THE ROLE OF THE PHARMACIST IN THE JACIE PROCESS

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1. INTRODUCTION

- Expansion of hematopoietic stem cell transplantations (HSCT) in adults and children

- HSCT accepted as “standard of care treatment”

- One-third of allogeneic and two-thirds of autologous HSCT recipients > age of 50 years

- Polymedication (often > 15 drugs)
  - Post-HSCT drugs: immunosuppressives, antimicrobials,...
  - Drugs for pre-existing comorbidities: antihypertensives,...
  - Risk of drug-drug interactions = real!!!
Specialist unit by experienced and fully dedicated **multidisciplinary team** to ensure safe and effective care

Pharmacist
- Suited to support and optimize patients’ medication therapy
- Important role in this team
  - Pretransplantation period
  - Posttransplantation (early and late phase) period
2. ROLE OF PHARMACIST

“Integral member of the multidisciplinary HSCT team who provides a variety of pharmacy and educational services to both the healthcare team and the patient in an effort to optimize collaborative, patient-centered care”

http://www.asbmt.org/
3. PHARMACIST’S ACTIVITIES

3.1. Pretransplantation period

Patient assessment
- Underlying pathology of patient
- Complete view of pharmacotherapeutic plan

Thorough medication profile review
- Drug history (allergies, side-effects,...), pre-existing organ toxicity
- Current drug information
  - Check prescribed medications with home medication (+ use of complementary alternative medicines)
  - Patient’s preferences (e.g. formulations)
  - Financial issues
Conditioning regimen

- Assist with
  - Treatment planning
  - Chemotherapeutic (electronic) order set
- Ensure follow-up of logistics (special commands, drug shortages, ...)

- Verification of Body Surface Area (automated or verified by pharmacist) or dose calculations (pediatrics!), dilutions, concentrations, stability, light sensitivity, ...

- Provide clear instructions to nurses
  - Administration route, infusion time, additional information, ...
PATIENT NAME

PATIENT NAME

01/03/2016 10:00

PED03 - 5103

PATIENT NAME

01/03/2016 10:00

PED03 - 5103

fludarabine = FLUDARABINE
40 MG bij 50 ML NACL 0,9 %
Tot. vol.: 51,6 ML IV in 60 min
Kamertemperatuur
Vervaldatum : 08/03/2016
Vervahuur : 16:45

Generic compound: FLUDARABINE
Standard dose: 40 MG/m²

Opm. artikel: Geen
Opm. kuurspecificiek:

fludarabine teva 2ml 25mg/ml

1,6 ML bij te spuiten bij 50 ML NACL 0,9 %

Lotnummer:
Theoretical dose: 40 MG
Aanpassingen:
Written dose: 40 MG

Preparation:
Preparation date: 01/03/2016
Latest print:

Control:
Preparation time: 16:45

SCT ALLO CML-IBFM : FLU-THIO-ATG-MEL (geen MTX)

Opm. apotheek: Geen

01/03/2016

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Ensure optimal communication between ward and cytotoxic manufacturing service to coordinate timely supply of chemotherapeutics e.g. high-dose etoposide, melphalan, IV busulfan

Participate in multidisciplinary rounding

Advice on dose adjustments based on therapeutic drug monitoring (TDM) (e.g. intravenous busulfan, ATG, ... )
3.2. Post-transplantation (hospital)

**Supportive care**
- Infection control: antifungal agents, antivirals, antibiotics,…
- Complex immunosuppressive strategies for prevention or treatment of graft-versus-host disease (GvHD)
- Chemotherapy induced nausea and vomiting
- ...

**Potential risk of**
- Significant drug interactions (azoles, cyclosporine,..)
- Drug incompatibilities
Lexi-Comp Online™ Interaction Analysis

Customize Analysis

Only interactions at or above the selected risk rating will be displayed. A ▼

View interaction detail by clicking on link.

Acetaminophen
  No interactions identified with others in the selection list.

CISplatin
  No interactions identified with others in the selection list.

