Acute Radiation Syndrome Treatment Guidelines

September 2010

Please forward comments or suggestions to C. Case at ccase@nmdp.org
Principles of ARS management at RITN centers (1)

1) After a nuclear detonation, RITN and other cancer/blood and marrow transplant (BMT) centers may receive large numbers of irradiated victims, especially those with little or no trauma or burns.

2) The goal of pre-event planning and post-event management is to maintain a “functional equivalent” of routine care for both victims and existing patients.

3) Biodosimetry can predict prognosis and need for treatment.

4) Prioritization for myeloid cytokines (e.g. G-CSF) and other key resources may be necessary due to limited supply.

5) Patient tracking and family re-unification will be key objectives.

6) Many evacuated patients will not require hospitalization, and thus outpatient facilities for housing and care will be required.

7) Current planning includes patient decontamination prior to transfer to RITN centers. However, RITN centers should have plans to confirm adequate decontamination upon transfer.
Principles of ARS management at RITN centers (2)

If adequate resources are available, management of victims with ARS should utilize the same approaches and decision points as for patients with cancer receiving myelosuppressive therapy, including:

1) Hospitalization, if necessary
2) Prophylactic antibiotics and myeloid cytokines
3) Central venous access
4) Management of emesis, gastrointestinal toxicity and nutrition
5) Reverse isolation and dietary restrictions
6) Irradiated and leukocyte-depleted transfusions
7) Pediatric care

Guidance on additional radiation-related issues, including internal decontamination, biodosimetry, template admission orders and event response are available at: www.remm.nlm.gov.
NOTES: Expected response to a nuclear detonation. This stylized diagram illustrates the expected flow of victims from the effected area to specialty centers around the country, including RITN. The injury pattern and required resources will vary depending on the location relative to the blast. Victims are expected to undergo decontamination prior to triage for evacuation.
Altered standards after a nuclear detonation
## Radiation Injury Treatment Network Acute Radiation Syndrome Treatment Guidelines

### Incident demand / resource imbalance increases
- Risk of morbidity / mortality to patient increases

<table>
<thead>
<tr>
<th>Space</th>
<th>Conventional</th>
<th>Contingency</th>
<th>Crisis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Usual patient care space fully utilized</td>
<td>Patient care areas re-purposed (PACU, monitored units for ICU-level care)</td>
<td>Facility damaged / unsafe or non-patient care areas (classrooms, etc) used for patient care</td>
</tr>
</tbody>
</table>

| Staff       | Usual staff called in and utilized | Staff extension (brief deferrals of non-emergent service, supervision of broader group of patients, change in responsibilities, documentation, etc) | Trained staff unavailable or unable to adequately care for volume of patients even with extension techniques |

| Supplies    | Cached and usual supplies used    | Conservation, adaptation, and substitution of supplies with occasional re-use of select supplies | Critical supplies lacking, possible re-allocation of life-sustaining resources |

| Standard of care | Usual care | Functionally equivalent care | Crisis standards of care |

### Usual operating conditions
- Indicator: potential for crisis standards

### Austere operating conditions
- Trigger: crisis standards of care

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**NOTES:** Institute of Medicine Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations (http://www.iom.edu/Reports/2009/DisasterCareStandards.aspx). The table describes the transition across different Standards of Care at individual medical venues, based on the discrepancy between available resources and need. Transition from conventional (normal operations) to contingency indicates a functional equivalent of routine care through alterations in approach (e.g. repurposing units, extending staff, substituting supplies). In contrast, transition to crisis standards occurs when a functionally equivalent of normal care cannot be maintained (e.g. severely injured victims must be triaged to expectant care) because of inadequate resources. See next slide for further details.

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BOX 2
Conventional, Contingency, and Crisis Capacity

Conventional capacity—The spaces, staff, and supplies used are consistent with daily practices within the institution. These spaces and practices are used during a major mass casualty incident that triggers activation of the facility emergency operations plan.

