

Automated interviewing of volunteer blood donors: where are we??

FDA and the Changing Paradigm for Blood Regulation



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Scott Co., IA Regional Authority



Quiet Please!

Donor interview
in progress.

Objectives

- Continued value of screening interviews for blood donors
- Relevant literature on alternate strategies
- Demonstrate computer-assisted screening superior to face-to-face, and paper-based techniques
 - Perceived clarity and comprehension
 - Donor and staff satisfaction
 - Staff time savings
 - Error reduction
 - Accuracy on sensitive questions

Why do we still interview donors? *(with current lab testing)*

- Test negative windows (**rare**)
- False negative test error (**even rarer**)
- “Other” bugs for which we don’t test
 - **Bacteria**
 - **Parasites**
 - **Viruses (Non-A, Non-B, Non-C, WNV)**
 - **Prions (CJD and vCJD)**
- Minimize input of infectious units in system
- Prevent staff exposure
- Donor safety

Does donor qualification work?

	US rate 2000*	ARC FTD rate 2001*	Rate ratio	Percent
HBV	444.8	75.6	5.9	17%
HCV	1387.9	299.1	4.6	22%
HIV	47.2	9.7	4.9	21%

*Prevalence/100,000 population

Sources:

WWW.CDC.GOV.

US Census Statistical Abstract 2001, US Population 2000.
Dodd RY et al. Transfusion. 42:975-79. 2002

But we still get false-negative histories from donors!!

- Inquiries seen as politically motivated or discriminatory may not be taken literally
- Peer and workplace expectations
- Incentives
- Test-seeking behavior
- Inadequate privacy
- Memory (post-donation information)
- Incomplete understanding esp. illiteracy
- “It’s not about me.”

Undisclosed “deferrable” risk

REDS survey shows 1.9% of donors have deferrable risk behaviors at time of donation

Comparison	Relative rate	95% CI
Male v. female	1.4	1.2-2.6
FTD v. repeat	1.6	1.3-2.0
Reactive v. negative screening test	2.7	2.0-3.6
Used CUE v. not	7.6	3.6-15.8

Incentives and undisclosed risk

% with UDR by response to
incentive among repeat
whole blood donors

Discouraged
or indifferent

Incentive	Encouraged	Discouraged or indifferent	OR	95% CI
Cash to donor	3.81	1.82	1.75	1.51-2.02
Discounts	3.46	1.91	1.58	1.40-1.79
Tickets	3.58	1.83	1.70	1.44-2.00
>2 hours off work	3.45	2.00	1.55	1.34-1.80

Donor screening alternatives

Advantages

Disadvantages

Face-to-face

Can be tailored to individual donor

Inconsistent, data errors, insensitive for “stigmatizing” inquiries, non-english can be cumbersome

Paper or computer self-administered written

Cheap, private, consistent, multilingual

Assumes literacy, poorly adaptable to new and complex algorithms

AVT-CASI

Consistent, private, few assumptions, adaptable to new and complex algorithms, multilingual

Start up costs (?), duplicate training

Some issues in donor interviewing

Almost 20% of US adults in literacy strata that would make understanding of prescription directions problematic.

1992 National Adult Literacy Survey.

30,000,000 US residents are foreign born;
21,000,000 speak English less than "very well."

Census 2000

Multimedia improves comprehension of HIV risk among blood donors.

Mayo, D et al. Transfusion. 1991. 31:446.

Medical illiteracy: Baltimore

Percent at REALM* grade level

$\leq 3^{\text{rd}}$ grade 4-6th grade 7-8th grade $\geq 9^{\text{th}}$ grade

Group

N

Some HS	15.6	15.0	30.4	38.9	221
Finished HS	5.7	7.2	22.6	64.5	297
Some college	3.7	3.4	10.6	82.3	285
Finished college	0.4	0.5	5.0	94.2	173

Al-tayib et al. AJP. 2002. 92(9):1478-81.

