The CYTOHILTON

Cytotoxic compounding –

Moving from ward to pharmacy

MEDICAL STUDENT CONCENTRATION DURING LECTURES

JOHN STUART

Department of Hæmatology, Queen Elizabeth Hospital, Birmingham B15 2TH

R. J. D. RUTHERFORD

Advisory Service on Teaching Methods, University of Birmingham, Birmingham B15 2TT

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Summary A simple procedure, based on a questionnaire, was used for the assessment of student concentration during lectures. Analysis of 1353 questionnaires from 12 lectures showed that student concentration rose sharply to reach a maximum in 10–15 min, and fell steadily thereafter. The data suggest that the optimum length of a lecture may be 30 instead of 60 min. This method by which student feedback is obtained may also be used to improve lecturing performance.

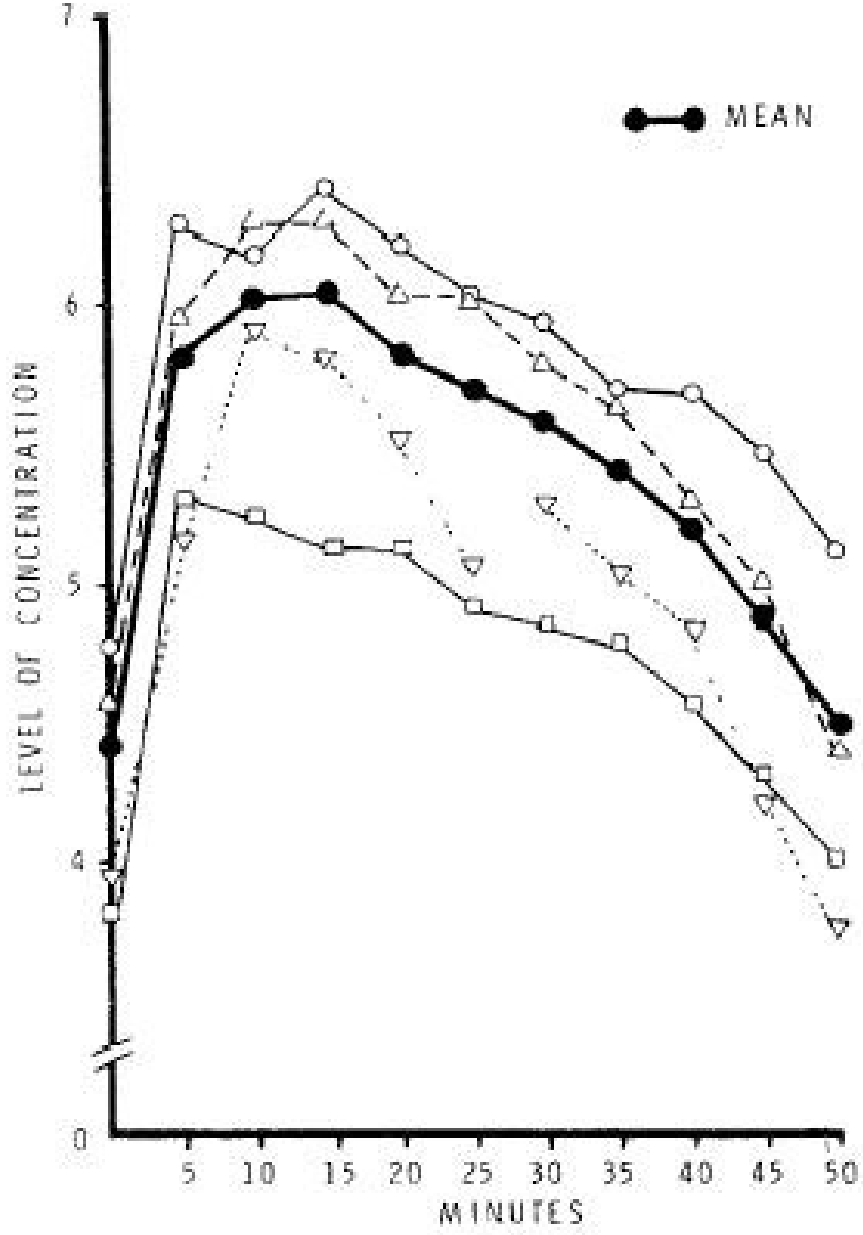


Fig. 2—Variation in mean level of student concentration with time from start of lecture (mean for 12 lectures plus profiles for each of the four lecturers).

Business Case

Executive Summary:

- To build and validate a clean room suite in an existing building, adjacent to the day care facility, in 6 months

Background:

- Switching from ward production to centralized pharmacy production.