Contingency capacity—The spaces, staff, and supplies used are not consistent with daily practices, but provide care that is functionally equivalent to usual patient care practices. These spaces or practices may be used temporarily during a major mass casualty incident or on a more sustained basis during a disaster (when the demands of the incident exceed community resources).

Crisis capacity—Adaptive spaces, staff, and supplies are not consistent with usual standards of care, but provide sufficiency of care in the setting of a catastrophic disaster (i.e., provide the best possible care to patients given the circumstances and resources available). Crisis capacity activation constitutes a significant adjustment to standards of care (Hick et al., 2009).

NOTES: Resources, operative standard and time after the event. Hypothetical representation of resource availability (left y-axis) after a nuclear detonation based on location, type of site, and relation to the operative standard of care (right y-axis). Centers close to the site would be immediately impacted and require crisis standards of care. RTR1 are impromptu triage sites established close to the epicenter and may be disbanded after a few days, as salvageable victims are evacuated. Distance from the detonation will be the primary determinant of timing and severity of resource shortages at regional medical centers (MC). Referral centers in other regions (like RITN centers) may experience abrupt resource shortages due to patient transfers or depletion of nationwide supplies that require changes in operative standards. With appropriate pre-event planning and post-event management, these shortages and transfers should not require transition at referral centers to crisis standards.

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Acute Radiation Syndrome

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NOTES: Combined injury increases mortality above radiation alone. Relationship between dose of radiation (rad) and probability of death for radiation alone and combined injuries (i.e., with burn or wound) based on a meta-analysis of animal data. Note that the studies utilized a burn with >40% mortality alone while trauma alone had no mortality. From the DHHS Scarce Resources Project.

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Victim triage after a nuclear detonation
Online algorithms for dosimetry are available at [http://www.remm.nlm.gov/ars_wbd.htm](http://www.remm.nlm.gov/ars_wbd.htm)

### Table 5. Biodosimetry Based on Acute Photon-Equivalent Exposures*

<table>
<thead>
<tr>
<th>Dose Estimate</th>
<th>Victims with Vomiting</th>
<th>Time to Onset of Vomiting</th>
<th>Absolute Lymphocyte Count†</th>
<th>Rate Constant for Lymphocyte Depletion‡</th>
<th>Dicentrics in Human Peripheral Blood Lymphocytes§</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Day 0.5</td>
<td>Day 1</td>
<td>Day 2</td>
</tr>
<tr>
<td>Gy</td>
<td>%</td>
<td>h</td>
<td>( \times 10^9 ) cells/L</td>
<td>k‡</td>
<td>n</td>
</tr>
<tr>
<td>0</td>
<td>–</td>
<td>–</td>
<td>2.45</td>
<td>2.45</td>
<td>2.45</td>
</tr>
<tr>
<td>1</td>
<td>19</td>
<td>2.30</td>
<td>2.16</td>
<td>1.90</td>
<td>1.48</td>
</tr>
<tr>
<td>2</td>
<td>35</td>
<td>2.16</td>
<td>1.90</td>
<td>1.48</td>
<td>0.89</td>
</tr>
<tr>
<td>3</td>
<td>72</td>
<td>2.03</td>
<td>1.68</td>
<td>1.15</td>
<td>0.54</td>
</tr>
<tr>
<td>4</td>
<td>72</td>
<td>1.90</td>
<td>1.48</td>
<td>0.89</td>
<td>0.33</td>
</tr>
<tr>
<td>5</td>
<td>86</td>
<td>1.79</td>
<td>1.31</td>
<td>0.69</td>
<td>0.20</td>
</tr>
<tr>
<td>6</td>
<td>94</td>
<td>1.68</td>
<td>1.15</td>
<td>0.54</td>
<td>0.12</td>
</tr>
<tr>
<td>7</td>
<td>98</td>
<td>1.58</td>
<td>1.01</td>
<td>0.42</td>
<td>0.072</td>
</tr>
<tr>
<td>8</td>
<td>99</td>
<td>1.48</td>
<td>0.89</td>
<td>0.33</td>
<td>0.044</td>
</tr>
<tr>
<td>9</td>
<td>100</td>
<td>1.39</td>
<td>0.79</td>
<td>0.25</td>
<td>0.030</td>
</tr>
<tr>
<td>10</td>
<td>100</td>
<td>1.31</td>
<td>0.70</td>
<td>0.20</td>
<td>0.020</td>
</tr>
</tbody>
</table>