* REALM = Rapid Estimate of Adult Literacy in Medicine

Errors in completion of written SAQ on same-sex intercourse & masturbation by REALM score

REALM level	Any error (%)	Skip error (%)	Inconsistent (%)	Other (%)	N
\leq Grade 3	79.6	60.7	17.9	0	28
Grade 4-6	67.6	55.9	5.9	5.9	34
Grade 7-8	61.4	51.4	7.1	2.9	70
\geq Grade 9	46.2	39.7	6.5	0	355

Impact of computer interviewing on provision of sensitive information

Behavior	Paper SAQ (%)	A-CASI (%)	Crude OR	Adj. OR	p
Any MSM	1.8	5.3	3.03	3.03	$\leq .001$
IDU ever	0.3	4.5	14.11	16.67	$\leq .001$
Marijuana use daily past year	1.9	5.1	2.78	3.51	$\leq .05$
Crack/cocaine use past year	0.9	5.7	6.67	7.15	$\leq .001$

Early blood donor data

- Improved reporting of HIV risk/symptoms with keyboard interview.
 - 272 blood donors previously screened and accepted by routine American Red Cross written questionnaires or face-to-face interviews
 - 12 donors reported HIV risk behaviors or symptoms when re-interviewed using conventional computer assisted self interviewing (traditional CASI, no audio, no touch screen).

Advantages of AVT-CASI

- Useable by any respondent who can hear
- Programmable in any spoken language
- Aural presentation and visual cues reduce requirement for literacy
- Absolutely standard presentation and pace
- Automated skip and branch patterns for complex inquiries *such as vCJD*
- Technologically simple method of response
- Strong perception of privacy
- Clean data files

Privacy & user friendliness keys to high quality data on sensitive topics

Use of audio-visual touch screen-CASI (AVT-CASI) to obtain data on sensitive topics from a sample of 108 STD clinic patients

- 2 to 1 general preference for AVT-CASI vs. keypad AV-CASI and face-to-face-interview
- Seen as the most private by 2 to 1 margin
- AVT-CASI has the potential to "yield more accurate recording of responses."

Mississippi Valley Regional Blood Center Quality Donor System™ (QDS)

- Headphone audio
- On-screen text
- Color pictures to highlight questions
- Touch screen response: no training
- AABB UDHQ questions
- Staff review mode with flags
- Electronic databases

Hardware & Microsoft OS for QDS

- ViewSonic ViewPad 1000 (other computers with similar configuration OK [IBM, Gateway])
 - Celeron processor ≥ 800 MHz.
 - 128 MB RAM
 - 10 GB Hard Drive
 - External CD-ROM (for loading software)
 - Ethernet Adapter
 - Windows 2000 Professional or Windows XP Professional with IE 5.5/6
- Hewlett-Packard DeskJet 350C printer (most any model OK)
- Total hardware cost ~ \$2000/workstation and falling

Mississippi Valley Regional Blood Center Quality Donor System™ (QDS)

- Implemented >1 yr at MVRBC (CBE-30)
- Deployed sequentially in 10 fixed sites, now on bus.
- >40,000 donor interviews
- Donor & staff modules, 60 multimedia donor screens and two machine readable databases
- Spanish version in development



Medical History

Question 24



Laurie Rogenski, RN

Male donors: Have you had sex with another male, even once, since 1977?



Male-Male Sex?

Back

Yes

???

No

Next

Medical History

Question 23A



Laurie Rogenski, RN

Have you ever used a needle, even once, to take drugs that were not prescribed by a doctor?



Self-injected Drugs?
Used a Needle?

Back

Yes

???

No

Next

Medical History

Question 14B1



Laurie Rogenski, RN

From 1980 through 1996, did you spend time that adds up to 3 months or more in the United Kingdom (England, Northern Ireland, Scotland, Wales, the Isle of Man, the Channel Islands, Gibraltar, or the Falkland Islands)?



United Kingdom Stay?

Back

Yes

???

No

Next



















Staff Review

Click on question to review.

-  -Needs Review
-  -Acceptable After Review by Staff
-  -Aberrant After Staff Review
-  -Answer Acceptable
-  -Donor Deferred Black-N/A

Donor: 233
Gender: Male

Reviewer Login: admin

- | | | | |
|--|---|--|--|
|  Question 1 |  Question 10D |  Question 18 |  Question 26B |
|  Question 2 |  Question 10E |  Question 19 |  Question 27A |
|  Question 3 |  Question 10E1 |  Question 20A |  Question 27B |
|  Question 4 |  Question 11 |  Question 20B |  Question 28 |

		<input type="checkbox"/>	brain covering) graft?
Y	15C	<input checked="" type="checkbox"/>	Have you or any of your blood relatives ever had Creutzfeldt-Jakob disease or have you ever been told that your family is at an increased risk for Creutzfeldt-Jakob disease?
Y	16	<input checked="" type="checkbox"/>	In the past 12 months, have you had close contact with a person with yellow jaundice or viral hepatitis, or have you been given Hepatitis B Immune Globulin (HBIG)?
Y	18	<input checked="" type="checkbox"/>	In the past 12 months, have you received blood or had an organ or tissue transplant or graft?

			anyone who was born in or lived in any African country since 1977?
Y	31	<input checked="" type="checkbox"/>	In the past 12 months, have you been in jail or prison?
<input checked="" type="checkbox"/>	32	N	Have you read and understood all the donor information presented to you, and have all your questions been answered?