Proposal:

- Previously was an OR – ventilation system already in place – D class room
- 3 isolators - non-VHP approx 50 to 60000

Business Case

Risk management

- Contingency plan for equipment – breakdowns etc

Costs/financing

- Staff costs – technician: 25000 to 35000 €
- Pharmacist: 50000 €
- Head of production:75000 €
- Validation -10000€
- Maintenance - 10000 €
- Installation – 1500 euro per m2 = 225000 €

Business case

Business Plan for Cytotoxics

- Competition: Other hospitals / private service providers/ homecare
- Customers: Oncology/haematology departments
- Trends: Increasing demand / staff safety expectations / change to oral forms of chemotherapy
- Other ways to solve the task – outsourcing?

Site Master File

- Mission: To safely compound in a ready to use form and deliver all the IV cytotoxic chemotherapy to the hospital clinic and wards.
- 95% delivered within 60 minutes of receipt of completed and confirmed Rx

Site Master File

- Product type: IV Chemotherapy products
- Batch size: 1
- Number of beds: 500
- Number of units: 24000 annually
- Patient group: Adult [70% day care; 30% in-patient]
- Location of facility: Next door to the day care unit.
- Use electronic prescribing
- Closed systems in aseptic manipulations – Health & Safety

Work contracted out:

- cleaning
- maintenance and validation
- QC sample incubation/reporting of results
- IT

VMP

Rooms – twice a year – HEPA filter testing; room pressures; air changes; Particle counts

Equipment – Isolators – twice a year

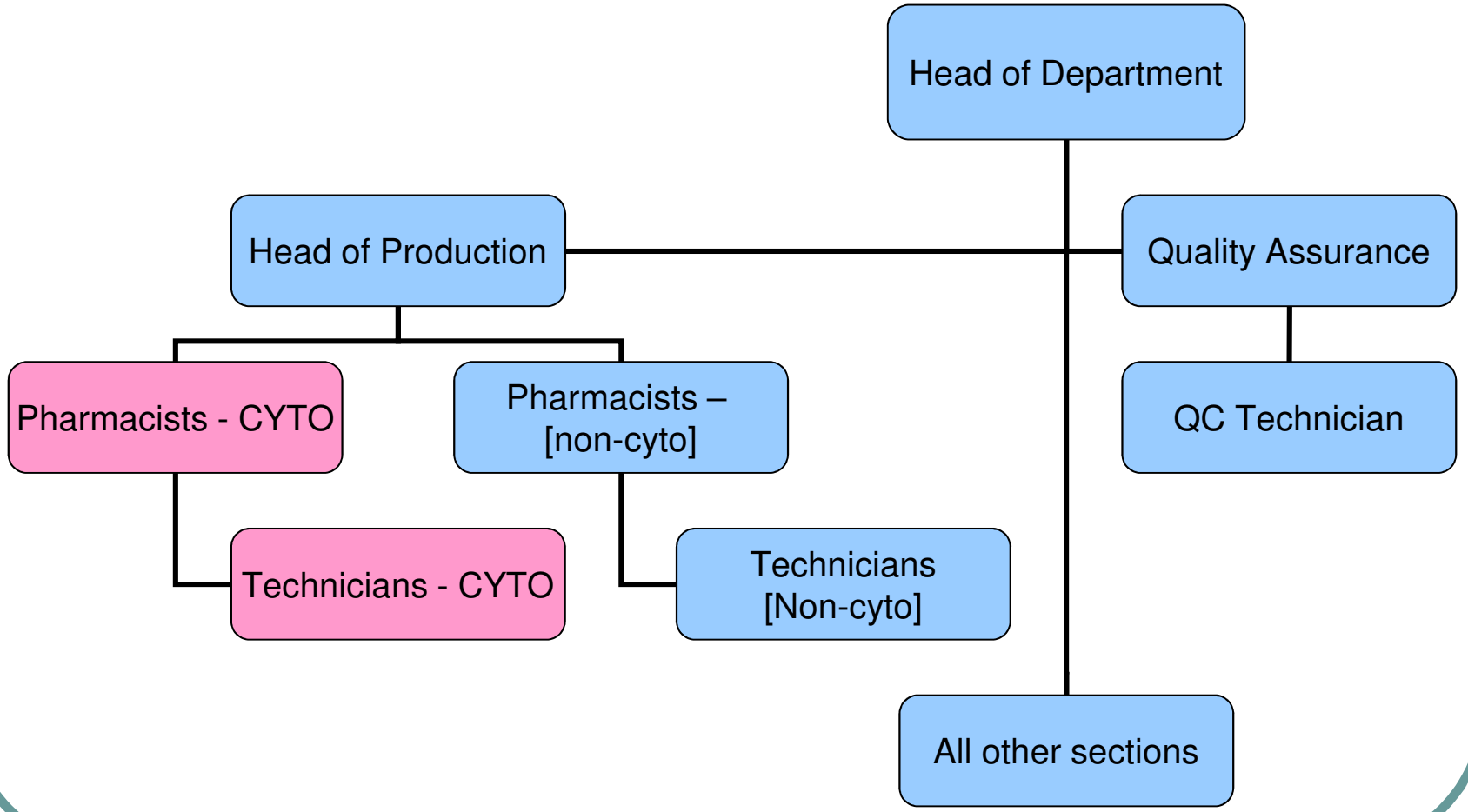
Electronic prescribing system – annual review/update