* Depicted above are the 3 most useful elements of biodosimetry. Dose range is based on acute photon-equivalent exposures. The second column indicates the percentage of people who vomit, based on dose received and time to onset. The middle section depicts the time frame for development of lymphopenia. Blood lymphocyte counts are determined twice to predict a rate constant that is used to estimate exposure dose. The final column represents the current gold standard, which requires several days before results are known. Colony-stimulating factor therapy should be initiated when onset of vomiting or lymphocyte depletion kinetics suggests an exposure dose for which treatment is recommended (see Table 7). Therapy may be discontinued if results from chromosome dicentrics analysis indicate a lower estimate of whole-body dose.

† Normal range, 1.4–3.5 \( \times 10^9 \) cells/L. Numbers in boldface fall within this range.

‡ The lymphocyte depletion rate is based on the model \( L_t = 2.45 \times 10^9 \) cells/L \( \times e^{-k(Dt)} \), where \( L_t \) equals the lymphocyte count \( \times 10^9 \) cells/L, 2.45 \( \times 10^9 \) cells/L equals a constant representing the mean lymphocyte count in the general population, \( k \) equals the lymphocyte depletion rate constant for a specific acute photon dose, and \( t \) equals the time after exposure (days).

§ Number of dicentric chromosomes in human peripheral blood lymphocytes.

NOTES: Biodosimetry based on signs and lymphocyte studies. Dose can be roughly estimated based on the presence and time to onset of vomiting, absolute lymphocyte count or the presence of dicentric chromosomes within peripheral blood lymphocytes. Vomiting can result from other factors (e.g., anxiety, pain) and timing relative to exposure will be very difficult to assess, especially for victims in the fallout zone who may be exposed over multiple hours. Dicentric chromosome analysis is only available at select reference laboratories. Estimates of dose will also be available from ground measurements of radiation (i.e., geographic dosimetry), which will be especially valuable for identifying large areas around the detonation with no radiation. Further information and online algorithms for dosimetry are available at [http://www.remm.nlm.gov/ars_wbd.htm](http://www.remm.nlm.gov/ars_wbd.htm).

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**Radiation Dose (Gy)**

- **> 10** Likely fatal (in higher range)
- **6 - 10** Severe
- **> 2 - 6** Moderate
- **> 0.5 - < 2** Minimal
- **<0.5** Minimal

**RADIATION INJURY ONLY**

- **Immediate**
- **Minimal**
- **Expectant**

**Resource availability:**
- **Normal**
- **Good**
- **Fair**
- **Poor**

**Standard of care:**
- **Conventional**
- **Contingency**
- **Crisis**

**NOTES:** Triage for victims with radiation injury only affected by resource availability. Most victims transported to RITN centers are expected to have minimal or no traumatic or burn injuries, and thus fit into the “Radiation Injury Only” group. Triage separates victims into those who should receive Immediate care, those Delayed after the Immediate cohort, those who require Minimal intervention and those who should receive Expectant (i.e. palliative only) management. Under crisis standards, those who received >6 Gy irradiation are triaged to Delayed or Expectant. Radiation doses are whole body or to a significant portion of the whole body. Legend for standard of care and myeloid cytokine treatment is included in the next slide. From the DHHS Scarce Resources Project.
Legend- Radiation Only

**Minimal B:** Consider repeating both biodosimetry and clinical reassessments, especially at high end of this dose range

**Minimal A.** <0.5 Those with physical dose estimates based on location below 0.5 rem need not report for medical evaluation. Joining a registry may be suggested after the incident.

The red/black split triage category for >10 Gy indicates that some victims may receive aggressive treatment at discretion of physician, especially if 10 Gy is received over prolonged time period.

