The Automated Health History Questionnaire: Use for Screening Apheresis Donors

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Disclaimer

Will discuss only one system in one center
Others exist
Gives you a taste of how this works
Automated Health History

What is an automated health history questionnaire?

• Use of computer to screen donors (Computer-Aided Screening – CAS)
• Self-screening by donor for initial step
• Use of standardized questionnaire (may be Uniform Donor History Questionnaire)
  • Validate questions
  • Avoid unnecessary questions
Advantages of CAS

- Significantly decreases gender question errors and question omissions
- Less ambiguity about answers (bad handwriting, strikeouts etc)
- Fewer staff errors
- Subsequently less loss of units
- Decreased auditing
- Decreased card entry into computer
- Saves paper and printing costs – only prints positive answers
- Most donors and staff love it – enjoy ease of use
- The lab knows what is being drawn
On paper forms, some answers can be ambiguous.

Cross-outs and stray marks, as well as marks in both columns can cause the unit to be discarded.
### Donor Center Comparison

<table>
<thead>
<tr>
<th></th>
<th>2006 (prior to CAS)</th>
<th>2012 (with CAS)</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>NFTs</td>
<td>1,249</td>
<td>113</td>
<td>1,136</td>
</tr>
<tr>
<td>EDRs</td>
<td>25,143</td>
<td>13,222</td>
<td>11,921</td>
</tr>
</tbody>
</table>

**Decreased Errors after CAS Implementation**
Disadvantages of CAS

• Does require a lot of computers/printers/servers
• May have difficult technical requirements:
  • Connectivity to server
  • Size limitations for drive
• May make older or computer-unsavvy donors and staff uncomfortable
• Transition period can be difficult – staff perceives new process to be longer; donors feel abandoned
• Signature at end of process requires donors to remember consent elements early on
• How to get signature? Must print card?
• If wrong gender chosen accidentally, wrong questions selected
History of CAS at CBC

Implemented in 2007, in stages: two donor centers first (6 weeks), then roll out of other donor centers. Later used on mobile coaches, then inside set-ups. Works with LifeTrak from Mediware (510k cleared).

First to implement this system; helped to design and configure it.

Required FDA submission (CBE-30) – took 3 months.

Training of staff takes about 1½ weeks.

Replaces the manual donor card – currently using on about 89% of mobile drives and at 100% of our donor centers. Took 5 years to get here.
How It Works
Informed Consent

I have been given information about the donation process and have read and understand it. I have been given information about high-risk activities for HIV and understand that I should not donate if I have practiced a high-risk activity. I give permission for this blood center to collect blood from me, either as whole blood or by apheresis. This blood may be used for transfusion into patients and rarely for research. I give permission for samples of my blood to be tested for markers of infectious disease including but not limited to, HIV types 1, 2 and O; HTLV types I and II; hepatitis B; hepatitis C; West Nile Virus, and syphilis. I understand my blood may be tested for Parvovirus B19, exposure to cytomegalovirus and T. cruzi (Chagas' disease) on some occasions. I understand that in some instances my blood may be tested for sickle cell trait, blood cell antigens or other markers necessary for appropriate transfusion therapy. I understand that if my blood tests positive for certain markers of infection my blood may be discarded, I may not be eligible for future donations and my name may be placed on a confidential list of donors no longer eligible to donate. I understand that under federal and state laws the blood center may have to report certain positive tests to the health department. I understand and consent to Carter BloodCare's use and disclosure of information as is necessary for their operations or as required by law. I am donating blood voluntarily. I understand that my eligibility to donate will be determined on the basis of my medical history, laboratory tests and physical findings at the time of donation. I understand that blood donation may have adverse consequences including but not limited to fainting, bruising (hematoma), arterial puncture, bleeding after leaving the donation site, nerve injury, seizure, temporary loss of bladder control, infection, blood clot formation (thrombosis) and vein inflammation (phlebitis). I agree to abide by the post donation instructions. If the blood needs of patients in our community have been met, Carter BloodCare
INFORMED CONSENT

