Shaukat Khanum Memorial Cancer Hospital and Research Center

Pharmacy Newsletter

JCI Special Edition

Volume X, Issue # 4, 2020

Issued By:

Drug Information Centre, SKMCH & RC

P&TC Updates:

Following drugs are approved by Pharmacy & Therapeutics Committee (P&TC) during 2020 SKMCH&RC:

For COVID-19 (Restricted by Services – ICU / IM & ID)

1. **Hydroxychloroquine Tab.**
2. **Chloroquine Tab.**
3. **Tocilizumab Inj**.
4. **Montelukast Tab.**
5. **Ascorbic acid (Vit C) Tab.**
6. **Remdesivir Inj.**

Others

7. **Valacyclovir Tab** – Approved as regular formulary item.
8. **Mometasone Nasal Spray** – Approved as regular formulary item.
9. **Sorafenib Tab** – 4 indigent patients / year (FLT3-ITD Mutated acute myeloid leukemia prior to allogenic transplant)
10. **Plerixafor Inj** – 6 Indigent patients / year (Patients with stem cell harvest failure)
11. **Pentoxifylline Tabs.** – Approved as regular formulary item.
12. **Tocopherol (Vitamin E) Caps.** – Approved as regular formulary item.
13. **Rasburicase Inj.** – Effective 2021, the slots for adult patients have been increased from 10 to 30 per year with following distribution,
    a. Therapeutic dose 0.2mg/kg = 05 Slots/Year
    b. Prophylactic flat dose 3mg = 25 Slots/Year
14. **Fexofenadine Tab** – Restricted by service (Employee health clinic - for hospital staff only)
15. **Doripenem Inj** – Approved as restricted by services (Infectious diseases)

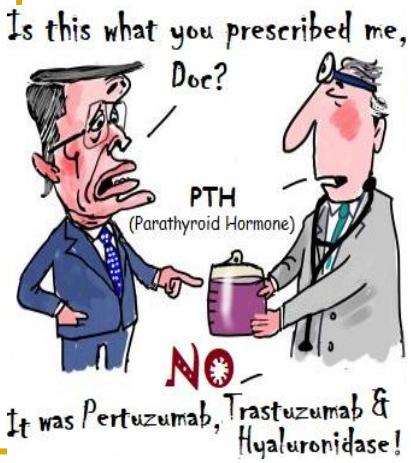
New Approvals:

Home Administration of Breast Cancer Treatment Receives FDA Approval

PHESGO™
pertuzumab/trastuzumab/hyaluronidase-zzxf
SUBCUTANEOUS INJECTION / 1,200 mg/600 mg/30,000 units
600 mg/600 mg/20,000 units

On June 29, U.S. Food and Drug Administration approved Phesgo™ to treat adult patients with early HER2-positive breast cancer, and for patients whose disease has spread to other parts of the body. It is a fixed-dose combination of Pertuzumab and Trastuzumab with hyaluronidase to be injected under the skin only by qualified health professionals. Initially, used in combination with chemotherapy, Phesgo™ could continue to be administered at home upon completion of chemotherapy. The product has been specifically developed in the wake of the novel coronavirus pandemic. Approval was based on the results of a phase III, multicentre, randomized, open-label, two-arm study involving 500 patients with HER2-positive early breast cancer. Results showed that patients preferred Phesgo™ as it was less time consuming and more easy to use as compared to standard intravenous administration. The product had comparable efficacy to IV formulations, except for administration-related reactions, which were higher in Phesgo™ due to subcutaneous administration. In addition, to a boxed warning about the risk of potential heart failure, fetal harm and lung toxicity, there are some other side effects, which include alopecia, nausea, diarrhoea, anemia, and asthenia. Monitoring parameters for taking Phesgo™, similar to IV dosage forms, are also suggested. Patients experiencing anaphylaxis or severe hypersensitivity were advised to discontinue its use.

