



Establishing a new Oncology Pharmacy

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The Vision

The Wits DGMC is an independent South African university hospital committed to providing the best patient care as well as advancing specialist training and research.

The Wits Donald Gordon Medical Center

- The Wits DGMC has been made possible thanks to a major founding donation of the Donald Gordon Foundation and a contribution from the University of the Witwatersrand.
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The Wits DG Medical Center

- The private oncology practice of Dr Ruff and partners, decided to move from a private facility in Rosebank to the Wits DGMC
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The Oncology Pharmacy Design

- I was asked to assist in the Oncology Pharmacy design
 - This task was undertaken working in close association of the Architects Mally Rall and Reynier Krause who have had a lot of experience with hospital designs
 - Air Filter Maintenance Services experts in clean room design, installed the Air-Conditioning and Ventilation systems
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Information

- As there is no South African Government standard or inspection of oncology clean rooms I asked the architects to design the pharmacy using, as reference
- ,Quality Standards for Oncology Pharmacy Service QuaposS 3 , Standards Australian, and and an article” Human resource issues in cytotoxic drug dispensing” from the Journal.Oncol.Pharm.Practice vol3 No4 1997.pp200-218

International Society of Oncology Pharmacy Practitioners (ISOPP)

- I would like to thank the many colleagues, members of ISSOP, around the world, who gave me valuable information on specific problems that were encountered
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SASCRO

- To day SASCRO issues a certificate of accreditation for a chemotherapy facility after making an inspection to check that the clinic complies with set standards
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Human Resource Issues

The following issues were considered for the design of the pharmacy:

Physical Conditions

- ✓ Temperature
- ✓ Size
- ✓ Comfort at the workbench
- ✓ External Windows
- ✓ Telephone & Radio

Workflow

Physical Conditions

- Temperature Control

The wearing of Protective clothing (coats gloves masks hats) and the heat generated by the motor blowers of the Biohazard Cabinet required that the temperature in the clean and ante rooms should be adjustable to lower than normal levels

- Size of Rooms.

The minimum requirements found in standards, for room size ,room height , freedom of movement and minimal separations were taken into account

Physical Conditions

- Comfort at the work bench

The type of chair and the height of the workbench was considered

- External Window, Telephone ,Radio

It was felt that the provision of natural light in the work place provided by the external window, communication, by the telephone and by bringing the outside world into the isolated work environment with a radio, would make it easier to work in the clean room .Visual contact between rooms was also important

