Intercept® Fibrinogen Complex

Implementation at a Large Level 1 Trauma Center

BARNES-JEWISH Hospital
BJC HealthCare

Barnes Jewish Hospital
St. Louis, Missouri

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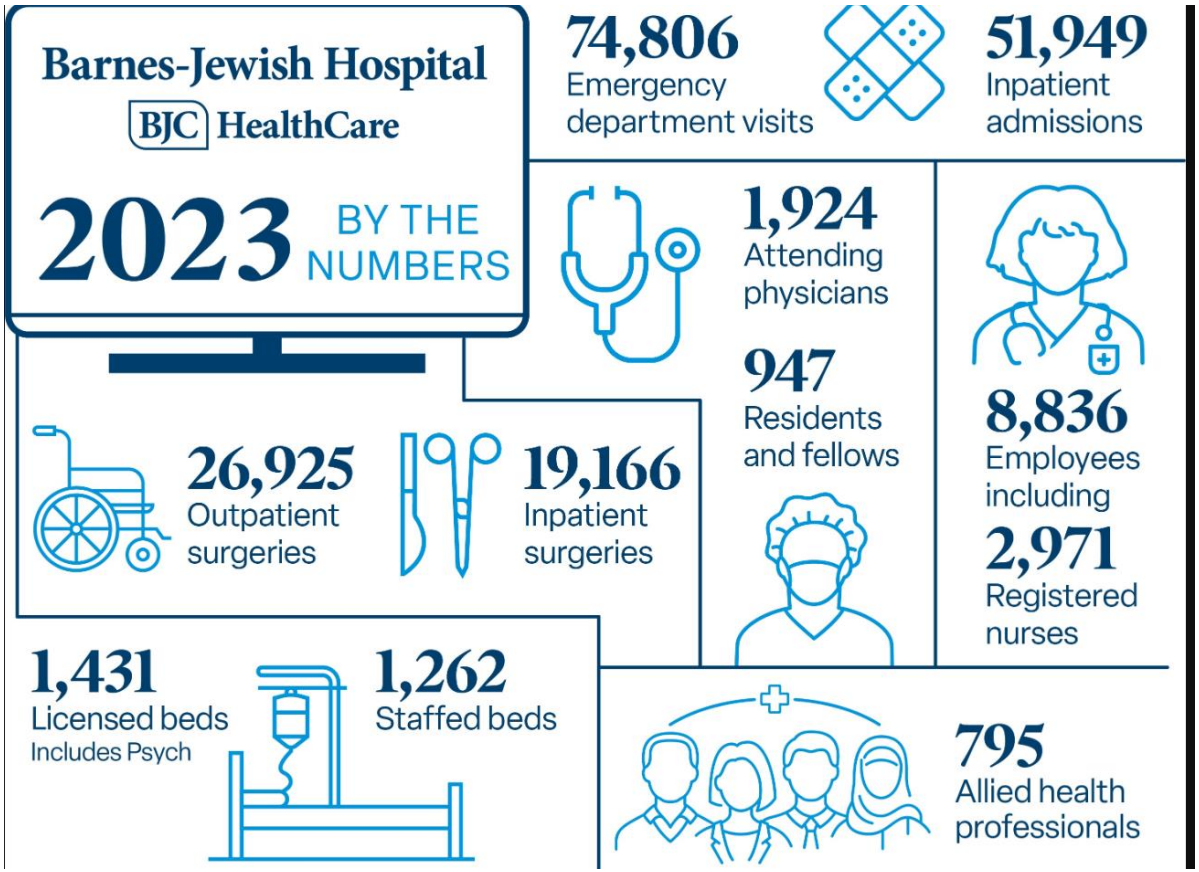

- **Siteman Cancer Institute**
- **High Risk OB Service**
- **Consistently ranked among best in U.S. News & World Report**

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Blood Bank Statistics

Annual Transfusions 2023 = 82,791

• RBCs	45,631
• Platelets	17,152
• Plasma	7,841
• Pooled Cryo	2,611
• LTWB	1,057

~250 products issued/day

Services:

- 3 Ortho Vision (~350 T&S/day)
- Advanced Reference Lab (~25 workups/day)
- Red Cell Exchange (~15/wk)
- Washed/Deglyced RBCs (~5/wk)
- Frozen RBC Inventory (~35)
- Platelet Modification (~10/day)

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What is **Intercept**® Fibrinogen Complex (IFC)?

- Approved to treat and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency
- Immediate*, enriched source of key factors in effective hemostasis[1-3]
- Pathogen reduced: produced from INTERCEPT treated plasma

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Why IFC?