Ref: 1)*https://cancerres.aacrjournals.org/content/80/4_Supplement/PD4-07*
2)https://iamanetwork.com/journals/jama/article-



News & Updates:

BNT162b2 mRNA Covid-19 Vaccine: Safety and Efficacy

BNT162b2 is a lipid nanoparticle–formulated, nucleoside-modified RNA vaccine that encodes a prefusion stabilized, membrane-anchored SARS-CoV-2 full-length spike protein. The primary end points of this study were efficacy of the vaccine against laboratory-confirmed Covid-19 and safety. A total of 43,548 participants underwent randomization, of whom 43,448 received injections: 21,720 with BNT162b2 and 21,728 with placebo. BNT162b2 was 95% effective in preventing Covid-19. The safety profile of BNT162b2 was characterized by short-term, mild-to-moderate pain at the injection site, fatigue, and headache. The incidence of serious adverse events was low and was similar in the vaccine and placebo groups.

Ref: *Walsh, E. E., Frenck, R., Falsey, A. R., Kitchin, N., Absalon, J., Gurtman, A., ... & Swanson, K. A. (2020). RNA-based COVID-19 vaccine BNT162b2 selected for pivotalefficacystudy. Medrxiv*

Identified Risk of Severe Cutaneous Adverse Reactions (SCARs) with Atezolizumab

Severe cutaneous adverse reactions (SCARs) are a heterogeneous group of immunologically mediated drug eruptions. Although rare, these events are potentially fatal, and are mainly constituted by acute generalised exanthematous pustulosis, Stevens-Johnson syndrome (SJS), Toxic Epidermal Necrolysis (TEN) and drug rash with eosinophilia and systemic symptoms (DRESS).

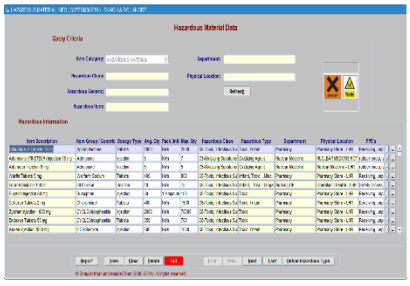
On 10th November 2020, manufacturer of Atezolizumab shared direct healthcare professional communication about new recommendations on the identified risk of severe cutaneous adverse reactions during treatment of patients with Atezolizumab. It is based on a cumulative analysis of the company safety database across the Atezolizumab program, which identified 99 cases, of which 36 cases of SCARs were confirmed by histopathology or specialist diagnosis, in patients who have received Atezolizumab. Based upon the totality of evidence in a recent analysis, SCARs are now considered an identified risk for Atezolizumab. Local label already reflects this information, but the risk-benefit of Atezolizumab as monotherapy, or as part of combinations in approved indications remains favourable. The recommendations are as follows;

- For suspected SCARs the patients should be referred to a dermatologist for further diagnosis and management.
- Atezolizumab should be withheld for patients with suspected SJS or TEN.
- Atezolizumab should be permanently withdrawn for any grade confirmed SJS or TEN.
- Caution should be used when considering the use of Atezolizumab in a patient who has previously experienced a severe or life-threatening skin adverse reaction on prior treatment with other immune-stimulatory anticancer agents.

Hazardous Drugs: Knowledge, Dealing and Handling

A hazardous drug is any drug identified by at least one of the following characteristics.

- Carcinogenicity
- Teratogenicity or developmental toxicity
- Reproductive toxicity in humans
- Organ toxicity at low doses in humans
- New drugs that mimic existing hazardous drugs in structure or toxicity



The goal of defining the list is to protect the healthcare workers from exposure to hazardous drugs. Common examples are anticancer drugs, warfarin, phenytoin and alpha guard etc.

Staff providing services and patient care assistants who handle drug waste and patient waste are also at risk and should be given safe handling training.

These drugs require safe handling precautions during receiving, storing, compounding, labelling, packaging, transport and administration. Spill kits should be available in all areas where cytotoxic drugs are prepared, dispensed, administered, transported and disposed. Trained personals will be responsible for clean-up of any spillage. In SKMCH & RC, in addition to a policy in MMU ref -11 about hazardous and cytotoxic spills management, there is also a detailed list of hazardous drugs available in HIS-Hazardous-Material.