Work Flow

- Clinic

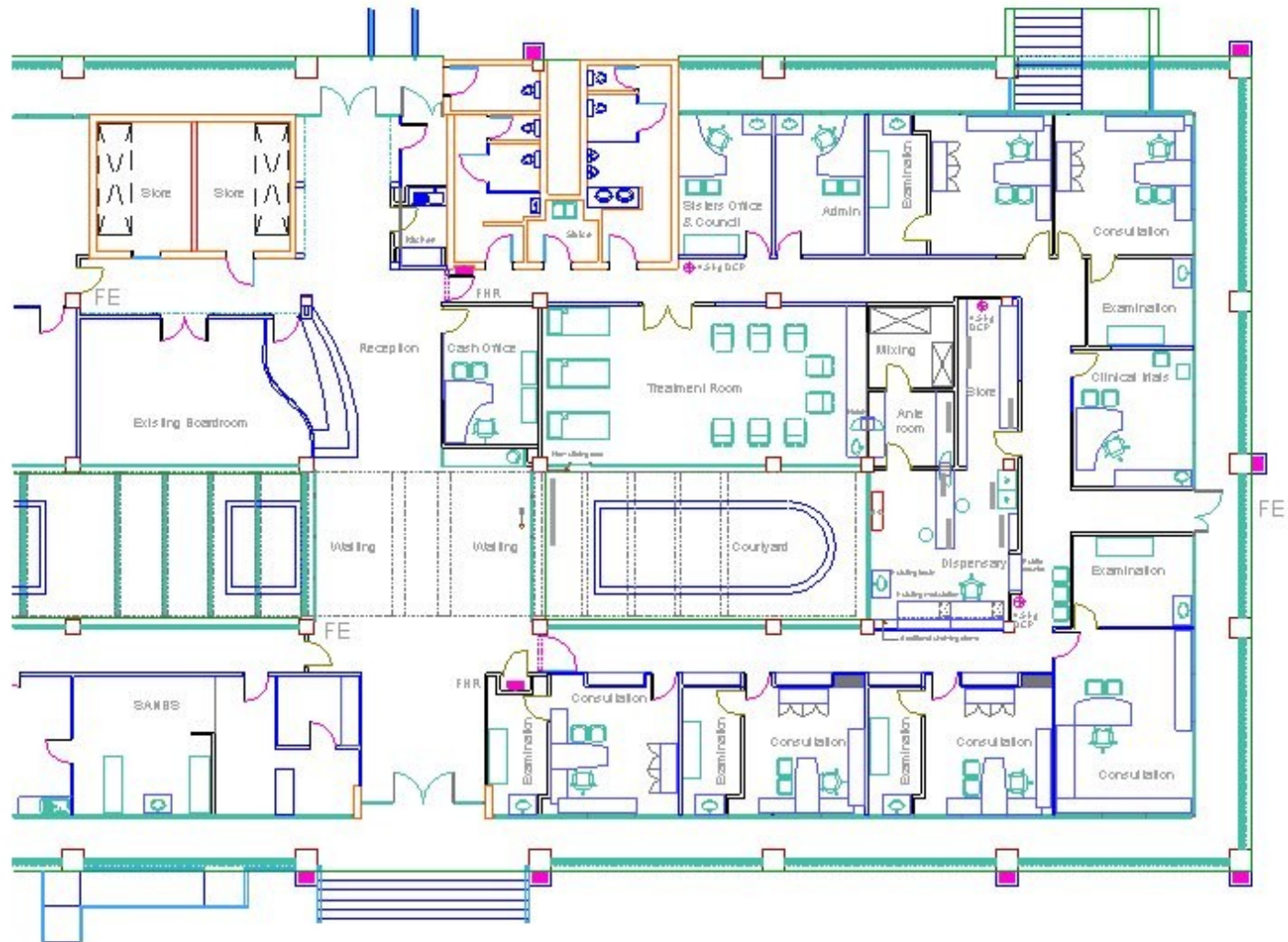
- Pharmacy

Design of Clinic

Included in the design are:

- Doctors consulting rooms
 - Clinical sisters office and counseling area
 - Clinical research office
 - Accounts office
 - Waiting area
 - Staff tearoom
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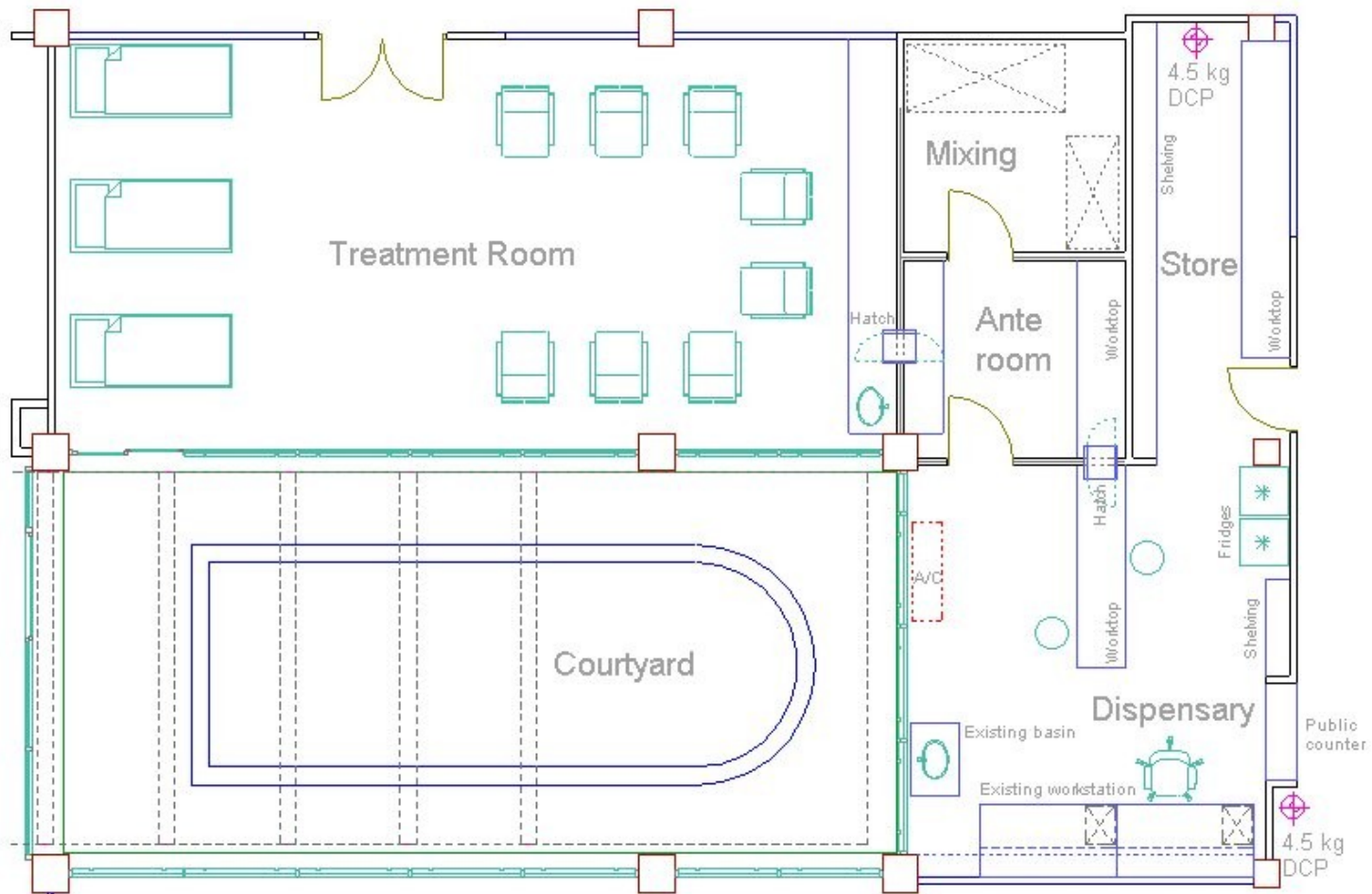
Clinic



Design of Pharmacy

- The pharmacy consists of:
 - ✓ A dispensing area
 - ✓ Ante Room
 - ✓ Mixing Room
 - ✓ Storage Facility/Filing Room
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Pharmacy



Construction

- ✓ For Room surfaces vinyl was used on floors with vinyl and enamel paint on walls that can withstand repeated cleaning & disinfecting. Work surfaces are of a smooth material
 - ✓ Doors have closures & elbow operated handles
 - ✓ The ceilings were not of unitary construction as the exhaust piping could not be housed in the ceiling of the clean room & the light fittings are not flush with the ceiling
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Construction

- ✓ There is a Store room and filing room
 - ✓ Refrigerators with minimum and maximum thermometers in the dispensary
 - ✓ Back up generator in case of power failure is available
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Air Supply

- Air supply to the anteroom pass through HEPA Filters .
- The clean room is served by both supply and exhaust air .
- The exhaust air quantity is adjusted so that the required pressure differentials are achieved. A capture hood is used above the biohazard cabinet to exhaust air through a HEPA filter & a Carbon Filter

Pressure Differentials

- The clean room operates at a pressure of 10 Pa and the ante room at 30 Pa
 - Air Flow goes from the ante room to the clean room and exhausted through exhaust system to the atmosphere
 - The rooms are relatively airtight allowing pressure differentials to be maintained
 - Door seals where necessary
 - Windows do not open
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Air Conditioning

- Air supplied to the filter and blower units from the air-conditioning plant is capable of providing cooling & heating requirements .
 - The air-conditioning plant is equipped with pre-filters at the outside air inlet to protect the 2 HEPA Filters that purify the inlet air to the clean room and anteroom
 - Humidification was found not to be necessary
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The Extraction System

- The antiblow back unit is used to prevent any possibility of outside air entering the extraction duct in the event of fan failure and pressurizing the biohazard cabinet
- In line with the extraction system is a final HEPA filter
- The extraction system is monitored by pressure switches and alarms. In event of a low or unsafe extraction rate an audible alarm is given off.
- The overall system was validated to prove conformity and is repeated bi-annually.

