Oral Anticancer Medicines – A Risky Business?

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Presentation Overview

- Increase in availability/usage of Oral Anticancer Medicines (OAM)
- Worldwide response to OAM
- Irish research
- IMSN briefing document on OAM
- Dispensing OAM from hospital – potential benefits and challenges
Prescribing Frequency/Cost of OAM covered under High-Tech Reimbursement Scheme (2006-2009)

- Frequency up 93%
- Cost up from €11m to €28.5m
BREAST CANCER PROTOCOLS
Oncology Department, St Vincent's University Hospital

BREAST CANCER
TC Docetaxel/Cyclophosphamide

Indications:
- Adjunctive treatment for HER-2 negative node negative or node positive disease
- Primary treatment: Docetaxel/Cyclophosphamide

Pre treatment investigations:
- Check CBC, differential, coagulation profile and LFTs prior to start of chemotherapy

Treatment cycles:
- Treatment on Day 1 every 3 weeks x 6 cycles (node negative x 7 cycles node positive cycles)

Prophylaxis:
- Take Zoladex 3.6mg IM on Day 1 of each cycle

Docetaxel Steroid Therapy:
- Day 1: 1.6 mg/m2
- Day 2: 8 mg/m2

Cyclophosphamide: 120mg/m2

Automatic protocol: Moderate risk

Caution:
- In the event of liver dysfunction, the consultant should determine the dose of Docetaxel
- Ensure that a PPI or H2 receptor antagonist is prescribed concurrently
- Use caution in the elderly
- Hypersensitivity reactions can occur during the infusion of Docetaxel, in particular, events of hypersensitivity reaction refer to the hypereosinophilia

Ensure that the patient is given a prescription for GCSF and that arrangements are made for the administration of same.

Written by: AM Co. Fran. O. Carroll
Approved by: Dr. O. Gicle
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CYTOXIC CHEMOTHERAPY PRESCRIPTION & RECORD SHEET

Name: ___________________________ Hospital No: ___________________________

Height: ___________________________ Weight: ___________________________

Date of Birth: _____________________ Consult: ___________________________

Chemical therapy: TC

Week number/Date: ___________________________

Consultant:

Date/Time: ___________________________

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<th>DRUG</th>
<th>DOSE</th>
<th>FORMULATION</th>
<th>Route</th>
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SAUCY FLUSH ADMINISTERED BETWEEN EACH DRUG

Signature of Doctor: ___________________________ Date: ___________________________

Signature of Consultant: ___________________________ Date: ___________________________

PHARMACY

STRICTLY CONFIDENTIAL

High Technology Medicines

Hospital: ___________________________

Address: ___________________________

Telephone No.: ___________________________

Fax No.: ___________________________

PART I PRESCRIPTION

Patient's Name: ___________________________

Date: ___________________________

Address: ___________________________

Consultant's Name: ___________________________

Tel No.: ___________________________

Date of Birth: ___________________________

Name or Drug: (Prescribes name, strength, quantity and dosage must be stated)

Doctor's Name: ___________________________

NHS No.: ___________________________

Doctor's Signature: ___________________________

PART II NOTIFICATION TO HIGH TECH LIASON OFFICER

Duration of Therapy:

Commencement of Therapy: Month: ______ Year: ______

Estimated Completion of Therapy: Month: ______ Year: ______

Review of Therapy:

Max treatment: Month: ______ Year: ______

Is this patient currently receiving this medication under this advice?

Patient's Eligibility Category: Please tick one

- Yes

- No

Name and Address of Nominated GP: ___________________________

Community Pharmacist: ___________________________

Address: ___________________________

Pharmacist: ___________________________

Address: ___________________________

Note:

1. To Hospital: This form should be forwarded by fax to the appropriate High Tech Liaison Officer.

2. To Patient: This is your prescription. Please ensure that you bring it to your pharmacist when you go to collect your medication.

Name: ___________________________

Address: ___________________________

Signature: ___________________________
Worldwide Responses to the Risks Associated with OAM
Current Situation In Ireland

- No relevant Irish guidelines
- No previous research re OAM management in Ireland
- Case reports of patient harm with OAM incidents globally, including Ireland

“I’ve been robbed of my wife after cancer drug mistake”

“.....death by misadventure”
Irish Research

• Assess the risks to patient safety with the current Irish system of prescribing and dispensing OAM
  – Community pharmacy survey
  – Hospital pharmacy survey
  – OAM Rx review

Community Pharmacists' Perspectives

Risks to patient safety with current system?