Clarithromycin
  [D] Fluconazole (Antifungal Agents (Azole Derivatives, Systemic))
  [D] Fluconazole (QTc-Prolon)
  [C] Methotrexate (P-Glycoprotein)
  [D] TraMADol (CYP3A4 Sub)
  [C] Zofran® (P-Glycoprotein)

Fluconazole
  [D] Clarithromycin (Macrolide)
  [D] Clarithromycin (QTc-Prolon)
  [C] TraMADol (CYP3A4 Sub)
  [C] Zofran® (CYP3A4 Inhibitor)

Methotrexate
  [C] Clarithromycin (P-Glycoprotein)

TraMADol
  [D] Clarithromycin (P-Glycoprotein)

IV Compatibility Report

Legend

= Compatible  = Incompatible  = Results uncertain, variable or dependent on conditions
ND = No Data Available

From Trissel’s 2nd Clinical Pharmaceutics Database

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Review of drug charts /laboratory parameters at least once daily

Check dosages, (potential) drug-drug interactions, side-effects

Advice on TDM of immunosuppressives, anti-infectives, anti-epileptics,…

Supportive care management
  - mucositis, pain, nausea/vomiting, nutrition,…

Document advices (electronically if available) in medical file

Communicate findings and recommendations to team (attending ward rounds or directly to physicians/nurses/….)
Development and implementation of supportive care guidelines for acute and delayed effects

- Development and implementation of pathways and algorithms in HSCT (multidisciplinary)
  - Mucositis
  - Prevention/treatment of bacterial, fungal and viral infections
  - Prevention and treatment of CINV
  - GvHD
  - Pain,…

- Evaluation of impact and adherence to algorithms / guidelines to ensure consistency and uniformity and quality in patient care (drug use evaluation,…)
But also…

“Compounding what we cannot get”

- Often very patient oriented in hospital pharmacy

- Compounding often provides direct answer to patient’s needs (or economic/market concerns)
  - Very young children in SCT unit need tacrolimus oral suspension … can you do it?
  - GvHD reaction is impairing the sight of this patient – could we try cyclosporine eyedrops or autologous serum eyedrops?

- Liaison function with other pharmacy colleagues
3.3. Post-transplantation (discharge)

- Assist with transition of care
  - Provide medication reconciliation
  - Collaborate on discharge planning and management

- At discharge
  - Ensure that patient has all drugs needed and/or prescriptions to take to community pharmacy
  - Help patients to find systems to support them (e.g. pill boxes)
  - Educate patients to improve medication adherence and understanding of drugs
  - Communication with community pharmacy
4. ROLE IN THE JACIE PROCESS

- Development of pharmacist standards
  - Strengthen the role of clinical pharmacist as part of multidisciplinary team
  - Include essential roles and responsibilities

- Pharmacist representatives formally appointed to work with FACT/JACIE on 6th Edition of Standards
  - US representative (C. Sizemore, Atlanta, USA)
  - Non-US representative (T. Bauters, Belgium)
PART B CLINICAL PROGRAM STANDARDS

B1  GENERAL
B2  CLINICAL UNIT
B3  PERSONNEL
B4  QUALITY MANAGEMENT
B5  POLICIES AND PROCEDURES
B6  ALLOGENEIC AND AUTOLOGOUS DONOR SELECTION, EVALUATION, AND MANAGEMENT
B7  RECIPIENT CARE
B8  CLINICAL RESEARCH
B9  DATA MANAGEMENT
B10  RECORDS
B2 CLINICAL UNIT

B2.8 There shall be a pharmacy providing 24-hour availability of medications needed for the care of transplant patients.

Explanation

- In addition to having medications available, there must always be a pharmacist available on-site or on-call
- Pharmacy must have mechanisms to prevent dosing errors during the preparation and the administration of high-dose therapies
B7 RECIPIENT CARE

B7.4.1 The treatment orders shall include

- the patient’s height and weight
- specific dates of administration
- daily doses (if appropriate)
- route of administration of each agent

Explanation

- ....
- Verification of Body Surface Area (BSA), automated or verified by a second qualified designee (e.g., pharmacy), should be performed.
B7.4.3 The pharmacist preparing the drug shall verify and document the doses against the protocol or standardized regimen listed on the orders

Explanation

Even if a validated electronic system is used (e.g., bar coding), there must be a method to document the verification of:

- drug and dose in the final container or pill against the orders and the protocol,
- identity of the patient to receive the chemotherapy

B8 CLINICAL RESEARCH

B8.1.1 Those Clinical Programs utilizing investigational treatment protocols shall have in place a pharmacy equipped for research activities, including a process for tracking, inventory, and secured storage of investigational drugs.
This sixth edition of Standards includes additional significant changes. A detailed summary is available on the FACT website. Most important to note are:

1) Increased emphasis on outcome analysis and improvement.
   a) Clinical Programs are required to assess at least 100 day and one year survival, and to compare one year survival to national or international outcome data. For US programs, at a minimum, the one year survival should be within the expected range as defined for that program by the CIBMTR Transplant Center-Specific Outcome Data. Corrective action plans will be expected if these outcomes are not achieved.
   b) Clinical Programs must regularly assess allogeneic transplant recipients for evidence of acute and chronic graft versus host disease according to an established grading scale, and actively evaluate patients for post-transplant late effects.
   c) Clinical Programs must also regularly assess central venous catheter infections.

