Disaster Management Planning for a Cellular Therapy Laboratory

Lessons Learned from the Brisbane Floods 2011

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Outline of Presentation

- Why disaster & contingency planning is required for Cellular Therapy facilities.
- Methods for formulating a disaster / contingency plan.
- Examples of disaster / incident prevention, mitigation, response and recovery experienced by staff of the facility.
- Lessons learned from the January 2011 flood of the Brisbane River.
Definition of Disaster

- “A sudden accident or a natural catastrophe that causes great damage or loss of life”.
- Disasters may be natural or man-made.
- “Strictly speaking, there are no such things as natural disasters, but there are natural hazards. A disaster is the result of a hazard’s impact on the society..” John Twigg, *Living with Risk: a Global Review of Disaster Reduction Initiatives*
- In Australia, the term Emergency Management Plan may be used interchangeably with Disaster Management Plan.
Disaster Management Plan
Hierarchies - Government
Disaster Management Plans

- **Prevention / Mitigation**
  - The taking of preventive measures to reduce the likelihood of an event occurring or, if an event occurs, to reduce the severity of the event.

- **Preparedness**
  - The taking of preparatory measures to ensure that, if an event occurs, communities, resources and services are able to cope with the effects of the event.

- **Response**
  - The taking of appropriate measures to respond to an event, including action taken and measures planned in anticipation of, during, and immediately after an event to ensure that its effects are minimised and that persons affected by the event are given immediate relief and support.

- **Recovery**
  - The taking of appropriate measures to recover from an event, including the action taken to support disaster-affected communities in the reconstruction of infrastructure, the restoration of emotional, social, economic and physical wellbeing, and the restoration of the environment.
Disaster Management Plan
Hierarchies – Institutional
Organisational Disaster Management Plan - Response

- Emergency Contact Numbers
- Emergency Management
- General Emergency Response
- Emergency Fire Evacuation Procedure
- Evacuation Communication Procedure
- Fire Fighting Equipment & Procedures
- Fire Extinguisher Use
- First Aid
- Medical Emergency
- Hazardous Materials
- Hazardous Material Emergency Procedure
- Bomb Threat
- Information, Training and Instruction
- Site Plan
- Evacuation Plan
- First-Aid Staff Register
- Training Register
- Dangerous Goods / Hazardous Chemical Register
- Emergency Response Drills
Institutional Disaster Management Plan - Response

Code Yellow - Internal Emergency
Code Black - Personal Threat
Code Brown - External Emergency
Code Red - Fire Emergency
Code Purple - Bomb / Arson Threat
Code Orange - Evacuation
Code Blue - Medical Emergency
Disaster Management Plan
Hierarchies – Processing Facility

• Many disaster or emergency scenarios are covered by the institutional disaster management plan but preparedness and response to disasters may require a facility specific approach eg. fire.

• Processing facilities need a plan that:-
  • specifically integrates with the institutional disaster management plan, and
  • addresses facility specific issues.
Necessity for Disaster Planning in a Cellular Therapy Facility

- Recipients of cellular therapy products such as HPC have been conditioned for allogeneic or autologous transplantation with radiotherapy and/or chemotherapy
  - Consequence of non-infusion may be fatal.

- Large scale investment in banked CT products.

- Staff of cellular therapy facilities often work in an environment containing large amounts of stored liquid nitrogen
FACT-JACIE CT Standards

- **D5.1** The Processing Facility shall establish and maintain policies and/or procedures addressing critical aspects of operations and management in addition to those required in D4. These documents shall include all elements required by these Standards and shall address at a minimum:
  - **D5.1.22 Emergency and disaster plan**, including the Processing Facility response.

- **D4.12** The Quality Management Plan shall include, or summarize and reference, policies and procedures for actions to take in the event the Processing Facility’s operations are interrupted.
FACT- Netcord CB Standards

C3.3 There shall be policies and Standard Operating Procedures to cover at least the following:

C3.3.13 Facility management including supplies, maintenance and monitoring of equipment, cleaning and sanitation procedures, disposal of medical and biohazardous waste, emergency and safety procedures, and a disaster plan.

B11 INTERRUPTION OF OPERATIONS AT ESTABLISHED SITES
NATA Requirements

- S1.9 A disaster response plan must be documented.
Disaster Plan / Continuity of Operations Plan

- CT Processing Facilities need to:
  - be prepared for any disasters or interruptions that do not rise to the disaster level.
  - ensure interruptions do not adversely affect recipients, donors, cellular therapy products or staff.