Sharing is Caring

19th Shaukat Khanum Cancer Symposium | November 8, 2020

Oncology Pharmacy Session

Department of pharmaceutical services SKMCH & RC proudly presents the highlights of oncology pharmacy session of 19th SKMCH & RC virtual cancer symposium held on 8th November 2020. International guest speaker accentuated on the modern and standardized pharmaceutical services. Rest of the speakers highlighted issues related to inappropriate use of medications, sterile compounding and treatment opportunities in the view of COVID-19

- **Era of Modernization: Stepping Towards Standardized Oncology Pharmaceutical Services**
  Presented by Mr. Khurram Shahzad, KSA
- **Inappropriate Use of Medications during COVID-19 Pandemic**
  Presented by Mr. Rehan Khan, SKMCH&RC
- **Sterile Compounding Consideration during COVID-19**
  Presented by Mr. Salman Nasir, SKMCH&RC
- **Pharmacist Role in Treatment of SARS-COV 2 Pneumonia in Critically Ill Cancer Patients**
  Presented by Mr. Ghulam Mujtaba, SKMCH&RC

A Visit to Pharmacy SKMCH & RC by WHO Delegate

A delegate from WHO, visited pharmacy SKMCH & RC, for the purpose of checking practices and procedures utilized to provide pharmaceutical care to the patients. The team visited pharmacy area SKMCH & RC and were briefed about the services provided.

Training Session Conducted by SKMCH&RC at Indus Hospital Manawa Campus

Indus hospital Manawa campus arranged a series of training sessions including Medication Management System (MMS) and Antimicrobial Stewardship Program. Significant numbers of health care workers including Physicians, nurses, and pharmacists participated. Both sessions were covered by Department of Pharmacy, SKMCH & RC. In coming months Indus hospital will send their nominated pharmacist to SKMCH & RC for observer ship on ASP and good Pharmacy practices.

World Pharmacy Technician Day - 20th October 2020

Pharmacy technicians are an integral part of the healthcare team and Pharmacy Technician Day recognizes the invaluable contributions made by them, towards patient health and safety. It's a day for pharmacy technicians to reflect on their careers and realize the impact they've had on patients and fellow pharmacy professionals.

We appreciated pharmacy technicians and their role in quality patient care during the COVID-19 pandemic.

Patient Assistance Program

UNMOL: Patient Assistance Program of Anticancer Drugs

Many patients in Pakistan are denied access to appropriate cancer care due to non-affordability of high cost medications. In order to provide financial relief to such patients, UNMOL, a patient assistance program has been introduced by Roche™ Pakistan.

What is UNMOL by Roche™ Pakistan?

In "UNMOL", program patients may get assistance up-to a maximum of 50% cost reduction in their complete therapy.
This program is applicable on the following medications only;

Medication	Brand	Criteria for Enrolment	Scheme offered by UNMOL for paying patients
Pertuzumab	Perjeta	100 % Paying	1+1
Bevacizumab	Avastin	50 % or Above	1+1 or 2+1
Rituximab S/C, I/V	Mabthera, Ristova	50 % or Above	1+1 or 2+1
Obinutuzumab	Gazyva	50 % or Above	1+1 followed by 2+1
Atezolizumab	Tecentriq	50 % or Above	1+1

Steps involved in enrolment:

- Physician will share prescription (restricted/ non-formulary form) with pharmacy.
- Pharmacy will share details of UNMOL program with patient / attendant and ask to submit documents required to proceed further.
- Company will evaluate each case and share the offering / support of free cycles/ vials etc.
- Estimated time of medication availability (3-4 weeks approx.) will be communicated.

International Pharmacy Practice Residency Program (IPPRP) by ASHP

Department of Pharmaceutical Services SKMCH & RC proudly announces ***MATCH DAY*** for the ***3rd*** intake of ASHP International Pharmacy Practice Residency Program (IPPRP). Due to ongoing COVID-19 pandemic, pharmacists graduated from all universities of Pakistan, will participate in the initial online screening test to be held on 14th January, 2021 for this residency program.

IDSA Recommendations for Stewardship of COVID-19 Treatments

COVID-19 is a pandemic with rapidly increasing incidence of infections and deaths. Various pharmacological treatments are being used or considered for its management. Given the high number of emerging literature, there is a need to develop an evidence-based guideline to support patients, prescribers and other health-care professionals in their decisions about treatment and management of patients. Infectious Diseases Society of America (IDSA) recommendations should be used as a general guide when considering appropriate use of treatments for COVID-19 patients.

