Mobile Applications in Apheresis

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Presented in Absentia
Conflict of Interest Statement

• I will be discussing a product (“ipheresis”), an ITxM product (No current relationship; I was a fellow 2009-2010)

• Not available in itunes. Available within ITxM

• RBCX portion of ipheresis discusses exchange on the COBE Spectra, a Terumo BCT product. I have served as an expert for Terumo BCT.
Overview

- Mobile Applications
- Opportunities in the Apheresis mobile space
- Discuss ipheresis
- Challenges/Regulatory Considerations
- Discussion
Mobile Applications

• These are software Applications ("Apps") developed for low-power handheld devices such as smartphones/ tablets

• Multiple platforms available including Android, Apple devices, and Blackberry
Apps

- Need for information “on the go”/while on call
- Promotes educational mission of societies, and meets practitioner need
- Embraced by numerous medical specialty societies
- Recently, there has been significant expansion of medical mobile applications
Apps in the Medical Space

• Numerous drug/disease database apps (eg. epocrates/medscape)

• Numerous of medical society apps (like the following example from the Am Acad of Pediatrics)
AAP APPS

Nelson’s Pediatric Antimicrobials
View In iTunes

Car Seat Check
View In iTunes

Iron Kids
View In iTunes

AAP Essentials: Type 2 Diabetes
View In iTunes
Opportunities in the Apheresis Space: Examples

- **RBCX**: Accurate and timely calculation of number of phenotype matched pRBC units needed for RBCX in sickle cell patients
- **TPE**: Complex calculations involving extracorporeal circuits/multiple types replacement fluids
- **Cellular Processing**: Numerous
- **JCA Sp Ed Guidelines**
The ITxM Apheresis App

• Aim: Develop an app that will accurately calculate replacement fluid volumes for RBCX and TPE

• Help with timely preparation of RBCs particularly in the setting of phenotype-matched RBCX, given that these units can be difficult to find

• Intent is NOT to replace MD consultation. Designed to be a calculation tool that helps the practitioner
ipheresis
Screenshots
Confidentiality Notice:

Protected Health Information (PHI). PHI is personal and sensitive information related to a person’s care. It is being sent to you, via this application, after appropriate authorization from the patient or under circumstances that do not require patient authorization. You, the recipient, are obligated to maintain it in a safe, secure and confidential manner. Please refer to your...
Disclaimer

The calculation tools in this program are only intended to serve as a guide, and should be used by qualified medical professionals. Final calculations, as determined by the apheresis device should be used for accurate determination of replacement volumes.
Apheresis Calculation Tools

Red Cell Exchange

Plasma Exchange
TPE
NOTE:

Blood Volume (BV) calculation for adults was performed using the Nadler-Allen formula (Nadler R, et al, Surgery 1962;62:224-32). 80ml/Kg and 100ml/Kg body weight were used for BV calculation for small children/infants, and neonates, respectively.
<table>
<thead>
<tr>
<th>Component</th>
<th>Volume (ml)</th>
</tr>
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<tbody>
<tr>
<td>Total Blood Vol.</td>
<td>------------</td>
</tr>
<tr>
<td>Red Cell Vol.</td>
<td>------------</td>
</tr>
<tr>
<td>1 Plasma Vol.</td>
<td>------------</td>
</tr>
<tr>
<td>Albumin (5%)</td>
<td>------------</td>
</tr>
<tr>
<td>Normal Saline</td>
<td>------------</td>
</tr>
<tr>
<td>Plasma</td>
<td>------------</td>
</tr>
<tr>
<td>1.5 Plasma Vol.</td>
<td>------------</td>
</tr>
<tr>
<td>Albumin (5%)</td>
<td>------------</td>
</tr>
<tr>
<td>Normal Saline</td>
<td>------------</td>
</tr>
<tr>
<td>Plasma</td>
<td>------------</td>
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</tbody>
</table>

Choose FFP and enter % to calculate.
RED CELL EXCHANGE
NOTE:
This calculation should only be used for red cell exchanges utilizing the COBE Spectra Apheresis device.
Important Note
If hemodiluting, enter post-hemodilution HCT
**FCR Definition:**

Fraction of Cells Remaining.
Challenges

• TPE app: Very straightforward
• RBCX app: Complex logic. Numerous iterations to demonstrate accuracy. App also incorporates technical limits of device
• Validation plan approved by ITxM quality dept, and was successful
We were ready to release the app, but in mid 2011, the FDA came out with guidelines to regulate some medical apps......
FDA and Apps

• “The FDA has a public health responsibility to oversee the safety and effectiveness of a small subset of mobile medical applications that present a potential risk to patients if they do not work as intended. In order to balance patient safety with innovation, it is important for the FDA to provide manufacturers and developers of mobile medical applications with a clear and predictable outlines of our expectations.

• Through draft guidance release on July 19, 2011 the FDA defined a small subset of mobile medical apps that may impact on the performance or functionality of currently regulated medical devices and as such, will require FDA oversight.”
FDA and Apps

The FDA seeks to regulate:

1) Apps that are used as an accessory to a regulated medical device; or
2) Apps that transform a mobile platform into a regulated medical device.
Ipheresis

- Ipheresis would not appear to fall under either category, when used as recommended

- ITxM attorneys discussing options at this point
JCA Special Edition Guidelines

• Most authoritative source of information on the use of apheresis in disease
• Proposal to move this to the app format overwhelmingly supported by ASFA membership* BUT, membership concerned about cost
• Like in other societies using apps, these views may evolve over time

* ASFA web survey, S McCarthy, 2011
Acknowledgments

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- The late G Dargo, and J Sevcik for help with validation studies
Questions