NRC Public Meeting on CsCl

AABB Presentation-Issue 2

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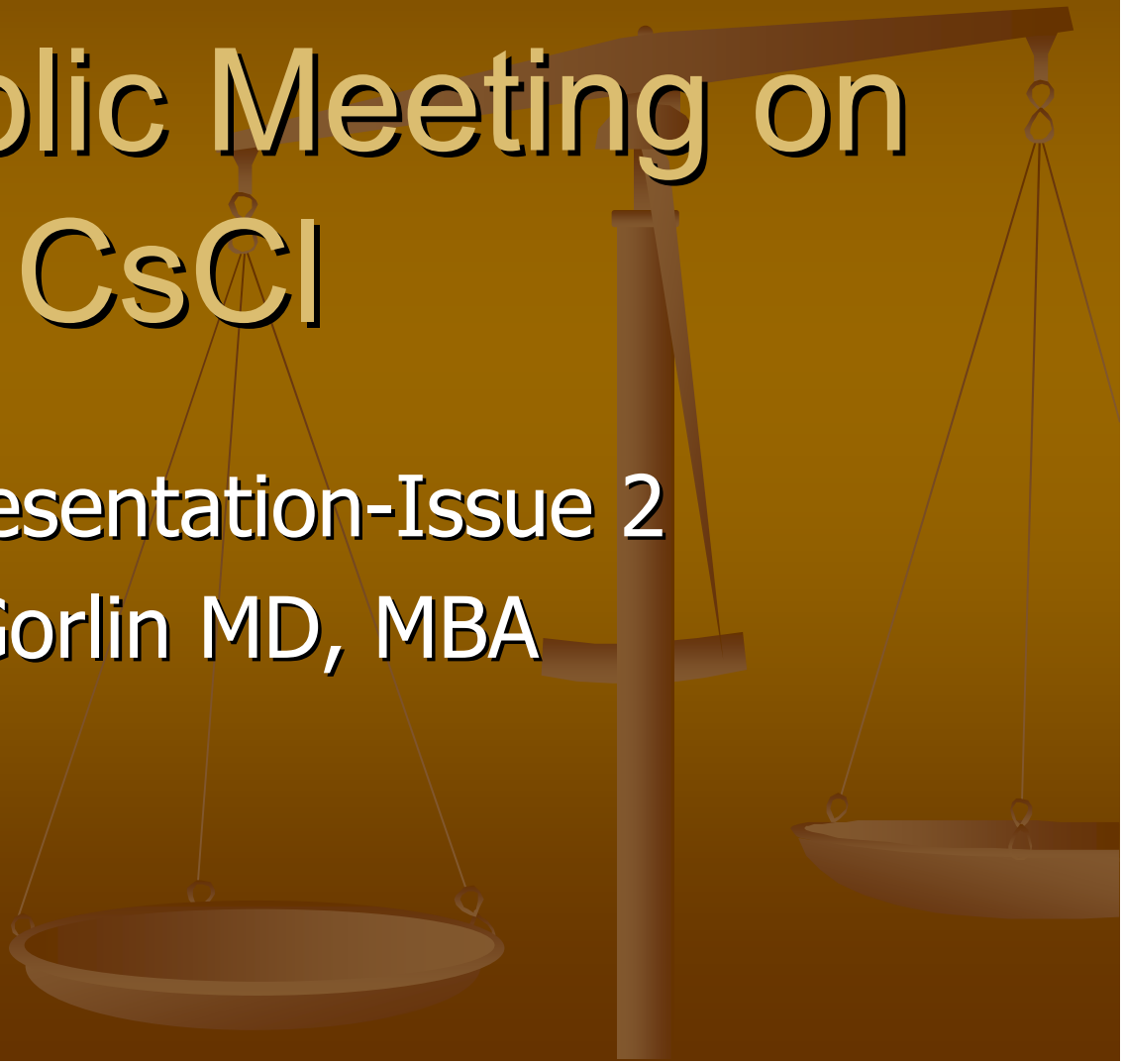


Over arching context

- AABB is not tied to any single technology
- Irradiation is used to prevent Transfusion-Associated Graft-Versus-Host disease, a lethal and untreatable complication of transfusion in immunocompromised recipients of cellular transfusion products.
  - TAGVHD may occur with related donors
  - Irradiation consistent with AABB standards has proven 100% effective in preventing this complication