2) Reporting of autologous transplant results is now recommended.

3) New requirements were added for pharmacists and physicians-in-training who are involved in the care of hematopoietic cell therapy patients.

4) Continuing education minimum requirements have been specifically defined as ten hours per year in topics related to hematopoietic cell therapies.
B3.8.1. Pharmacists shall be licensed to practice in the jurisdiction of the Clinical Program and shall be limited to a scope of practice within the parameters of their training and licensure

Pharmacist included as “key personnel”

- Part of the official organisation chart
- Official names of designated pharmacists (leadership role or routine involvement in the care of transplant patients)

Apart from basic education as hospital pharmacist and training as clinical pharmacists → no formal or recognized education program in Europe so far

Function description as defined by national/institutional policies
B3.8.2. Training shall include

- B3.8.2.1. An overview of hematology/oncology patient care, including the cellular therapy process

- B3.8.2.2. Therapeutic drug monitoring, including, but not limited to, anti-infective agents, immunosuppressive therapy, anti-seizure medications, and anticoagulation

- B3.8.2.3. Monitoring for and recognition of drug/drug and drug/food interactions and necessary dose modifications

- B3.8.2.4. Recognition of medications that require adjustment for organ dysfunction
Explanation

Training of pharmacists would ideally include one year of supervised training in the management of hematology/oncology patients, including hematopoietic stem cell transplant recipients.

Documentation of training may include a list of pharmaceutical related transplant topics, such as:

- Prevention and treatment of viral, bacterial and fungal infections.
- Febrile neutropenia.
- Nausea/vomiting and mucositis.
- .....
B3.8.3. Pharmacists should be involved in the development and implementation of guidelines or SOPs related to the pharmaceutical management of transplant recipients

Explanation

Pharmacists must be knowledgeable of relevant guidelines or SOPs and facilitate their creation, revision, and approval when a pharmacist’s expertise is needed.

Evidence

- Documentation of designated pharmacist(s) responsibilities
- Minutes from protocol development meetings that include identified pharmacist(s)
- (Co-) Authorship of new standard operating procedures (SOP)
- Reviewer of revised SOPs
B3.8.4. Designated transplant pharmacists shall participate in ten (10) hours of educational activities related to cellular therapy annually at a minimum

B3.8.4.1. Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation.

Explanation

- Field of transplant medicine continues to evolve rapidly (keep up with current advancements).
- Documented number and content of continuing education activities
Evidence

- To assess appropriateness of the amount and type of continuing education in which the designated transplant pharmacists participated
  - Title of activity.
  - Type of activity (webinar, meeting, grand round, etc.).
  - Topic of activity (hematology, cell transplantation, etc.).
  - Date of activity,
  - Approximate number of hours of activity.

- Provided in variety of formats (reports or listings)
- Content must reflect regular education in cellular therapy and/or diseases in which cellular therapy is a therapeutic option.
The Clinical Program may choose to establish its own guidelines for the number of hours from each type of activity that can be counted toward the minimum requirement in this Standard.

Examples

- Annual meeting of several professional societies
- Presentation of a paper at scientific meeting
- Publication of a manuscript related to cell therapy,
- Participation in a webinar or on-line tutorial
- Review of article in medical literature related to cellular therapy
- Local or regional journal club, potentially including the preparation time
- ...

Example(s)
Additional resources are available through the ASBMT Pharmacists’ Special Interest Group (SIG)

Conferences

European Society for Blood and Marrow Transplantation

NEW TO 2016

1st Pharmacist Day - As part of the 2016 annual meeting, EBMT is proud to present the very first Pharmacist Day in Valencia. This day-long session will take place on Tuesday 5 April and represents a unique initiative in Europe. Key leaders in the field will highlight the challenges faced by pharmacists involved in Stem Cell Transplantation and haematology in general. This original cutting-edge program will include sessions that will tackle the perspective of the Pharmacists on the different therapies, side effects and drug dosage in a variety of circumstances. Please see the full program online using the below link.
5. CONCLUSION

Pharmacists uniquely suited to support healthcare team to optimise patients’ pharmacotherapy and contribute to improved patient care

Pharmacists’ role in HSCT recognised in FACT-JACIE Standards

Pharmacists should be involved in preparing for and maintaining accreditation (in pharmacy and on the ward)

Accreditation is opportunity for quality improvement