FIBRINOGEN

A New TML Adventure

Excellent health and care for everyone, everywhere, every time.

Once Upon a Time...

Gather around friends and let me share a tale of the implementation of Fibrinogen for Island Health

As with any good adventure, this story has

- An entertaining plot
- Amazing characters
- And a happy ending.....

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Our hero is Fibrinogen….so what is it?

- Fibrinogen is a plasma glycoprotein with a molecular weight of 340 kDa
- Is synthesized by the liver
- Is essential for haemostasis
- Is also referred to as Factor 1
- Product available from CBS is manufactured by CSL Behring with trade name: RiaSTAP

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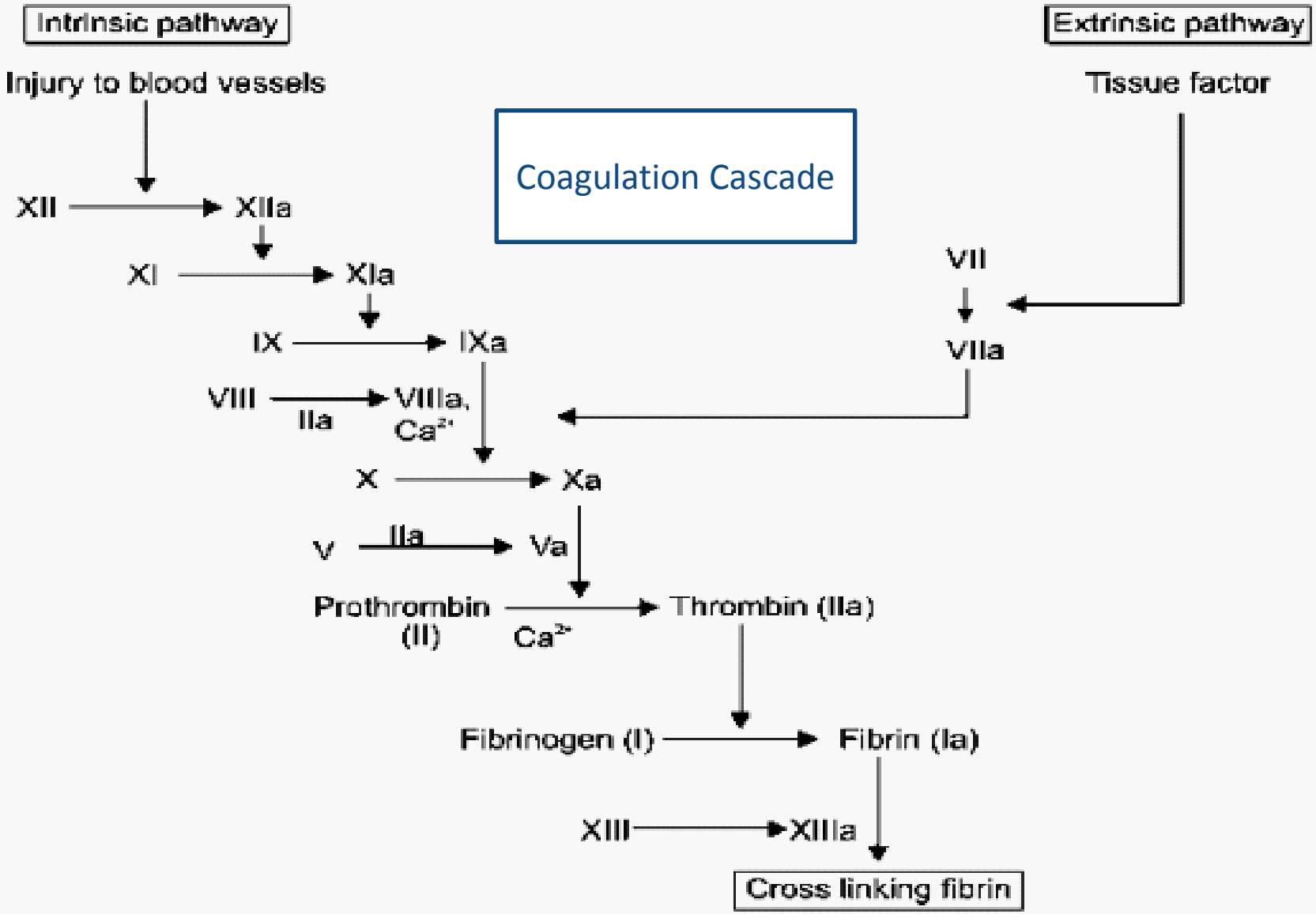
Coagulation Cascade