<table>
<thead>
<tr>
<th>Resource availability below <strong>NORMAL</strong>*:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GOOD</strong></td>
</tr>
<tr>
<td><strong>FAIR</strong></td>
</tr>
<tr>
<td><strong>POOR</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Myeloid cytokine category</th>
<th>Recommendation for G-CSF or comparable agent</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Indicated</td>
</tr>
<tr>
<td>2</td>
<td>Indicated only if supply widely available</td>
</tr>
<tr>
<td>3</td>
<td>Not indicated</td>
</tr>
</tbody>
</table>

**NOTES:** From the DHHS Scarce Resources Project. There may be special populations (e.g. very young or very old, those with comorbid conditions) who received between 1-2 Gy radiation and would benefit from myeloid cytokines. The most experience using myeloid cytokines after radiation exposure is with G-CSF, although GM-CSF and pegylated G-CSF may be acceptable alternatives. Additional triage for myeloid cytokines is included in slides 18 & 19.
TRAUMA and COMBINED INJURY

<table>
<thead>
<tr>
<th>Injury severity</th>
<th>Combined injury (radiation with trauma and/or burns)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ Moderate trauma + radiation &gt; 2 Gy</td>
<td>Immediate</td>
</tr>
<tr>
<td>Severe trauma</td>
<td>Immediate</td>
</tr>
<tr>
<td>Moderate trauma</td>
<td>Delayed</td>
</tr>
<tr>
<td>Minimal trauma</td>
<td>Minimal</td>
</tr>
</tbody>
</table>

Resource availability

- Normal
- Good
- Fair
- Poor

Standard of care:

- Conventional
- Contingency
- Crisis
- Crisis

NOTES: Triage for victims with trauma or burn alone, in combination or with radiation injury. Most victims transported to RITN centers are expected to have minimal or no traumatic or burn injuries, and thus be triaged according to “Radiation Injury Only” (slide 14). Triage separates victims into those who should receive Immediate care, those Delayed after the Immediate cohort, those who require Minimal intervention and those who should receive Expectant (i.e. palliative only) management. Under crisis standards, those with severe injuries are deprioritized to Delayed or Expectant because of their worse prognosis and their greater need for resources. Radiation dose >2Gy indicates whole body or to a significant portion of the whole body. Legend and definitions of trauma categories are on the next slide. From the DHHS Scarce Resources Project.
Legend- Trauma and combined injury

Adding > 15% body surface area burn to trauma reduces triage priority by 1 category.

<table>
<thead>
<tr>
<th>Trauma category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combined injury</td>
<td>• Radiation dose of &gt; 2Gy to whole body or significant portion of whole body plus moderate or severe trauma and/or burn injury (a)</td>
</tr>
<tr>
<td>Severe trauma</td>
<td>• Stabilization requires complex treatment;</td>
</tr>
<tr>
<td></td>
<td>• &gt;20% chance of death even with treatment.</td>
</tr>
<tr>
<td>Moderate trauma</td>
<td>• Without stabilization, potential for death within hours</td>
</tr>
<tr>
<td></td>
<td>• &lt;20% chance of death with stabilization and treatment.</td>
</tr>
<tr>
<td>Minimal trauma</td>
<td>• Injuries pose no significant risk to life and limb</td>
</tr>
<tr>
<td></td>
<td>• Limited or no treatment necessary</td>
</tr>
</tbody>
</table>

NOTES: From the DHHS Scarce Resources Project. Standards of care are from Institute of Medicine Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations (http://www.iom.edu/Reports/2009/DisasterCareStandards.aspx)
Myeloid cytokines with “Normal” or “Good” resource availability

**COMBINED INJURY**

**Moderate or severe injury + radiation > 2 Gy**

<table>
<thead>
<tr>
<th>Radiation dose (Gy)</th>
<th>Radiation only or Minimal trauma</th>
<th>Moderate trauma</th>
<th>Severe trauma</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;10 Gy</td>
<td>Expectant&lt;sup&gt;3&lt;/sup&gt;</td>
<td>Expectant&lt;sup&gt;3&lt;/sup&gt;</td>
<td>Expectant&lt;sup&gt;3&lt;/sup&gt;</td>
</tr>
<tr>
<td>&gt; 6 – 10 Gy</td>
<td>Immediate&lt;sup&gt;2&lt;/sup&gt;</td>
<td>Delayed&lt;sup&gt;2&lt;/sup&gt;</td>
<td>Expectant&lt;sup&gt;3&lt;/sup&gt;</td>
</tr>
<tr>
<td>≥ 2 – 6 Gy</td>
<td>Immediate&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Immediate&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Delayed&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