#	Drugs	Setting and severity of illness			
		***Ambulatory Care**: mild to moderate disease*	***Hospitalized**: mild to moderate disease without need for suppl. oxygen*	***Hospitalized**: Severe but non-critical disease (spO2<94% on room air)*	***Hospitalized**: critical disease (e.g., in ICU needing MV, or septic shock, ECMO)*
1	***Hydroxychloroquine (HCQ)✶***	NA	Recommend against use ✪✪✪☆	Recommend against use ✪✪✪☆	Recommend against use ✪✪✪☆
2	***HCQ✶+ azithromycin***	NA	Recommend against use ✪✪☆☆	Recommend against use ✪✪☆☆	Recommend against use ✪✪☆☆
3	***Lopinavir+ ritonavir***	NA	Recommend against use ✪✪✪☆	Recommend against use ✪✪✪☆	Recommend against use ✪✪✪☆
4-6	***Corticosteroids***	NA	Suggest against use ✪☆☆☆	Suggest use ✪✪✪☆ ***N:****If dexamethasone is unavailable, equivalent daily doses of alternative glucocorticoids maybe used✶✶*	Recommend use ✪✪✪☆ ***N:****If dexamethasone is unavailable, equivalent daily doses of alternative glucocorticoids maybe used✶✶*
7	***Tocilizumab***	NA	Suggest against routine use ✪✪☆☆	Suggest against routine use ✪✪☆☆	Suggest against routine use ✪✪☆☆
8	***Convalescent plasma***	NA	Recommended only in the context of a clinical trial (knowledge gap)	Recommended only in the context of a clinical trial (knowledge gap)	Recommended only in the context of a clinical trial (knowledge gap)
9-11	***Remdesivir***	NA	Suggest against routine use ✪☆☆☆	Suggest use ✪✪☆☆ ***N:****In patients on mechanical ventilation or ECMO, the duration of treatment is 10 days*	Suggest use ✪✪✪☆ ***N:****For considerations in contingency or crises capacity settings (i.e., limited remdesivir supply): Remdesivir appears to demonstrate the most benefit in those with severe Covid-19 on supplemental oxygen* rather than in patients on mechanical ventilation or ECMO
12	***Famotidine***	NA	Suggest against use except in a clinical trial✪☆☆☆	Suggest against use except in a clinical trial✪☆☆☆	Suggest against use except in a clinical trial✪☆☆☆
13	***Bamlanivimab***	*See below*	NA	NA	NA
		Suggest against routine use ✪☆☆☆ ***N:*** *In patients at increased risk ✶✶✶ bamlanivimab is a reasonable treatment option if, after informed decision-making, the patient puts a high value on the uncertain benefits and a low values on uncertain adverse events*			

NA: *not applicable****; MV:*** *mechanical ventilation****; ECMO:*** *extracorporeal membrane oxygenation****; N:*** *note*
✶Chloroquine is considered to be class equivalent to hydroxychloroquine.
✶✶Dexamethasone 6 mg IV or PO for 10 days (or until discharge) or equivalent glucocorticoid dose may be substituted if dexamethasone unavailable. Equivalent total daily doses of alternative glucocorticoids to dexamethasone 6 mg daily are methylprednisolone 32 mg and prednisone 40 mg.
✶✶✶Patients at increased risk, see EUA at *https://www.fda.gov/media/143603/download*
Strength of Recommendations:
Recommend: Strong recommendation, Suggest: Weak or conditional recommendations
Certainty of evidence:
✪✪✪✪ High, ✪✪✪☆ Moderate, ✪✪☆☆ Low, ✪☆☆☆ Very low
Ref: *IDSA: https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-anagement/*

COVID-19 Vaccine Trial at SKMCH & RC

Randomization of a Chinese Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) has been successfully completed at SKMCH & RC. Pharmacists were an integral part of this trial and actively participated during each randomization.

Medication Management & Use Summary 2020

A comprehensive review of medication management system (MMS) encompassing planning, organizing, selection, procurement, storage, ordering, transcribing, preparing, dispensing, administering, monitoring, adverse drug events and evaluations is completed and presented in P&TC. All essential elements were reviewed and approved.