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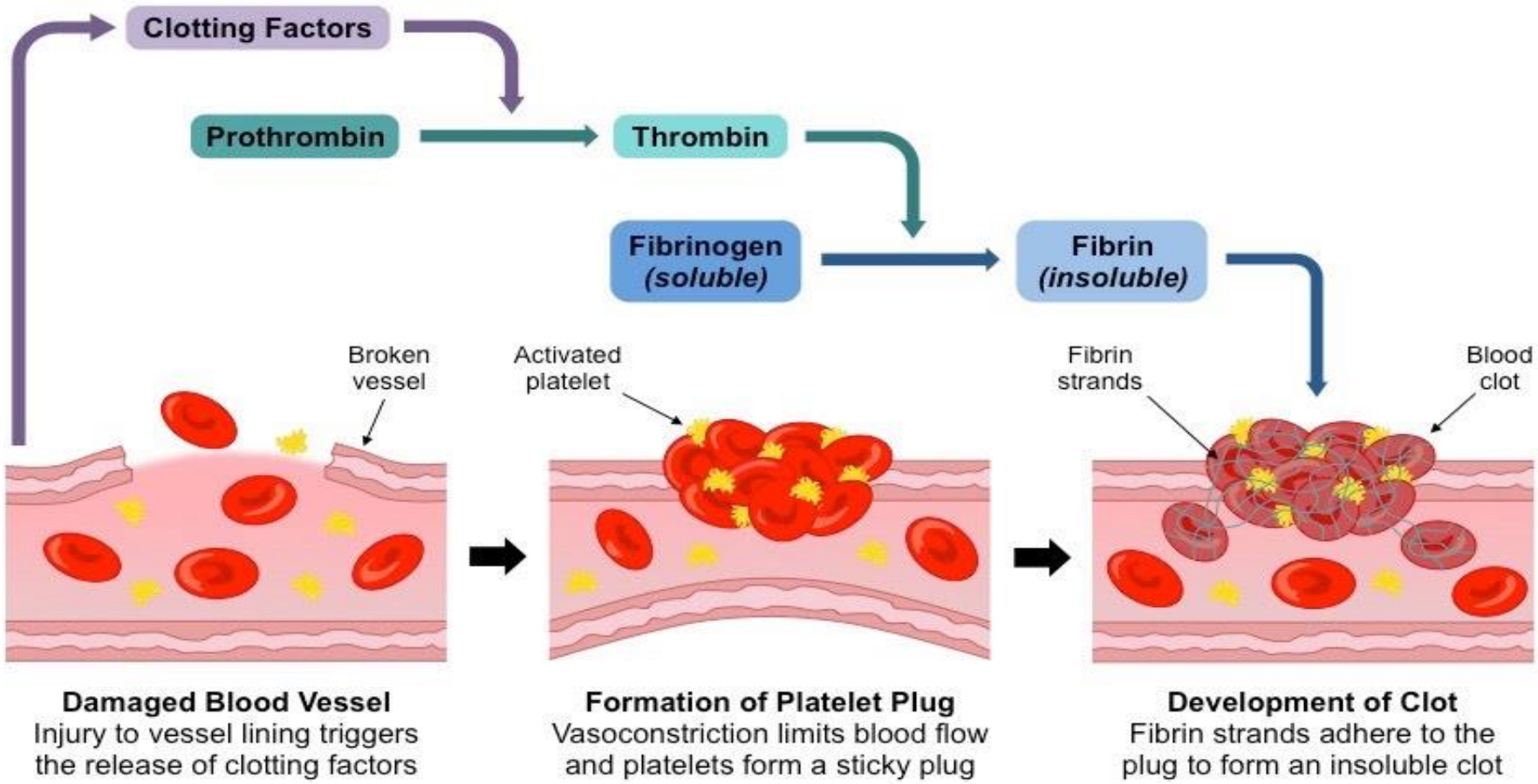
Fibrinogen in Action



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Why the change?