- I have been given information about the donation process and have read and understand it.
- I have been given information about high-risk activities for HIV and understand that I should not donate if I have practiced a high-risk activity.
- I give permission for this blood center to collect blood from me, either as whole blood or by apheresis. This blood may be used for transfusion into patients and rarely for research.
- I give permission for samples of my blood to be tested for markers of infectious disease including but not limited to, HIV types 1, 2 and 0; HTLV types I and II; hepatitis B; hepatitis C; West Nile Virus; and syphilis.
- I understand my blood may be tested for Parvovirus B19, exposure to cytomegalovirus, and T. cruzi (Chagas' disease) on some occasions.
- I understand that in some instances my blood may be tested for sickle cell trait, blood cell antigens or other markers necessary for appropriate transfusion therapy.
- I understand that if my blood tests positive for certain markers of infection my blood may be discarded. I may not be eligible for future donations and my name may be placed on a confidential list of donors no longer eligible to donate.
- I understand that under federal and state laws the blood center may have to report certain positive tests to the health department.
- I understand and consent to Carter BloodCare's use and disclosure of information as is necessary for their operations or as required by law.
- The information I have provided is true and correct to the best of my knowledge.
- I am donating blood voluntarily.
- I understand that my eligibility to donate will be determined on the basis of my medical history, laboratory tests and physical findings at the time of donation.
- I understand that blood donation may have adverse consequences including but not limited to fainting, bruising (hematoma), arterial puncture, bleeding after leaving the donation site, nerve injury, seizure, temporary loss of bladder control, infection, blood clot formation (thrombosis) and vein inflammation (phlebitis).
- I agree to abide by the post donation instructions. If the blood needs of patients in our community have been met, Carter BloodCare may ship blood to cities outside of the area to meet patient needs.
- I understand remaining samples of my blood could be tested for markers of cardiovascular risk and/or diabetes and results of such tests could be used for population health research.
Gender Question - Male

From 1977 to the present have you had sexual contact with another male, even once?

Yes  No

Answer by clicking on the appropriate "Yes" or "No" button.
Gender Question - Female

**Donor Response**

**Question Number:** 83  
**Question Code:** 83  
**Have you given birth four or more times?**

Answer by clicking on the appropriate "Yes" or "No" button.
After donor self-screen:
   staff reviews card
   go over any positive responses
   code assigned to positive responses
   determine eligibility with the computer
   go on to vital signs if appropriate
   print card for signature
What Kind of Donors?

Only allogeneic – whole blood and apheresis
Not therapeutic, autologous – decreased questions; needs a different template
Not cellular therapy – lots of exceptions
Advantages:
Direct access to database
Real-time update

Disadvantages:
Unreliable connectivity
Slow response
Not scalable
Advantages:
- Reliable connectivity
- Great response time
- Highly scalable
- Local connectivity

Disadvantages:
- No real-time update

Each master laptop is refreshed every night with current copy of DB.

One Master laptop is configured for the network on each of the Coaches.

The Master Laptop is connected to the network on the coach at the start of the drive.

When each drive returns to headquarters, data from the master laptop is extracted and loaded into LifeTrak database.
Mobile Inside Drives – Laptops for Lookup Only

Each lookup laptop is refreshed every night with current copy of DB which are deployed to mobile inside drives.

Everything Manual - except lookup:
- Mini-Physical
- Screening
- Registration
- Back office data entry
Inside Mobile Drives – Full Automation with CAS

Full Automation:
- Mini-Physical Screening
- Registration
- Bleed-Time Entry

Each master laptop is refreshed every night with current copy of DB.

One Master laptop is paired with a WiFi router for each drive.

When each drive returns to headquarters, data from the master laptop is extracted and loaded into LifeTrak database.

Mobile Team sets up WiFi router and connects Master laptop. All client laptops connect via wifi to access LifeTrak running on Master Laptop.
CAS Mobile Unit – Standard

One CAS Mobile Unit for drives with projected show up to 50 donors

**Master Laptop and Router**

- 1 wireless Dual-Boot Laptop for Look-up
- 2 wireless Touch-Screen Tablets (with back-up battery) for Donor Response Entry
- 1 wireless Laptop/Tablet & Tablet with Printers for HH Review and Physical in Screening Area

**Bleed-Time & Link Unit**
When do we still use manual donor cards?

- If over 500 donors are expected at a mobile drive (it exceeds the capacity of 22 workstations)
- If a donor requests a manual screening
- If the computer is down
- If a supervisor determines that some component of the system is not operable
- If the company’s security does not allow it
- Non-English speaking donor
- Non-allogeneic donor
Questions?