supplied diluent prior to administration. A diluent is provided with artesunate.
- Administer intravenously as a slow bolus over 1 to 2 minutes
- The recommended dosage of Artesunate for Injection is 2.4 mg/kg administered IV at 0 hours, 12 hours, and 24 hours, and thereafter, administered once daily until the patient is able to tolerate oral antimalarial therapy.

3. Methods

- Review period (start and end dates): 10/01/2021 – 05/31/2022
- How patients were identified: Receipt of Artesunate on Epic MAR
- Data elements captured during chart review:
  - Diagnosis
  - Service
  - Indication for Use
  - Infectious Disease Consultation
  - Location of administration
  - Dose / Administration issues
  - Side effects
  - Issues with administration
  - Safety issues
  - Patient outcomes

4. Results

- Total number of patients: 1
- Total number of doses: 3
- Dosing – describe as flat or weight-based dosing as appropriate for the product
  - Min, max, mean, SD, median of doses/dosage per patient (if relevant)
- Present results in table format with % of patients or doses that met criteria
- Results reviewed with member of relevant clinical service

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Artesunate Medication Use Evaluation (MUE)

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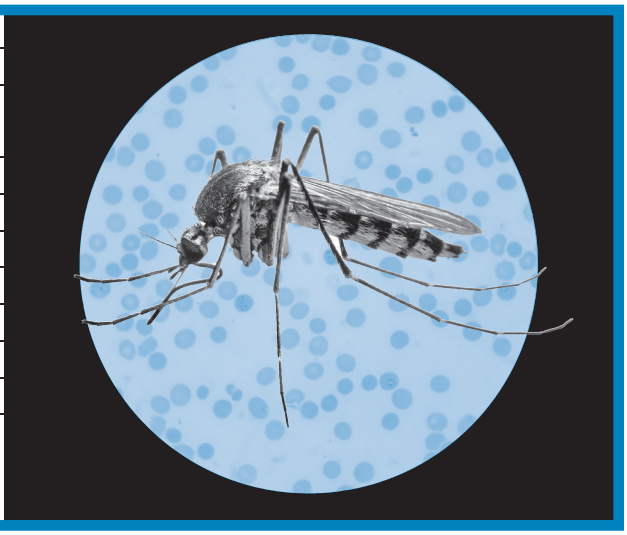
Diagnosis	Severe Malaria
Service	Medicine
Indication for Use	Severe Malaria (Impaired consciousness)
Infectious Disease Consultation	Yes
Location of administration	Emergency Department
Dose Given	2.4 mg/kg q12hr x 3 doses
Dose / Administration issues	None
Side effects	None
Issues with administration	None
Safety issues	None
Patient outcomes	Conversion to PO & discharge ~48 afters after initiation of treatment



5. **Cost**
   - Cost per unit: $4,980 for each 110mg (pricing same for GPO, WAC, 340b)
   - Cost for total treatment: $34,860 (7 vials used for treatment)

6. **Summary**

   Artesunate is utilized in the management of severe malaria for patients presenting to University Hospital. This MUE indicates UH P&T approved indication for use & UH policies/procedures were followed for medication order entry, verification, preparation and administration. One patient received treatment during MUE period with clinical benefit & positive outcome. Cost for total treatment: $34,860.

7. **Recommendation(s)**
   - Recommended status on formulary
     - Maintain on formulary given ONLY treatment option available for severe malaria (standard of care)
   - Recommended changes to prescribing/dispensing workflow: None
   - Plans for re-assessment or follow-up MUE: Evaluation based on future use and/or changes to standard of care

Discharge Anti-Infective Utilization in Patient with Listed Diagnoses of "Cellulitis", "UTI", and"Pyelonephritis"