- 74%: Risks to patient safety
- 19%: No risks to patient safety
- 7%: Did not answer this question
Management of Anticancer Medicines in Irish Hospitals

Parenteral versus Oral Anticancer Medicines

Percentage of Hospitals

- Prescribing Policy: 64% Parenteral, 39% Oral
- Dispensing Policy: 79% Parenteral, 43% Oral
- Individual Tx Protocols: 46% Parenteral, 25% Oral
- Preprinted Prescriptions: 21% Parenteral, 4% Oral

Legend:
- Blue: Parenteral Anticancer Medicines
- Red: Oral Anticancer Medicines
Management of Anticancer Medicines in Irish Hospitals

Review of Parenteral versus Oral Anticancer Rx

- **Parenteral Anticancer Medicine**: 100%
- **OAM (Part of Parenteral Regimen)**: 79%
- **OAM (Inpatients)**: 61%
- **OAM (Day Centre)**: 21%
- **OAM (Outpatients)**: 11%
Review of OAM Prescriptions

- OAM being used for a licensed indication?
  - Yes: (77) Yes
  - No
    - Unknown: (3) STOP
    - Yes: 20 Rx STOP
- Dosing schedule used same as the licensed dose?
  - Yes: (39) Yes
  - No
    - Yes: Unknown (3) STOP
    - No: 58 Rx STOP
- Dosing information available in the BNF/SPC?
  - Yes: (39) Yes
  - No
    - Yes: Unknown (3) STOP
    - No: 81 Rx STOP
- Standard dose (i.e. not based on BSA)?
  - Yes: (22) Yes
  - No
    - Yes: 74 Rx STOP
    - No: (16) STOP
- BSA (or ht and wt to calculate BSA) documented on Rx?
  - Yes: (1) Yes
  - No
    - Yes: 74 Rx STOP
    - No: (16) STOP
- Patient had known factors resulting in decreased dose (e.g. toxicity or heavily pretreated)?
  - Yes: (7) Yes
  - No
    - Yes: 74 Rx STOP
    - No: (16) STOP
- Reasons for dose reductions noted on Rx?
  - Yes: (7) Yes
  - No
    - Yes: 74 Rx STOP
    - No: (16) STOP
- Total Rx: 81 Rx STOP
  - Go: 16 Rx
Recommendation from the IMSN OAM Working Group

The number of oral anticancer agents available, particularly the targeted therapies, is likely to increase substantially in the near future. Risks to patients are known to be increased if non-specialist practitioners prescribe, dispense or administer these oral medicines and bypass the normal safeguards used for injectable anti-cancer medicines

The IMSN working group recommends that clinical verification and dispensing of all OAM prescriptions should take place in the hospital where the patient’s clinical information is available, and where treatment is undertaken.

OAM prescriptions should be verified by pharmacists with specialist chemotherapy knowledge (specialist pharmacists) to ensure patient safety. Doctors, pharmacists and nurses must prescribe, dispense, administer and monitor oral anti-cancer medicines to the same standard as injected (parenteral) chemotherapy.

The requirement for verification of all OAM prescriptions by specialist pharmacists and dispensing from hospital pharmacies will present challenges in terms of human resources and drug costs, and allocation of specific resources will be necessary. The resources for OAM are currently in primary care therefore reallocation to the secondary care/acute sector would be required.
Potential Benefits

- Improved patient safety
  - Clinical verification by pharmacists with oncology/haematology experience and access to
    - patient details
    - treatment protocols
    - specialist references
    - prescribing team
- Allows a “centre of excellence” approach
- Patient counselling
- Economic
Challenges

• Resource issues
  – Staffing
  – Drug costs

• Specialist pharmacist training

• Logistics
  – No clinical pharmacy services to outpatients
  – Pharmacy opening hours

• Less convenient for patients?
Alternative Approaches

- Clinical verification by specialist pharmacists in hospital with community dispensing
- Provision of information to community pharmacists to enable verification
  - Protocols, treatment plans
- Implementation of a national OAM Rx
Conclusion

- The current Irish system of prescribing and dispensing of OAM has inherent risks for patients
- National guidelines for the management of OAM required
- Input from all relevant stakeholders