Total P&TC in 2020: **4**

New Drugs Approved	Drug Request Rejected	Drugs Excluded	Rx Restriction Applied
14	9	7	Nil

Tender 2020-21

New Pharma Co. Participated	Chemical Equivalency Conducted
10	4

Drug Recall	Hospital Formulary Edition	Parenteral Handbook Edition	Pharmacy Newsletter
1	9th	6th	4

Adverse Drug Events (ADE's) Reported

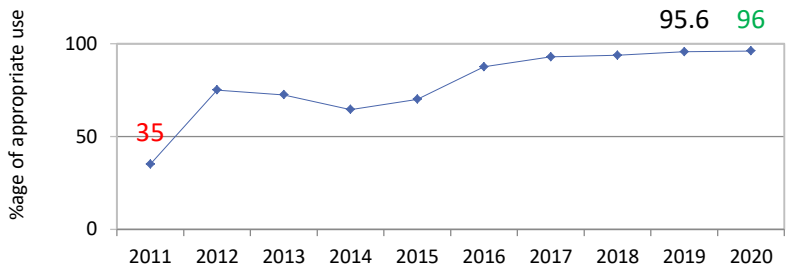
ADR's		Med. Error		Near Miss	
Lahore	Peshawar	Lahore	Peshawar	Lahore	Peshawar
170	12	30	10	160	11

Accreditation by the American Society of Health-System Pharmacists (ASHP) – Resident Status

Completed	Ongoing
01	02

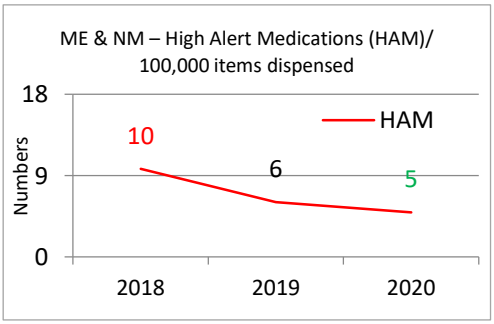
ashp Accredited

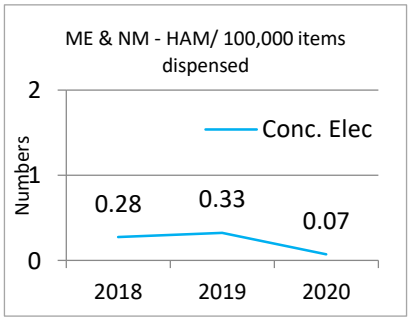
Antibiotic Stewardship Compliance - DUR

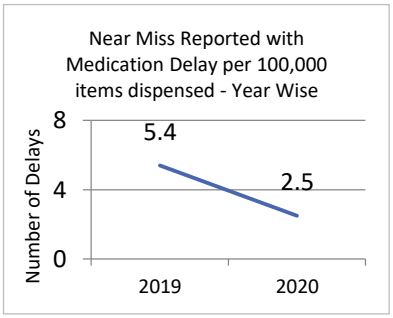


Monthly Ward Stock Audits

Medications stored outside pharmacy were reviewed on periodic basis and problems were fixed on site.



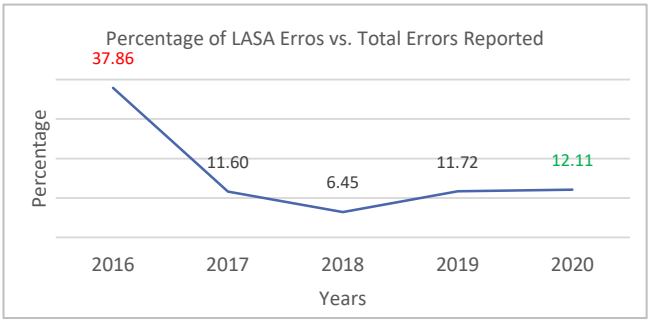


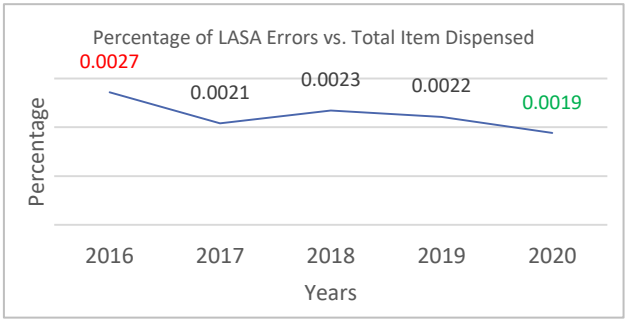


DUR - Drug Utilization Review of all new formulary drugs included in 2020 were presented in P&TC