QC equipment – annual calibration

Personnel – Refer to QC monitoring

Cleaning – initial validation/on-going monitoring

Organogram – Cytotoxic Unit



Organogram

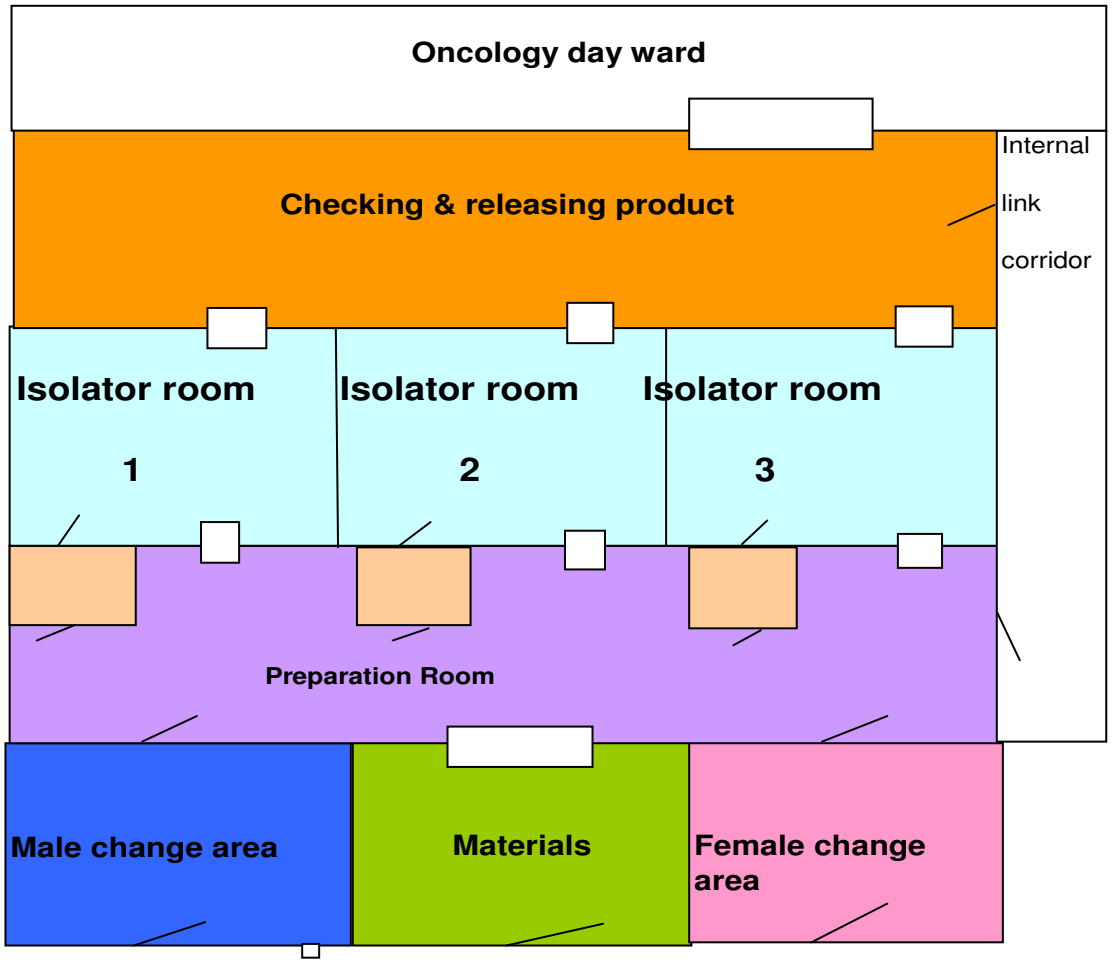
Staff numbers

- Technicians: 6 (operation number x 1.3)
- Pharmacists: 1.5
- QA – 0.5
- Head of production: 1