- Disaster Management Plan
- Contingency Plan or Continuity of Operations Plan
Disaster Management Plan

- The DMP should recognise the separate disaster risk management components of risk assessment (identify the risks & their impact) and risk treatment options of prevention or mitigation, preparedness and response to minimise the impact of, or if possible, eliminate the resulting risk.
Disaster or contingency plan management involves a cyclical process of four phases:

- Prevention: regulatory, physical or operational measures to prevent disasters / incidents, or mitigate their impact
- Preparedness: arrangements made to ensure all necessary resources and services are available to maintain essential services when possible
- Response: actions taken during and immediately after a disaster or incident to minimise its impact
- Recovery: arrangements to restore the facility to normal as quickly and efficiently as possible
Disaster Management Plan – Identify the Risks

- Difficult to anticipate every possible situation that may occur.
- Prepare a risk analysis that includes a range of possible disasters, including natural, technical and human hazards or threats.
- Prepare an impact analysis to determine the potential consequence.
- Estimate the impact associated with several disaster scenarios - provide for the “worst case”
- Evaluate the safety of critical documents and records.
Identification of Potential Natural & Man-Made Disasters

- Cyclone
- Severe Thunderstorm and Associated Microbursts
- Flood
- Fire
- Illness / Pandemics
- Terrorism
- Physical Damage to Facility
- Volcanic Eruption

Disasters may affect the operation of a cellular therapy facility either locally or from a great distance.
Interruption to Operations

- Power Outage
- Network Interruption / Computer Downtime
- Critical Equipment Failure
- Critical Supplies Shortage
- Availability of Trained Staff
Identification of Impact of Disasters on CT Facility

- Inability to provide haemopoietic progenitor cells to patients conditioned for transplant resulting in death of the recipient
- Physical damage to facility with total destruction as worst case scenario
- Loss of records (paper and electronic)
- Inability of staff to attend work (physical or health related)
Prioritisation of Essential Functions

- List and prioritise the procedures performed in the facility
  - Essential procedures that must continue with no or minimal disruption
  - Important procedures that may continue dependent upon the availability of resources
  - Non-essential procedures that may be suspended
- List all the critical supplies, equipment and staff trained to perform these procedures.
- Determine the maximum amount of time that operation may continue in the absence of critical supplies, equipment & staff.
  - How long may the facility store HPC in the absence of LN2 deliveries?
  - What is the static holding time of LN2 tanks and availability of LN2 on-site?
Define and Prioritise Essential Functions of the Facility

- Availability of fresh or cryopreserved HPC for infusion into patients who have commenced conditioning for transplant. Potential fatal consequence - ESSENTIAL
- Maintenance of the long term storage integrity of cryopreserved products e.g. HPC. Potential fatal consequence if patient requires transplant - ESSENTIAL
- Maintenance of laboratory processing records. Potential fatal consequence if records damaged - ESSENTIAL
- Reception, testing, processing (and cryopreservation) of HPC. Potential fatal consequence if allogeneic transplant / may be delayed if autologous donor – ESSENTIAL / IMPORTANT but may be delayed
- Provision of autologous serum eyedrops. NON ESSENTIAL
- Other laboratory duties such as chimerism analysis, viable CD34 analyses. NON ESSENTIAL
Alternative Strategies in a Disaster or Interruption

- Propose, test and validate alternative strategies for operation when a critical procedure cannot be performed
  - Eg. Breakdown of controlled rate freezer.
  - Flow charts may be useful for formulating alternative strategies.
- Staff should have periodic training of any alternate procedures for use in an emergency to ensure competence should the need arise.
- Staff training and practice to execute emergency operation plans should be documented.
- Ensure policies, procedures and associated worksheets are available to Processing Facility staff at all times.
  - Paper copies in the absence of electronic systems
Disaster Management Plan

- Should describe generic actions to take when a disaster or interruption to operation presents.
- Should document:
  - Responsibility for communication / notification.
  - Contact details:
    - Consultants, collection centres, registry, transplant coordinators, vendors, equipment providers, hospital security, emergency services.
  - Responsibility for prioritisation of duties and identification of alternative strategies to continue operation of the facility.
With preparation, a facility should be capable of implementing disaster or contingency plan with and without warning.
Resumption of Operation

- Responsibility for setting priorities for reestablishment of operation and return to normal operating conditions.
  - Vendor contacts for re-establishment of critical supplies and repair of equipment
  - Organisation of building repairs
  - Restoration of electronic records
  - Analysis of the facilities response to disaster or interruption and implementation of corrective & preventive actions to ensure that the facility is better prepared for any future events.
Risk of Fire in Processing Facility

- Extreme risk - HPC in refrigerated or LN2 storage for patients who have commenced conditioning for allogeneic or autologous transplant
- High risk - HPC in LN2 storage for patients who may proceed to allogeneic & autologous transplant
Institutional Fire Preparation and Response

- Mandatory fire training
- Fire practice drills
- Fire Wardens
Fire - Non-cryopreserved HPC