Look-alike/Sound-alike (LASA) Medications

Department of pharmacy SKMCH works on strategies to improve safety of high alert and LASA medications. Strategies adapted at various steps of medication management system which include formulary selection, procurement, prescribing, storage, preparation, dispensing, administration, monitoring and evaluation. We have adopted uniform stacking plan across the hospital with colour codes – "Red" for high alert drugs and "Yellow" for LASA drugs. List of High alert and LASA medications is reviewed annually.

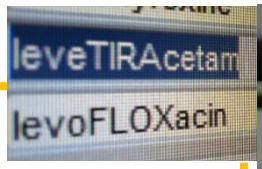




Common LASA error reported.

Sound-alike (Generic LASA)

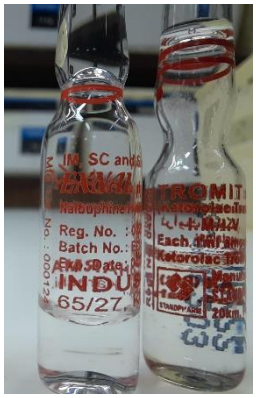
LeviTIRAcetam vs LevoFLOXacin



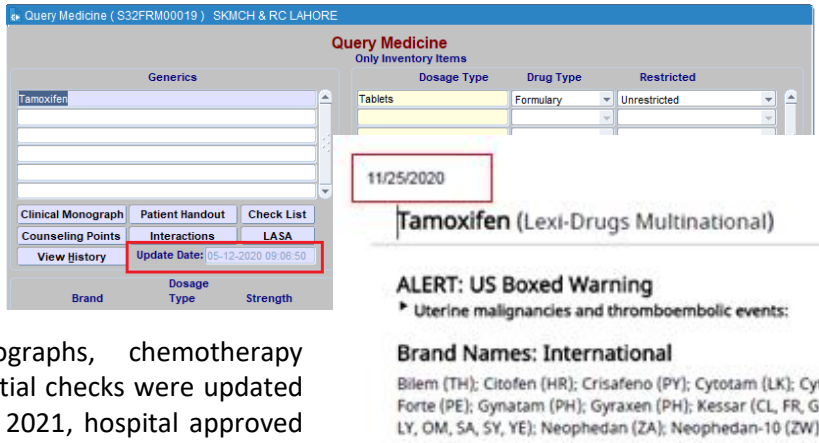
Look-alike (Brand LASA)

Vexenil (Tramadol) vs Kamedex (Dexamethasone)

Exnal (Nalbuphine) vs Tromit (Ketorolac)



Drug Data Update In HIS



Periodic upgradation of drug data is essential to ensure that health informatics is updated and optimum for management and decision making. Drug data update based on clinical decision support system (CDSS) and knowledge-based system (KBS) was updated in 2020. All necessary information including clinical monographs, chemotherapy protocols, oral chemo leaflets and essential checks were updated from Lexicomp, NCCN guidelines etc. In 2021, hospital approved few more drug information resources through which we believe it will add to strengthen the drug data and drug information services we provide.

Reporting Makes Medicine Safer

Enhancing Pharmacovigilance Capabilities by Reporting Suspected Medicine Adverse Effects

Report ADR

1 – Online

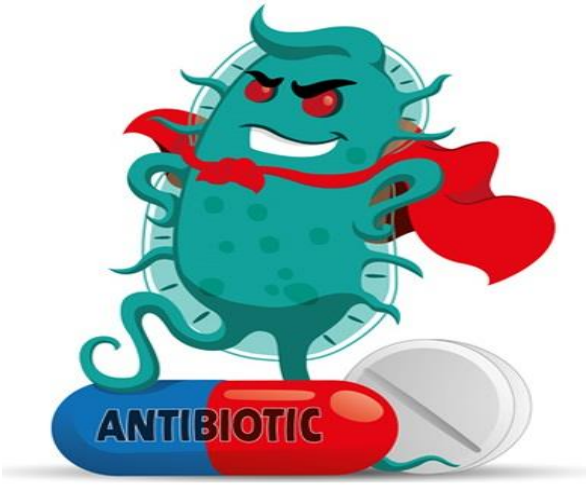
HIS - Clinical - Menu->Adverse Drug Reaction Reporting