Facility:

- Number of rooms with isolator- 3 – Grade D

Floor plan


Oncology day ward
Internal
link
corridor
Checking & releasing product
Isolator room
1
Isolator room
2
Isolator room
3
Preparation Room
Male change area
Materials
Female change
area

Process

- Prescription – verified by clinical pharmacist
- Receipt of Rx in manufacturing unit
- Generation of production documentation
- Production & labeling
- Product check & release
- Dispatch

QC Monitoring

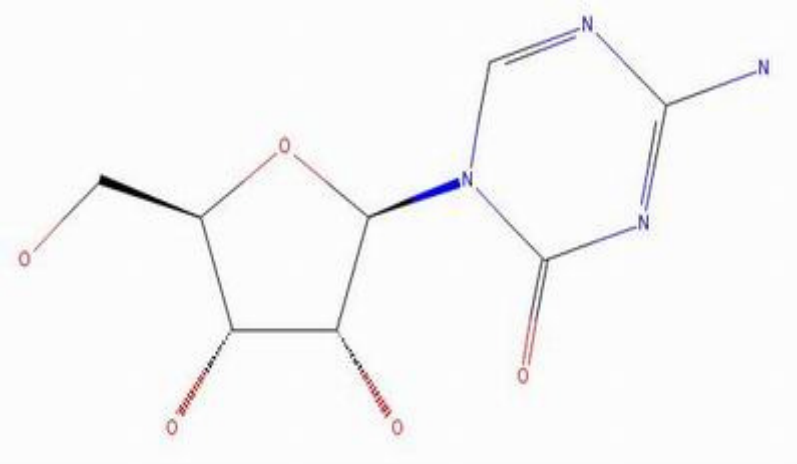
- Process Simulation – daily
- Environmental monitoring –
  - Sessional – in critical areas – settle plates and finger dabs
  - Weekly - active air sampling; swabs – all surfaces; particle counting - one room per week
  - All incubation, testing and reporting outsourced – contract with the QC lab (external to the hospital) and annual audit
  - Trending results – reviewed on a monthly basis

From the general to the specific

Azacitidine

- Clinical need – decided by doctor and pharmacist for Myleodisplastic Syndrome
- Funding approval
- Formulation: ***Syringe***
- Bolus related side effects
- Stability: ***60 minutes – Room temperature***

  (90% available at 60mins)



QC & Monitoring

Drugs and materials:

- Azacitidine (Vidaza®)= registered product
- Diluent: WFI = registered product
- Syringe and cap CE marked

No QC required on starting materials.

Technician skills: GMP training

Aseptic technique (personnel):

1. Validation – broth test – worse case simulation – 30 manipulations
2. On-going monitoring of staff – daily finger dabs; reassessment of aseptic technique.

Drug Development

- Packaging: Plastic syringe & stopper
- Health & Safety: Cytotoxic
- Training: Emphasis on importance of dilution time and patient treatment time
- Future development – Azacitidine administered daily for 7 days – made daily – expensive. Can the azacitidine solution be frozen and defrosted prior to administration – make in advance and vial save.

Process Risk Assessment - Azacitidine

Risk (>20)	Severity	Occurance	Detection	Total
Wrong drug	5	1	1	5
Wrong diluent	5	3	1	15
Wrong dose	3	1	1	3
Contamination - product	**5**	**1**	**5**	**25**
Wrong patient - label	**5**	**3**	**3**	**45**
Staff health & safety	**5**	**1**	**5**	**25**

Risk 1

Wrong patient – label problem

Preventative measures:

Electronic prescribing process – automatic label generation.

Risk: Label mix-up

Action: one in/one out

Future: Closed cycle – e.g. barcoding

Risk 2

Product contamination

Microbiological:

Processes in place:

Staff: Training; re-accreditation; validation

Equipment: Validation, monitoring & maintenance programme in place.

Additional actions for new product not required.

Risk 3

Staff health & safety

Processes in place:

Staff: Training; re-accreditation; validation; SOPs; Using closed systems – needlestick injury risk low; consider staff rotation

Equipment: Validation, monitoring & maintenance programme in place.

[Consider establishing/contributing to risk register.]

Conclusion

From ward to pharmacy –

Better, Faster, Safer

Just Do It...