- On evacuation order, the safety of patients and staff is of highest priority.
- Non-cryopreserved HPC in the blood product refrigerator are placed inside preconditioned temperature shells at 2 - 8°C, transferred to a “Blood In Motion” cooler and removed from the building by on call scientist (Responsibility - Fire Warden).
- Adequate stock of preconditioned temperature shells maintained in laboratory.
Non-cryopreserved HPC
Fire - Cryopreserved HPC

- Cryopreservation storage facility located 2 levels below laboratory in a modern compartmentalised building (11 large LN2 storage vessels).
- Cryopreserved HPC for recipients of an allogeneic or autologous transplant are transferred during the bag integrity check into a designated section of a “released HPC” inventory tank prior to commencement of recipient conditioning.
Location of Release Racks

- Cryomed 1
- Cryomed 2
- Cryomed 3
- Cryomed 4
- Cryomed 5
- Sink
- Control Panel
- Emergency Shut Down
- Exhaust Fan
- Spare PLCs & Dry Shippers
- Hose for Manual Filling
- Phone
- Emergency Shut Down

- O₂ Sensor Display
- -80°C Freezer
- CBS 6
- CBS 7
- CBS 8
- CBS 9
- CBS 10
- CBS 11
- Door

O₂ Alarm (Flasing Light) Outside Above Door
Fire - Cryopreserved HPC

- Arrangements made with Security Staff / Fire Wardens to notify laboratory if fire alarm activated.
- Access permitted for on call scientist to retrieve HPC from cryopreservation facility (if safe).
- On evacuation order, cassettes containing HPC are transferred to a dry shipper and evacuated from the building by on call scientist (Responsibility - Fire Warden).
- “Charged” dry shippers maintained at all times.
Fire - Cryopreserved HPC for Conditioned Recipients
Risk During Transportation of HPC

- Critical but often overlooked process in the provision of HPC for allogeneic transplantation using voluntary unrelated donors and occasionally related donors especially when HPC must be retrieved from overseas destinations with 24h+ flight times and multiple flight changes.

- Recipient conditioned – scientist accompanies HPC
Transportation of HPC Metropolitan Area

- Transportation of non-cryopreserved HPC between collection centres & processing laboratory is provided by external couriers (autologous HPC) or scientists (allogeneic HPC).
- HPC is transported in clearly labelled Blood In Motion coolers
- Datalogged
- Delays – traffic gridlock & flood
Couriers of HPC – Allogeneic Transplantation

- Training of couriers to ABMDR Guidelines (Policies and Procedures for Couriers of Haemopoietic Stem Cells) & Institutional SOPs
- Provision of communication devices suitable for use in country of collection
- Courier Manuals (for overseas / interstate travel)
  - Quarantine Permits
  - Prescription / Verification
  - Flights & accommodation
  - Detailed delivery instructions
  - Extensive contact lists
  - Maps
  - Instructions
  - IDMs
Snow storm at London Heathrow resulting in flight from Singapore to LHR returned to Bangkok. DLI collection delayed for approximately 4 weeks.
Eyjafjallajökull / Puyehue-Cordón Caulle
Eyjafjallajökull

- Collection centre of HPC, Marrow for European transplant centre
- Collection proceeded following communication between donor-recipient registries / centres
Eyjafjallajökul

- Flights from Brisbane to European centre (& most of Europe) cancelled on day of collection and for approx 1 week
  - Courier unable to depart or obtain alternative flights
- HPC, Marrow – buffy coat & cryopreservation
- Shipped to southern Spain with arrangements to transport by truck to transplant centre
  - Transported by aircraft to transplant centre during break in ash cloud
- Recipient infused and engrafted.
Dresden Flood 2002
Dresden Flood 2002

- Courier scheduled to depart by ICE train
- Dresden Main Railway Station submerged by time of HPC collection & scheduled departure
- Urgent alternative travel arrangements
“Incident” on morning that courier was scheduled to retrieve HPC from interstate collection centre.
Transportation of Cryopreserved HPC for Infusion

- Cord Blood Units from Cord Blood Banks – Recipient conditioning should never commence until cord blood unit is receipted & bag integrity checked by processing facility.

Photos provided by Vicki Antonenas, Westmead
Loss of Liquid Nitrogen Supply

- A constant and reliable supply of LN2 is essential for long term cryopreservation of HPC products.