**Myeloid cytokine category**

<table>
<thead>
<tr>
<th>Category</th>
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**NOTES:** Triage and myeloid cytokine prioritization with “Normal” or “Good” resource availability. Under these conditions, standards will be either conventional or contingency and the “functional standards of care” will be maintained. Definitions of trauma severity are on Slide 17. Radiation doses are to the whole body or a significant portion of the whole body. There may be patients with trauma or special populations (e.g. very young or very old, those with comorbid conditions) who received between 1-2 Gy radiation and would benefit from myeloid cytokines.
Myeloid cytokines with “Fair” or “Poor” resource availability

COMBINED INJURY
Moderate or severe injury + radiation > 2 Gy

<table>
<thead>
<tr>
<th>Radiation dose</th>
<th>Radiation only or Minimal trauma</th>
<th>Moderate trauma</th>
<th>Severe trauma</th>
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<tr>
<td>&gt;10 Gy</td>
<td>Expectant&lt;sup&gt;3&lt;/sup&gt;</td>
<td>Expectant&lt;sup&gt;3&lt;/sup&gt;</td>
<td>Expectant&lt;sup&gt;3&lt;/sup&gt;</td>
</tr>
<tr>
<td>&gt; 6 – 10 Gy</td>
<td>Delayed&lt;sup&gt;2&lt;/sup&gt;</td>
<td>Expectant&lt;sup&gt;3&lt;/sup&gt;</td>
<td>Expectant&lt;sup&gt;3&lt;/sup&gt;</td>
</tr>
<tr>
<td>≥ 2 – 6 Gy</td>
<td>Immediate&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Immediate&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Delayed&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

Resource availability: Fair | Poor | Fair and Poor

<table>
<thead>
<tr>
<th>Myeloid cytokine category</th>
<th>Recommendation for G-CSF or comparable agent</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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</tr>
<tr>
<td>3</td>
<td>Not indicated</td>
</tr>
</tbody>
</table>

NOTES: Triage and myeloid cytokine prioritization with “Fair” or “Poor” resource availability. Under these conditions, crisis standards will be necessary. Definitions of trauma severity are on Slide 17. Radiation doses are to the whole body or a significant portion of the whole body. There may be patients with trauma or special populations (e.g. very young or very old, those with comorbid conditions) who received between 1-2 Gy radiation and would benefit from myeloid cytokines.
ARS management
Myeloid cytokines

• In animal studies, overall survival is improved if G-CSF is initiated within 24 hours after radiation exposure and continued until resolution of neutropenia

• Transfer to RITN centers is not expected for multiple days-weeks after exposure and many victims will have received no or inconsistent cytokines prior to transfer

• At RITN centers, use of myeloid cytokines should follow standard approaches with the goal of shortening neutropenia and preventing neutropenia-associated complications
Transfusions

• Unless the victim is known to have received < 1Gy irradiation, all transfused blood products should be irradiated and leukoreduced

• Assuming adequate resource availability, standard thresholds for transfusions should be utilized
Prophylactic antibiotics

- Use standard approaches during neutropenia*:  
  - Anti-HSV (e.g. acyclovir)  
  - Anti-bacterial (e.g. levofloxacin)  
  - Anti-fungal (e.g. fluconazole)

- After resolution of neutropenia in victims who received higher doses (>4 Gy), consider:  
  - Anti-VZV (e.g. acyclovir)  
  - Anti-PCP (e.g. bactrim)  
  - Monitoring for CMV reactivation

NOTES: *See ASCO, IDSA and NCCN treatment guidelines for fever and neutropenia.
Stem cell support

Check www.RITN.net for updates to these guidelines.