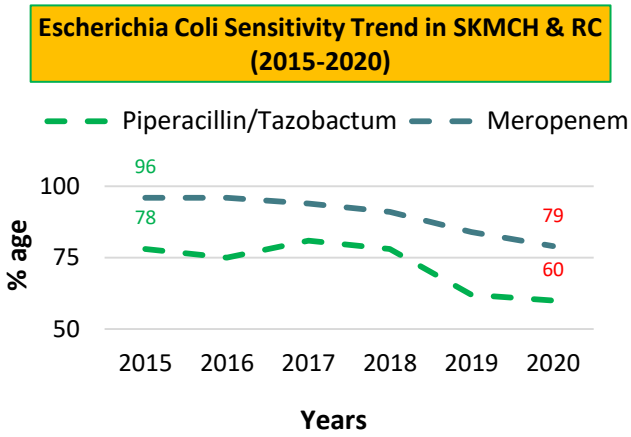
2 – Inform Pharmacy

Drug Information Centre: Call @ Ext; 3260-61

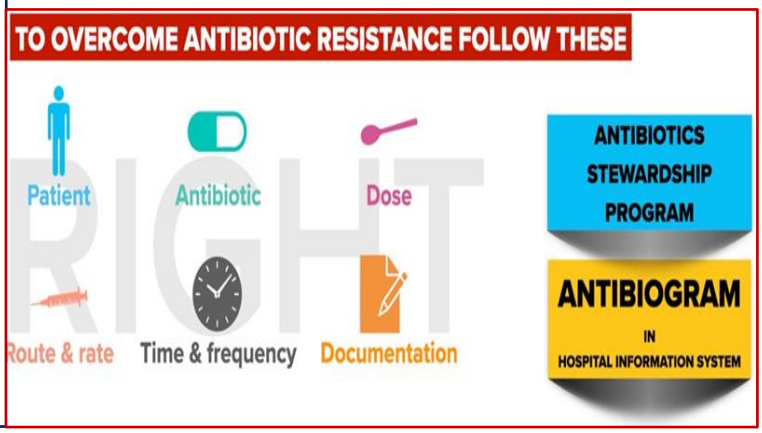
Antibiotic Resistance

Irrational prescribing and utilization of antibiotics has led to an increase in antibiotic resistance all over the world. The trends of resistance may vary from one place to another, but collectively they are moving towards increasing end. The antibiogram of Escherichia Coli from 2015 to 2020 at SKMCH & RC has shown a gradual decrease in sensitivity of Piperacillin/Tazobactam (78% → 60%) and Meropenem (96% → 79%). This trend of decreasing sensitivity is alarming and indicating that one day we would not be able to use these antibiotics against this organism. Six rights of medication administration must be followed to prevent antimicrobial resistance.





Six Rights of Medication Administration



High Alert Medication is: TECHNICAL

T	Thrombolytic
E	Electrolytes
C	Chemotherapeutic Agents
H	Hazardous Drugs
N	Neuromuscular Blockers
I	Insulin & Investigational Drugs
C	Controlled Drugs
A	Anticoagulants
L	LASA Drugs

Abstract Poster Presentation:

1. **Comparative Effects of Perioperative and Adjuvant Chemotherapy on Outcomes of Operable Gastric Cancer: Experience from a Cancer Care Center**

   Contributors: Jamshed Ali, Nuzhat Humayun, Shameen Ikram, Muhammad Abu Bakar, Samia Yasmeen, Rizwan Masood Sheikh, Umm e Kalsoom Awan

   Journal: 19th Shaukat Khanum Virtual Cancer Symposium 2020

Comparative Effects of Perioperative and Adjuvant Chemotherapy on Outcomes of Operable Gastric Cancer: Experience from a Cancer Care Center

Jamshed Ali*[1], Nuzhat Humayun[2], Shameen Ikram[2], Muhammad Abubakar[3], Samia Yasmeen[1], Rizwan Masood Sheikh[1], Umm e Kalsoom Awan[1]
[1]Department of Medical Oncology, Shaukat Khanum Hospital and Trust, Pakistan.
[2]Department of Pharmacy, Shaukat Khanum Hospital and Trust, Peshawar, Pakistan.
[3]Department of Cancer Registry and Clinical Data Management, Shaukat Khanum Hospital and Trust, Lahore, Pakistan.