- The vendor of LN2 has-
  - a policy of treating medical emergencies with the highest level of priority
  - negotiated alternative transport routes during floods and road closures
  - arranged for deliveries of LN2 from interstate when their manufacturing site inoperable.
Loss of Liquid Nitrogen Supply

- Although LN2 reticulated from bulk supply to storage tanks, several PLCs maintained to overcome delay in supply.
Liquid Nitrogen Spillage

- Adequate warning signs
- Secure restricted separate facility
- Oxygen sensors – wall mounted
- Oxygen sensors – personal
- Emergency ventilation / extraction activated by oxygen sensor alarm trigger
- PPE
- Weekly testing of alarms
- SOPs for staff working in liquid nitrogen facility (on site written instructions)
- Training in liquid nitrogen handling
Safety Features To Minimise Impact of LN2 Spill
Safety Features To Minimise Impact of LN2 Spill
Failure of Critical Equipment

- Cryopreservation
  - Controlled rate freezer
  - Liquid nitrogen storage tanks

- HPC processing
  - COBE 2991
  - Biosafe Sepax
  - Terumo Spectra Optia
Failure of Essential Equipment – Controlled Rate Freezer

- Malfunction of solenoids may result in a sudden temperature plummet and loss of CD34+ cell viability.
- Staff should be remain within vicinity of CRF to retrieve HPC if malfunction during freezing.
- In the event of non-operation & if DMSO not added:
  - Validated passive freezing SOP
  - Transfer to another processing facility
  - Storage at 2-6°C until service scheduled.
Failure of Critical Equipment
Failure of Critical Equipment

Back up empty LN2 storage tank
Alternative: Vendor arrangements if tank can be provided within acceptable timeframe
Data Loss / Electronic & Paper Records

- Hospital network drives
  - Responsibility of hospital IT staff
  - Drives backed up nightly at 20:00
  - Data retained for 7 years

- Offsite archiving of laboratory patient files (in conjunction with paper patient medical records)

- Electronic data & record recovery must be validated and tested regularly
Absence of Scientists Competent for Processing HPC

- Food Poisoning – 2 occasions after functions attended by laboratory staff
- Influenza
- Inability to travel to work (flooding events)

- HPC collection may be stored for up to 48h in a blood product refrigerator (validated)
- Use of alternative processing facilities
- Referral of some tests to private laboratories
- Prioritisation of procedures depending upon urgency
Brisbane River Flood – January 2011
Wivenhoe Dam / Brisbane River Flood – January 2011
The flooded Brisbane River spills into residential areas close to the CBD. Photo: REUTERS/Tim Wimborne
South Bank is flooded on January 13. Photo: REUTERS/Tim Wimborne
Floodwaters cover streets in Brisbane’s CBD early on January 13. Photo: Michelle Smith
Impact of 2011 Brisbane Flood

- 35 people deceased
- 5488 houses inundated above floorboards
- 21,144 houses received some form of inundation
- 3572 businesses inundated
- 3600 houses evacuated
- 5912 people evacuated
- 148 schools flood affected
Areas of Inundation – January 2011
Management of Flooding Event by CTL (12/01/11)

- Code Brown - All visitors left hospital at approx. 10am
- Quiet time in BMT Unit due to school holidays
- No related or unrelated donors scheduled
- Autologous HPC, Apheresis at collection centre south of river was suspended due to concerns regarding delivery to processing facility and staff availability to process.
- Staff left at midday except one scientist resident in close proximity to hospital - managed alarms.
Impacts for CTL

- Laboratory “closed” for 2 days.
- Access to hospital for staff especially for those living south of the river.
- Triggering of multiple alarms in laboratory and LN2 facility.
- Communication problems (did not have all the contact numbers required).
- Concern about family, friends, relatives whose houses were inundated.
- Company storing archived records required to move records during middle of night.
Hospital Problems

- Communication issues with switchboard.
- Unreliability of automatic and switchboard-initiated pages.
- Multiple electrical fluctuations between the mains and emergency power supply over 4 days.
- Power fluctuations triggered multiple alarms within the laboratory and liquid nitrogen storage room necessitating repeated action by a scientist.
Protection of Records

- Archived Laboratory Processing Records are Heat Sealed in Protective Plastic Bags
Laminated Communication Leaflets

- Responsibilities
- Contact numbers

- Staff member to remain on site during designated Code Brown events (if possible & required).
Queensland floods: disaster plan a disaster

BY AMANDA GEARING | APR 29, 2011 1:18PM | EMAIL | PRINT

A young shire engineer in Gatton pointed out the failure of the local council to have current disaster plans four months before the flash-flood disaster on January 11 which killed 22 people in the shire (of whom three are still missing) and destroyed more than 100 houses.

Justin Fisher’s report is eerily foreboding: “... little work has been done to improve (council’s) disaster response capability ... there have been no (disaster management group) meetings for 12 months, the Local Disaster Management Plan requires updating, there are no ... sub-plans for emergencies where council is the lead agency and there is no dedicated disaster response command centre.”
Our Disaster Recovery Plan Goes Something Like This...
ASBMT COMMITTEE REPORT
Preparing for the Unthinkable: Emergency Preparedness for the Hematopoietic Cell Transplant Program

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GUIDELINE
World Marrow Donor Association Crisis Response, Business Continuity, and Disaster Recovery Guidelines

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