- Providers asked for it!
- Safer product for the patient
- 5 Day Expiration vs 6 Hour Expiration
- Ability to pre-thaw; ready to go!
- Potential for improved Turn Around Time (TAT) delivery

Considerations for Implementation

- Does our Blood Supplier have it?
- Cost – how to offset impact to budget?
- Dual Inventory or not?
- How much inventory to keep on hand?
  - Cryo usage ~10/day
- Staff Triage of Orders (IFC vs Cryo) – Delays?
- Where to store prethawed IFC (20-24C)?

Solutions

- Inventory built up over 6 months to offset cost
- How much IFC inventory to keep on hand?
- Tabletop Incubator to hold pre-thawed inventory
  - Helmer PC100-PRO; Rees Temperature Monitor
- Determination of pre-thawed IFC to keep on hand
  - average daily use calculated from past year
- IFC as primary; pooled cryo as back up only
- Staff stress levels alleviated – no triage of orders

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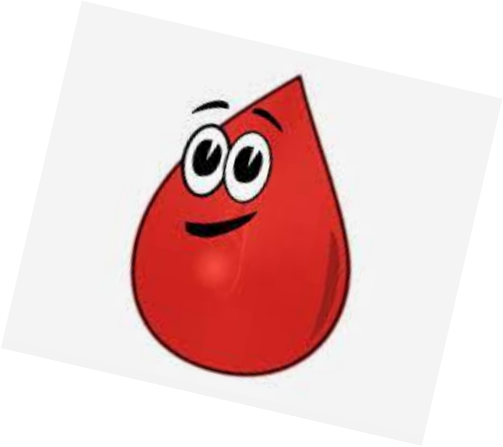
Where are we today?



- Implemented April 18th
- Inventory on hand ~100 product
  - Shipment of 60 IFC/week
- Maintain 6 thawed IFC at all times
- Waste to date – 1 (*not Blood Bank error*☺)

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Wins

- Safer product for the patient: Pathogen Reduced
- Marked improvement in TAT:
  - Order to Issue
  - Order to Transfuse
- Cost Recovery as an institution

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TAT Improvement

- Order to Issue – 40 minutes to 10 minutes!
- Order to Transfuse – 90 minutes to 40 minutes!

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Potential Cost Savings – OR *(@ BJH)*

- OR Time saved of 50 minutes
- OR room turned over to support other cases sooner
- Average cost of one minute of OR = $55/minute
- 50 minutes equates to $2,750 saved for each patient used
- Institutional savings achieved!

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The future to explore….

- OR Time/Cost Savings by specialty
- Replacing Fibrinogen Concentrate currently used by OB Services
- Use of IFC earlier in MTP Cycle
- Share IFC utilization across HSO consortium
  - Reduce waste for smaller HSOs/transfer to BJH
- Reduction in use of other blood products? (less donor exposure)

(*HSO - Hospital Service Organization*)

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For Barnes Jewish Hospital

The Good:

- Great Decision Made! Worth the effort!
- Staff LOVE the process!
- Anesthesiologists LOVE the product!
  - It's a gamechanger!
- Trust gained with the surgical staff
  - High quality product
  - Patient safety
  - Received when needed – no delays

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Pathogen Reduced Cryoprecipitated Fibrinogen Complex
Indications, Contraindications, Warnings, Precautions

INDICATIONS

- Treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency
- Control of bleeding when recombinant and/or specific virally inactivated preparations of Factor XIII or von Willebrand factor (vWF) are not available
- Second-line therapy for von Willebrand disease (vWD)
- Control of uremic bleeding after other treatment modalities have failed

Limitations of Use: Should not be used for replacement of Factor VIII.

CONTRAINDICATIONS

- Contraindicated for preparation of blood components intended for patients with a history of hypersensitivity reaction to amotosalen or other psoralens.
- Contraindicated for preparation of blood components intended for neonatal patients treated with phototherapy devices that emit a peak energy wavelength less than 425 nm, or have a lower bound of the emission bandwidth <375 nm, due to the potential for erythema resulting from interaction between ultraviolet light and amotosalen.

WARNINGS AND PRECAUTIONS

- Only the INTERCEPT Blood System for Cryoprecipitation is approved for use to produce Pathogen Reduced Cryoprecipitated Fibrinogen Complex.
- For management of patients with vWD or factor XIII deficiency, Pathogen Reduced Cryoprecipitated Fibrinogen Complex should not be used if recombinant or specific virally-inactivated factor preparations are available. In emergent situations, if recombinant or specific virally-inactivated factor preparations are not available, Pathogen Reduced Cryoprecipitated Fibrinogen Complex may be administered.

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