Version September 2010
Stem cell support after a nuclear detonation

- Stem cell transplant
  - Sustained aplasia
  - Available donor
  - Acceptable pre-transplant condition
- Expedited HLA typing and donor search
  - Potentially irreversible marrow injury
  - Salvageable
  - Minimal combined injury
- Supportive care
- Marrow injury

Affected population

NOTES: Although thousands of victims may be transferred to RITN centers, there will be very few who would benefit from and will be eligible to receive stem cell support.
Granulocyte kinetics with severe but reversible (H3) versus irreversible (H4) toxicity

- Decline between day 4 and 10
- Abortive recovery (shoulder)
- Nadir days 20 to 30

- Initial granulocytosis
- Nadir by day 6

NOTES: Peripheral blood cell kinetics can predict marrow recovery. Data from industrial radiation accidents suggest that victims with reversible but severe hematologic toxicity (H3) have different peripheral blood granulocyte kinetics than victims with irreversible (i.e. myeloablative) toxicity (H4). Those with H4 have an abortive initial granulocytosis followed by nadir within 6 days, while those with H3 have measurable granulocytes for 10 or more days after exposure. From Fliedner et al. Br J Radiol 2001;74:121.

Platelet kinetics with severe but reversible (H3) versus irreversible (H4) toxicity

- Shoulder on curve
- Nadir after day 10

NOTES: Peripheral blood cell kinetics can predict marrow recovery. Data from industrial radiation accidents suggests that victims with reversible but severe hematologic toxicity (H3) have different peripheral blood platelet kinetics than victims with irreversible (i.e. myeloablative) toxicity (H4). Those with H4 have a progressive decline over 10 days while those with H3 have a “shoulder” on the curve characterized by a precipitous decline between 5-10 days after exposure. From Fliedner et al. Br J Radiol 2001;74:121.


Check www.RITN.net for updates to these guidelines.

Version September 2010
Decision to perform HLA typing

Factors favoring HLA typing

• Estimated whole body dose > 3 Gy
• Neutrophil count < 100/μl by day 6 (see slide 26)
• Rapid drop of platelets (see slide 27)
• Expected to survive other injuries

Expedited HLA typing will be available using buccal swab, with high resolution DNA typing of HLA-A, -B, -C, -DRB1, and -DQB1
Decision to proceed with stem cell support

Factors favoring stem cell support

- Estimated whole body dose > 3Gy
- Neutrophil and platelet count kinetics consistent with irreversible (H4) toxicity (see slides 26 and 27)
- Peripheral blood neutrophil count < 100/uL extending beyond 14 despite >5 days of myeloid cytokines
- Expected to survive other injuries
- Aplastic marrow at 2 or more sites on day 14-21
- Suitable HLA compatible donor available

Check [www.RITN.net](http://www.RITN.net) for updates to these guidelines. Version September 2010
RITN approach for stem cell support of victims with irreversible marrow toxicity

- Based on BMT Clinical Trials Network #03-01
- Donor matching and selection process:
  - Matched sib > 7-8/8 URD > 4/6 UCB with 2.5x10^7 MNCs/kg

NOTES: Alternative approaches with minimal mucosal toxicity and low risk for severe acute GVHD could also be considered. BMT CTN #03-01 is available at: https://web.emmes.com/study/bmt2/protocol/0301_protocol/0301_Aplastic_Anemia_Synopsis_and_Schema_v7.pdf. Figure from Weinstock et al. Blood 2008;111:5440-5.

Check www.RITN.net for updates to these guidelines.

Version September 2010
Additional resources

Radiation Injury Treatment Network (RITN):  www.RITN.net
Radiation Emergency Assistance Center/Training Site (REAC/TS):  www.orau.gov/reacts
Radiation Countermeasures Center of Research Excellence (RadCCORE):  www.radccore.org
Armed Forces Radiobiology Research Institute (AFRRI):  www.afrri.usuhs.mil
IAEA Library:  http://www.iaea.org/DataCenter/Library/catresources.html

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