Abstract

Purpose: Gastric Cancer is one of the leading causes of cancer related deaths worldwide. We compared the overall survival (OS) and disease-free survival (DFS) with perioperative or adjuvant chemotherapy regimens in operable gastric cancer.

Methods: This is a retrospective observational study of operable gastric cancer patients treated at SKMCH & RC Pakistan, with perioperative or adjuvant chemotherapy from January 2015 till December 2019. Patients having Tis, T1, N0, inoperable disease or incomplete chemotherapy were excluded. OS and DFS were evaluated through Kaplan-Meier survival analysis and Log-rank tests using SPSS. The results were considered significant at an alpha level of ≤ 0.05.

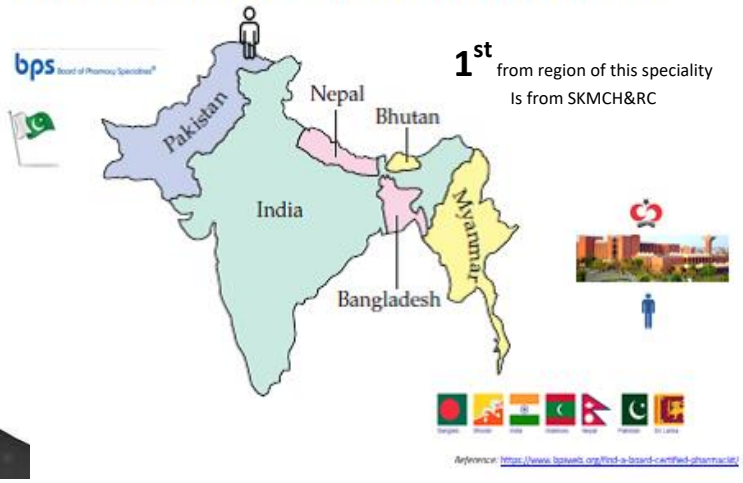
Results: A total of 96 patients were enrolled with 71 patients in the perioperative group and 25 patients in the adjuvant chemotherapy group. The probability of a 2 and 3-year overall survival was 68% and 58% for the perioperative chemotherapy, while in the adjuvant chemotherapy it was 58% and 48%, respectively. The probability of 2 and 3-year DFS were 56% and 40% for perioperative chemotherapy, while for the adjuvant chemotherapy group the 2-year DFS was 44% and the patients were unable to reach the 3-year mark. The median OS & DFS were 49 months & 138 months for the perioperative chemotherapy group while they were 28 months & 14 months respectively for the adjuvant chemotherapy arm. The difference of OS and DFS between the two arms was not statistically significant but with a trend towards superiority with peri-operative chemotherapy arm.

Conclusion: In the operable gastric cancer, perioperative chemotherapy group has trend toward improved OS and DFS in comparison to adjuvant chemotherapy arm. However, this difference in the two arms was not statistically significant.

Pharmacy Staff Capacity Building

Mr. Shoaib Shammas
Assistant Manager Aseptic Services
(ASHP Preceptor – Aseptic Services)

Board Certified Pharmacists in Subcontinent



First US Board Certified Pharmacist with speciality of "Compounded sterile preparation" in the subcontinent.

P&TC Update

MMU Policies Updated:

- MMU Manual
- Policy on Continual Quality Improvement
- Policy on Safe Handling of Hazardous Drugs
- Policy on Medication Reconciliation and Patient Own Medication Use
- Policy on High Alert Medications
- Policy on Drug Product Recall

Feedback

To keep the Pharmacy Newsletter updated,
Please contact at druginfo@skm.org.pk