Other alternatives to CsCl

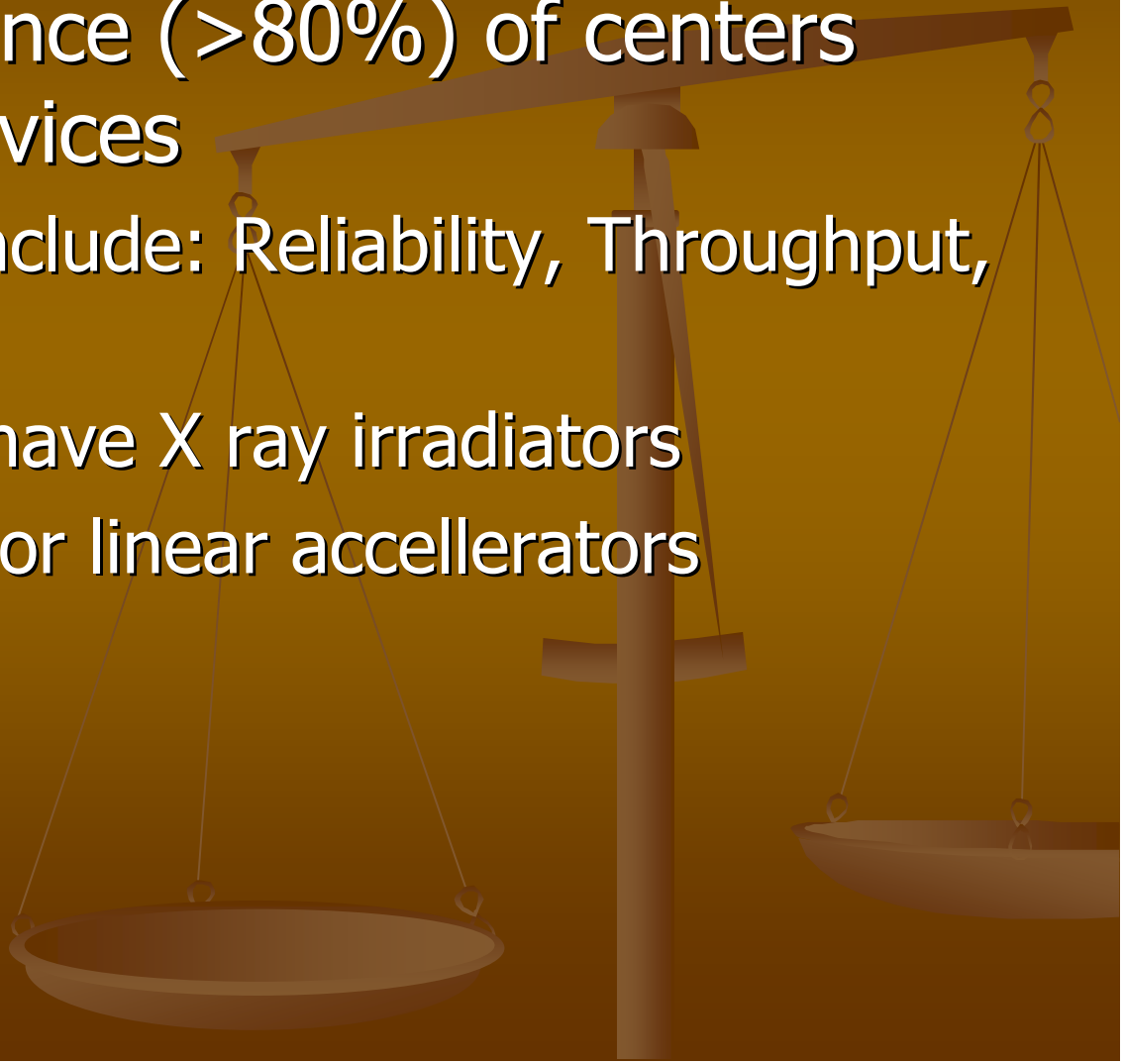
- Cobalt is less desirable due to its much shorter ½ life, and hence higher shielding requirements to accommodate a stronger initial radioactive source
- Linear accelerators are not available 24/7 and require dedicated staff.
- Pathogen inactivation techniques (For example, chemical cross-linking of DNA) have shown promise in in-vitro studies, but none are currently licensed. Furthermore, to function as a replacement, they would need to be available for all cellular products.

Data from constituents

- AABB represents hospital transfusion services, community blood centers including America's Blood Centers (ABC) and American Red Cross (ARC) who will give separate presentations. AABB also represents cellular therapy interests for which irradiation may also be relevant
- A recent survey elicited data from centers not represented by ABC or ARC data
  - 345 responses from 195 centers that irradiate

Major observations from survey

- The preponderance (>80%) of centers have Cesium devices
  - Cited reasons include: Reliability, Throughput, Economics
  - Some (~10%) have X ray irradiators
  - Few use cobalt or linear accellerators



Down time

- The down time of the CsCl irradiator is not significant with 92.4% down less than 2 days and only 5% non-operational greater than 30 days.
- X-ray irradiators are non-operational more often than a cesium-137 irradiator – 78.6% responded that their irradiator was non-operational 0-2 day annually with 21.4% non-operational greater than 30 days.

Economics

- CsCl irradiators somewhat more expensive to purchase, but significantly longer estimated functional life (>25 years vs. ~10) and ongoing potential for replacement of expensive parts (power source and X ray tubes) make the X-ray irradiators over $300,000 more expensive over the equivalent life of the Cesium irradiator (National Academy of Sciences est).

Recommendations

- Consider both risk/benefit and cost/benefit in decision making
- If CsCl irradiators are to be replaced economic considerations must include:
  - Cost and timeline of disposal
  - Availability of replacement devices, service capabilities and increased back-up requirements
  - Reimbursement of all additional costs generated by the requirement to replace the CsCl devices including purchase price, decomissioning costs, additional service fees and training.