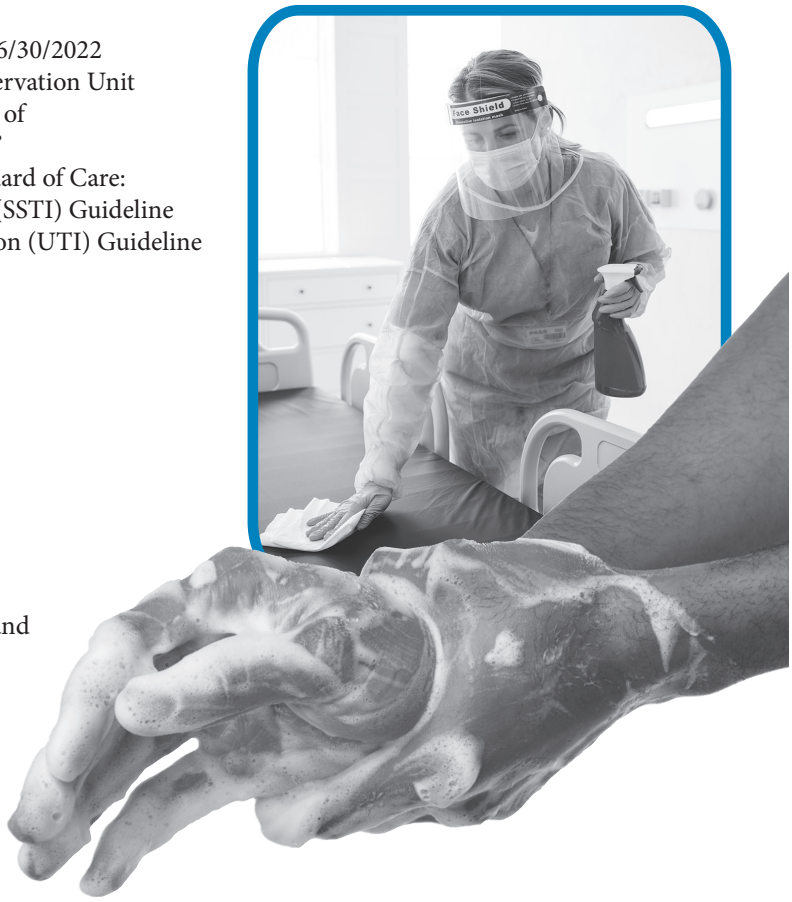
1. **Background**

UH Antimicrobial Stewardship (UH ASP) has collaborated with University Hospital Observation Unit since UH ASP inception in 2017 to improve antimicrobial utilization for patients with infectous disease diagnoses.

The intention of this review is to evaluate discharge antimicrobial prescribing practices within the University Hospital Observation Unit for patients with the following listed diagnosis during the review period (06/01-30/2022) encounter: "Cellulitis", "UTI", and"Pyelonephritis".

2. **Methods**

- Review period (start and end dates): 06/01/2022 – 06/30/2022
- How patients were identified: Discharged from Observation Unit with antimicrobial prescription and listed diagnoses of encounter as: "Cellulitis", "UTI", and"Pyelonephritis"
- UH Clinical Guidelines Utilized in Review for Standard of Care:
  - University Hospital Adult Skin and Soft Tissue (SSTI) Guideline
  - University Hospital Adult Urinary Tract Infection (UTI) Guideline



3. **Results (Summary of Attached Utilization Report)**

- 29 Discharge Antimicrobial Prescriptions Identified
  - **Cellulitis: 17**
  - **UTI: 8**
  - **Pyelonephritis: 4**
- 27 Unique Patients Identified
  - **Cellulitis: 15**
  - **UTI: 8**
  - **Pyelonephritis: 4**
- **Cellulitis**
  - **Adherence to** "University Hospital Adult Skin and Soft Tissue (SSTI) Guideline" (% Adherence)
    i. Discharge Antimicrobial **Selection: 100 %**
    ii. Discharge Antimicrobial **Duration: 100 %**
      1. Days: 14: 1 Prescription
      2. Days: 10: 2 Prescriptions
      3. Days: 8: 2 Prescriptions
      4. Days: 7: 8 Prescriptions
      5. Days: 6: 1 Prescription
      6. Days: 5: 2 Prescriptions
      7. Days: 3: 1 Prescription
  - **Assistance** from UH Antimicrobial Stewardship Service: 4 patients (25 %)
- **UTI**
  - **Adherence to** "University Hospital Adult Urinary Tract Infection (UTI) Guideline" (% Adherence)
    i. Discharge Antimicrobial **Selection: 100 %**
    ii. Discharge Antimicrobial **Duration: 100 %**
      1. Days: 5: 5 Prescriptions
      2. Days: 7: 3 Prescriptions

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Discharge Anti-Infective Utilization in Patient with Listed Diagnoses of "Cellulitis", "UTI", and"Pyelonephritis"

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- Assistance from UH Antimicrobial Stewardship Service: 0 patients (0 %)

- **Pyelonephritis**
  - **Adherence to** "University Hospital Adult Urinary Tract Infection (UTI) Guideline" (% Adherence)
    i. Discharge Antimicrobial **Selection: 100 %**
    ii. Discharge Antimicrobial **Duration: 100 %**
  - **Assistance** from UH Antimicrobial Stewardship Service: 2 patients (50 %)

4. Summary

UH Antimicrobial Stewardship (UH ASP) has collaborated with University Hospital Observation Unit since UH ASP inception in 2017 to improve antimicrobial utilization for patients with infectous disease diagnoses.

University Hospital Observation Unit providers (primarily Advanced Nurse Practitioners) demonstrate excellent utilization and adherence to UH Clinical Guidelines for the listed diagnoses of **"Cellulitis", "UTI", and"Pyelonephritis" upon encounters from 06/01-30/2022.**

Continued UH ASP collaboration is required to maintain optimal antimicrobial prescribing practices.

This information will be shared with University Hospital Observation Unit Providers & University Hospital Organization Structure (P&T Commmittee).

Contributed by:
UH Antimicrobial Stewardship Team Works

Biosimilars: The Biologics Price Competition and Innovation Act (BPCI Act)

Biosimilars:
The Biologics Price Competition and Innovation Act (BPCI Act) passed by congress in 2009 was to create an abbreviated licensure pathway for biological products that are demonstrated to be biosimilar to, or interchangeable with an FDA-approved biological product. This purpose is to provide more treatment options, and potentially lower health care costs through competition.