- Cryoprecipitate was previously the only source available for fibrinogen
- Cryoprecipitate dose not an exact science
  - Doses were usually 5 or 10 units
  - Unknown amount of the dose of fibrinogen
  - Risk of exposure to multiple donors
- Product required to be thawed, pooled physically and electronically prior to dispense
  - 30 to 45 minutes to provide a usable product

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Fibrinogen Concentrate to the Rescue!

- 1 vial provides 1g of fibrinogen
- Product requires to be reconstituted and pooled
  - New practice for TML techs!
  - Challenges with learning a new skill
  - Challenges providing a clean environment to pool a blood product
  - How to teach so that we don't use actual product?

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Benefits to having Fibrinogen….

Cryoprecipitate

- 5-10 considered a dose
- Unknown amount of fibrinogen in product
- Only larger sites carry
- Pooling time 45 minutes
- Pooling bags hard to come by (shortages)
- Cumbersome to pool

Fibrinogen

- 1g-4g considered a dose
- Physician knows exactly how much fibrinogen
- Can be carried at any site (room temp product)
- Pooling time 30 minutes
- Supplies easily available
- Easy to pool

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Sounds like it's time for a pilot!

- The Royal Jubilee Hospital would be the site of the pilot
- The recipients would only be cardiac patients intra/post-op
  - All orders for cryoprecipitate would be screened by the hematopathologist with the intent to convert them to fibrinogen and educate ordering physician

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So, how do we put this into action?

- Two avenues for education
  1. ordering physicians (usually anesthetist)

     -Hematopathologist would have education sessions with cardiac anesthetists
  2. TML technologists

  - techs needed to learn about the product

  - techs needed to learn how to reconstitute/pool in a timely fashion

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And….how did that work?

- Rapid buy-in from ordering physicians
- Direct conversations between anesthetists and hematopathologist converted orders
  - New order could be written on document for cryo request reducing time of written request
- Anesthetists and surgeons learned that the product was superior to cryoprecipitate
- New studies proved intervention at a fibrinogen level of 1.5 controlled bleeding better

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And….how did TML deal with this NEW thing?

- Education provided to RJH techs about the product
- Product ordered from CBS for visual
- Bottles of saline and bags of water ordered for training
  - Not optimum but was the best we could do
- 1 to 1 training (at most 2 to 1) for each tech in a show one/do one technique

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Challenges for TML:

- Initially, the Fibrinogen was a stand alone product so what to use to reconstitute?
- What supplies do we need to reconstitute and pool?
- What do we pool it into?
- How do we pool?
- There are 25 techs to train!
- We *really* need a procedure!

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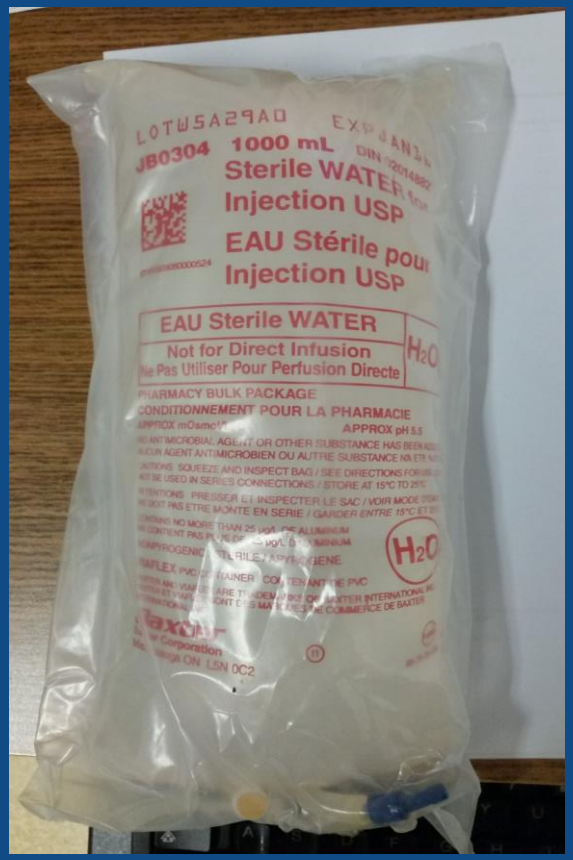
Supply list:

- Product!
- Sterile water



- Blunt needles (21 gauge)
- Alcohol swabs
- Pooling bag: IntraVia 250 ml bag
- Labels for product which meet standards

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CSTM Standards for labeling blood products

5.6.1.3
Blood components and blood products that are modified shall have a new or additional label applied. The label shall include where applicable:

a. unique identification number/letters/symbols or combinations
b. blood component or blood product name
c. modifications performed
d. number of units in the modified blood component or blood product
e. name of the modifying facility
f. volume
g. ABO and Rh types
h. expiry date and time
i. storage temperature [7.5.5.3,/8.6.3.1/8.6.4/8.6.1.6/8.6.1.7/10.8.2]

Policies, processes and procedures shall be established to ensure that the new or additional label has been compared to the original supplier label and there is no visible discrepancy.

5.6.1.4
All blood component and blood product modification labels shall be:

a. firmly attached to the blood component or blood product
b. clear and legible
c. confirmed by the label manufacturer to have only adhesives and inks that are safe for use on blood bags [8.6.1.2]

5.6.1.5
Handwritten additions or changes to labels may be made in permanent moisture-proof ink that will not leach through label.[8.6.1.2]

5.6.1.6
When bar-coded labels are used, ISBT 128 coding system developed by the International Council for Commonality in Blood Banking Automation (ICCBBA), should be followed. [8.6.1.4]

Action Plan!

- Technical Coordinator worked with pharmacy to determine aseptic reconstitution/pooling technique
- Procedure for reconstitution and pooling was written and validated by TML staff
- Supplies ordered
- Labels created, outsourced and ordered

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Aaaaand, Action!

- RJH pilot rolled out April 2015
- Cooperation between investors enhanced providing correct product in a timely manner
  - OR/CVU
  - Core lab
  - TML
  - Hematopathologist
- Time assessments made for reconstitution / pooling times

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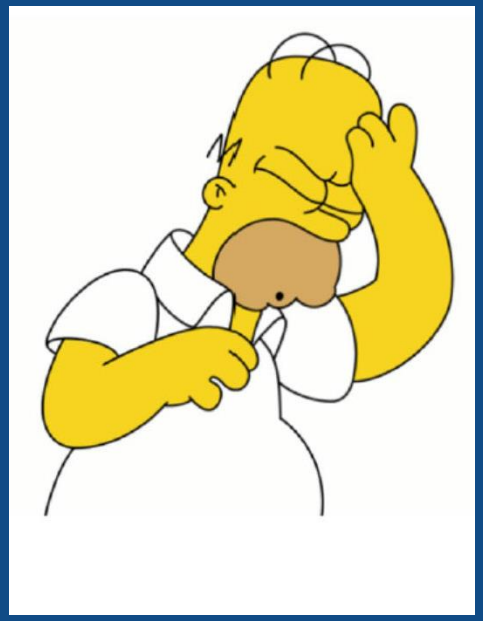

What could have gone better?

- Some techs more proficient than others; caused delay in product dispense

- Method required strength in hand to perform the task….some learn they were not strong enough!
- Delay in order change resulting in cryoprecipitate pooling rather than fibrinogen

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What went right?