Particle Count

- The cleanliness class of the Biohazard cabinet and the rooms have shown to have a Class 100 for the laminar flow bench and 1000 for the rooms
 - Aseptic techniques are strictly adhered to
 - Cleaning protocols are in place
 - Bin for chemo waste and a sharps container are available in the preparation room
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Biohazard Cabinet

- The Cabinet in use is a Biological Safety Cabinet Class 2 Type A with a thimble anti blow back duct.

Air flow is drawn around the operator into the front grill of the cabinet which provides personal protection ,downward laminar flow of HEPA-filtered air protects product by providing particulate –free air to the work surface.Laminar airflow reduces turbulence in the work zone minimizing the chance of cross contamination along the workbench and environmental protection is achieved by HEPA- filtered exhausted air from the cabinet

The Biohazard Cabinet

- It was felt that an additional safety measure was achieved by installing an exhaust system containing both a HEPA & Charcoal Filters.
 - A canopy hood with a small space above the cabinet exhaust was put in place The volume of the exhaust was adjusted so that it did alter the balance of the cabinet exhaust system.
 - The cabinet is on casters so it can be moved to allow for testing of hood.
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Biohazard Cabinet

- No additional HEPA cassette filter stages are fitted underneath the work bench, as this technology is not yet available in SA .
 - As the Cabinet was moved from our Rosebank rooms to the new center it had to be validated after air flows were adjusted to proper levels.
 - Test are done for bacterial & fungal contamination.
 - The cabinet operates continuously
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Personal Protective Equipment

- A protective disposable gown made of lint-free low-permeable fabric with protected front long sleeves and tight fitting knit cuffs are used
 - Powder free single gloves changed every 30 minutes are used
 - Syringes Luer-Lock type fittings are in use
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Standard Operating Procedures

- Minimum Standards for Handling ,Preparation of cytotoxics

(Formulated and adapted for our clinic from various references & updated at regular intervals)

- SOP from Good Pharmacy Practice in SA that gives guidelines cold chain management,stock control etc.
- Cleaning procedures and handling of spills
- Management of Extravasations and Anaphalaxes
- Transportation &handling of Cytotoxic drugs by lay personnel

Documentation

- Pathology reports FBC, LFT U&E & Creatinine.
 - Validations of Cabinet
 - Microbiology: Bacterial & Fungal monitoring
 - Needle sticks
 - Staff rotation records
 - Prescriptions
 - Spills
 - Temperature logs
 - Drug information
 - Extravasations
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Continuing Education

The staff is encouraged to continue their education in the following ways:

- To resource from text books , from drug companies and the Internet
 - Attending and taking part in symposia
 - Subscribing to a journal
 - Joining ISOPP
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Clinical Studies

- Start Up Meetings
 - Drug Accountability
 - Temperature logs
 - Correct storage
 - Preparation
 - Trial Drug Information
 - Trial protocol
 - Distribution and destruction
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The South African Pharmacy Council

- The pharmacy was registered by the Council as a Community Pharmacy with a condition that the Pharmacy will specialize in Oncology
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Conclusion: Standards not met:

- No variable speed blowers to enable the air system to be balanced and permit the blower speeds to be adjusted to compensate for increased pressure drop as filters become loaded
- No Air Lock
- No alarm if blowers fail, except for exhaust system that is fitted with an Alarm & Gauge
- No pressure switches but separate switches for Exhaust, Anteroom Clean room & Main power

Conclusion

- Pass through hatches do not interlock
 - Exhaust system ducting could not be put in ceiling thus causing a dust hazard in the clean room. This was overcome by boxing the exhaust piping.
 - The light fittings are not flush with the ceiling
 - Biohazard Cabinet contains no under bench filter to comply with latest standards for Cabinets
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Although not all expectations were met because of financial constraints and technical difficulties it is felt that the final results where satisfactory





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