What is a biosimilar?

a. A biological product that is highly similar to the FDA-approved reference product notwithstanding minor differences in clinically inactive components

b. There are no clinically meaningful differences between biological product and the reference product in terms of safety, purity and potency

What is a reference product?

a. The single biological product, already approved by the Food & Drug Administration (FDA), against which a biosimilar product is compared

b. Also referred to as an "originator product

What does "clinically meaningful differences" mean?

a. Generally proven through human pharmacokinetic and pharmacodynamic studies, an assessment of clinical immunogenicity, and if required by the FDA, additional clinical studies

b. Examples of meaningful differences is differences in expected range of purity.

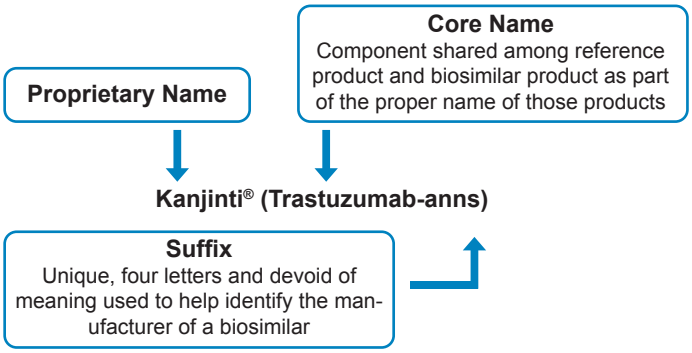
What does "interchangeability" mean in terms of biosimilars?

a. Interchangeability status is a second level of FDA approval beyond biosimilarity, According to a guidance issues by the FDA in May 2019 interchangeability is only granted if:
   (1) additional clinical trials demonstrate that the biosimilar can produce the same clinical result as the reference product in any given patient, and
   (2) additional clinical trials demonstrate the risk to efficacy or safety with alternating or switching between the biosimilar and reference product is not greater versus consistent use of the reference product.

b. In the state of NJ A bill passed in 2015 authorizes a pharmacist to substitute a biosimilar for a prescribed biological product if the biosimilar has been approved by the US Food and Drug Administration as interchangeable and the prescriber has not indicated 'do not substitute'. However the only interchangeable biosimilar approved so far is Semglee (insulin glargine-yfgn)

NOMENCLATURE & LABELING 1. The naming of biosimilars requires the assignment of a four-character alphabetic suffix to the nonproprietary name of the original product to distinguish between reference medications and their biosimilar.

a. Example:



Currently University Hospital replaced the reference product Neupogen (filgrastim) by Zarxio (filgrastim-sndz), and the oncology subdivision is also evaluating Fulphila (pegfilgrastim-jndb) to replace reference product Neulasta.

Citations:

1. U.S. Food& Drug administration 09/16/2022 Available https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars
2. National Comprehensive Cancer Network : NCCN Chemotherapy order Templates (NCCN Templates) Appendix H
3. Lyman GH, Balaban E, Diaz M, et al. American Society of Clinical Oncology Statement: Biosimilars in Oncology. J Clin Oncol. 2018;36(12):1260-1265. Available at: https://pubmed.ncbi.nlm.nih.gov/29443651/
4. U.S. Food and Drug Administration. Biosimilar Development, Review, and Approval. Available at: https://www.fda.gov/drugs/biosimilars/biosimilar-development-review-and-approval
5. U.S. Food and Drug Administration. Biosimilar Product Regulatory Review and Approval. October 2017. Available at: https://www.fda.gov/files/drugs/published/Biosimilar-Product-Regulatory-Review-andApproval.pdf 5. U.S. Food and Drug Administration. Labeling for Biosimilar Products; Guidance for Industry. July 2018. Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/labelingbiosimilar-products-guidance-industry
6. U.S. Food and Drug Administration. Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations. August 2020. Available at: http://www.fda.gov/purplebook
7. U.S. Food and Drug Administration. Questions and Answers on Biosimilar Development and the BPCI Act; Guidance for Industry. December 2018. Available at: https://www.fda.gov/regulatory-information/search-fdaguidance-documents/questions-and-answers-biosimilar-development-and-bpci-act-guidance-indust

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Newark, NJ

Pharmacy News

National Pharmacy Week

National Pharmacy Week — October 16-22, 2022
Happy #PharmacyWeek! We're proud to support the UH Pharmacy Department and their efforts to make a difference in patient care at University Hospital. National Pharmacy Week (happening now!) is an annual observance that acknowledges the invaluable contributions that pharmacists and pharmacy technicians make to help ensure safe and effective medication use. Thanks to our wonderful pharmacy colleagues for continuing to make a difference in patient care! #PharmacyStrong

Welcome New Pharmacy Technician

Sydney Mendoza

Sydney was born in Brighton Beach, Brookyln; near Coney Island; which is where her father moved to when they immigrated to America. The reason she got into pharmacy was because of her grandmother! She is from Peru and when she lived there, she used to work for a pharmaceutical lab in Lima! Her grandma is a big inspiration to Sidney, and she always carries a representation of her grandmother via the 1955 tattoo on her chest!