- TML staff took to the process eagerly
- Evening shift staff became the most proficient but were the ones who performed the task the most
- Cryoprecipitate stock reduced
- RJH served as a model for the rest of the island to carry the product

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And don't forget Process Improvement

- The procedure has been modified
  - Order of some tasks rearranged to maximize efficiency
  - Changed from only cardiac patients to everyone!
- Change in pooling to dispense action
  - Data assessed from Major Hemorrhage Protocol use of fibrinogen
- Pre-prepped pooling packages created

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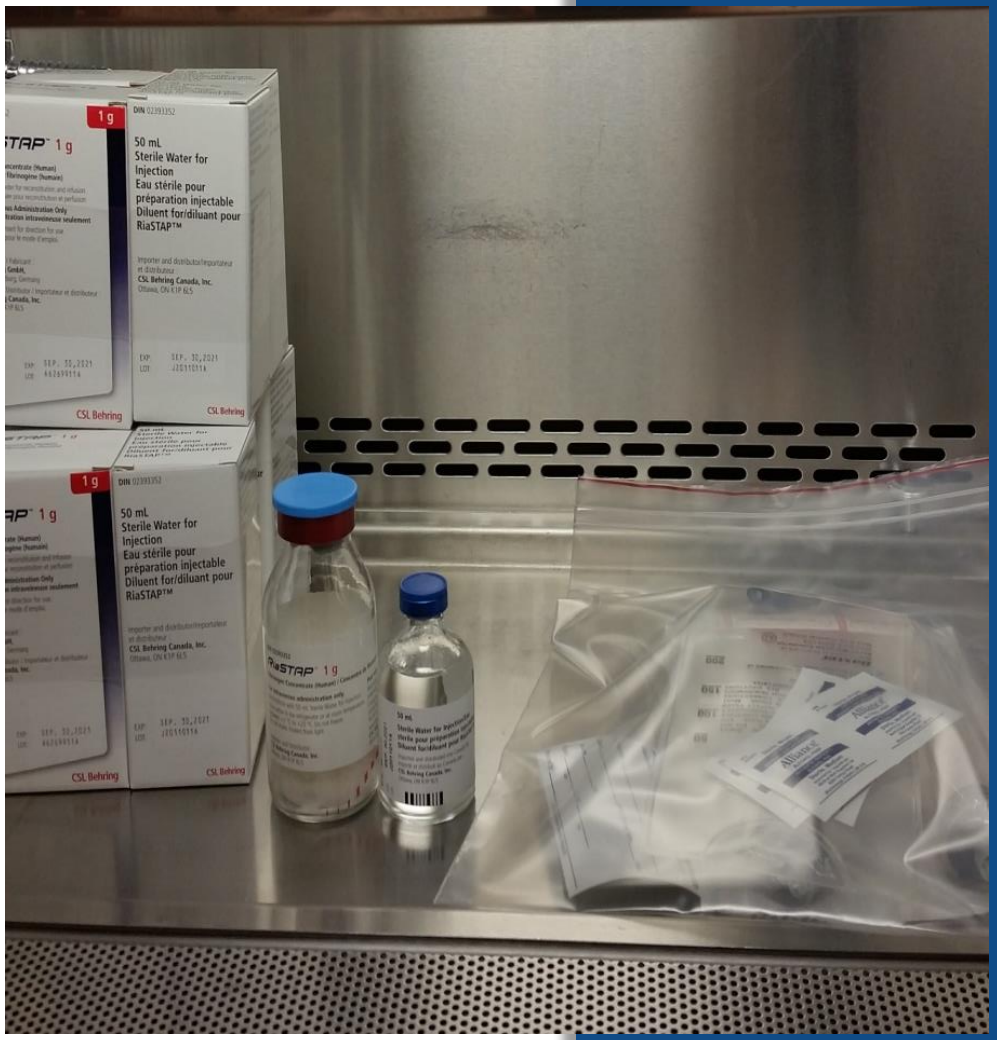

What the product looks like now…

- CSL Behring updated product to have 50 ml water
- Packages for reconstitution created
- Task list item to ensure they are always available

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So, what is next?

Well, our fairy tale ending has already come true for other sites on the island:

- Fibrinogen rolled out to all users at RJH Dec 2015 (not just the cardiac cases)
- Fibrinogen was rolled out to Victoria General (trauma hospital) Dec 2015
- Nanaimo Regional General was instructed next and went live Nov 2017
- Comox Valley came next in July 2018

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To infinity and beyond!

Ok, well, maybe not infinity, but definitely all of Vancouver Island!

- Provide product where cryoprecipitate is not available
- Product has a very long shelf life and a redistribution process is already in place for the island

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Questions?

Thoughts?

Suggestions?

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