Accepted Deferred

Signed

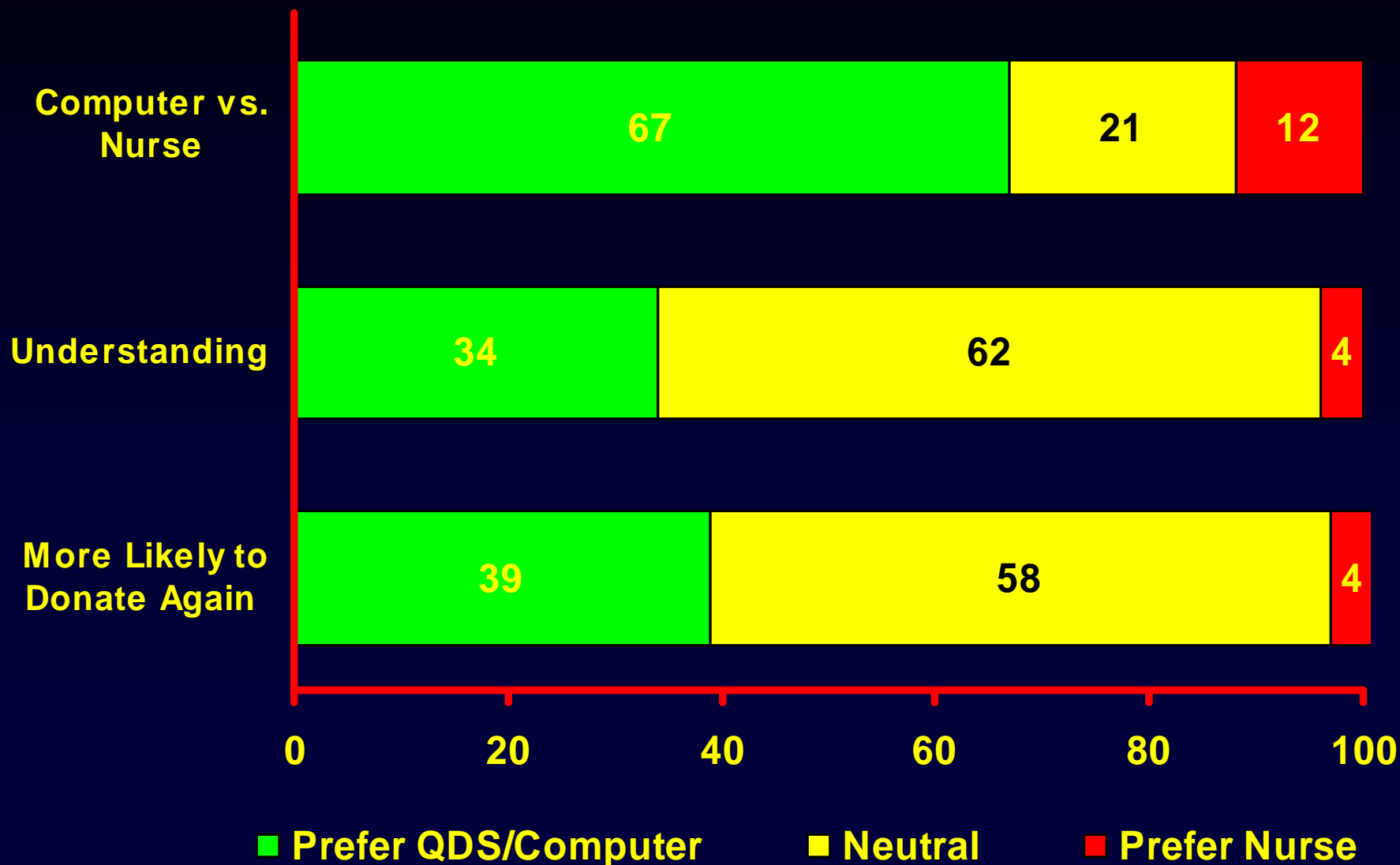
Comments: Q4. Not feeling well, may be low BP

Privacy Comments: Donor now understands

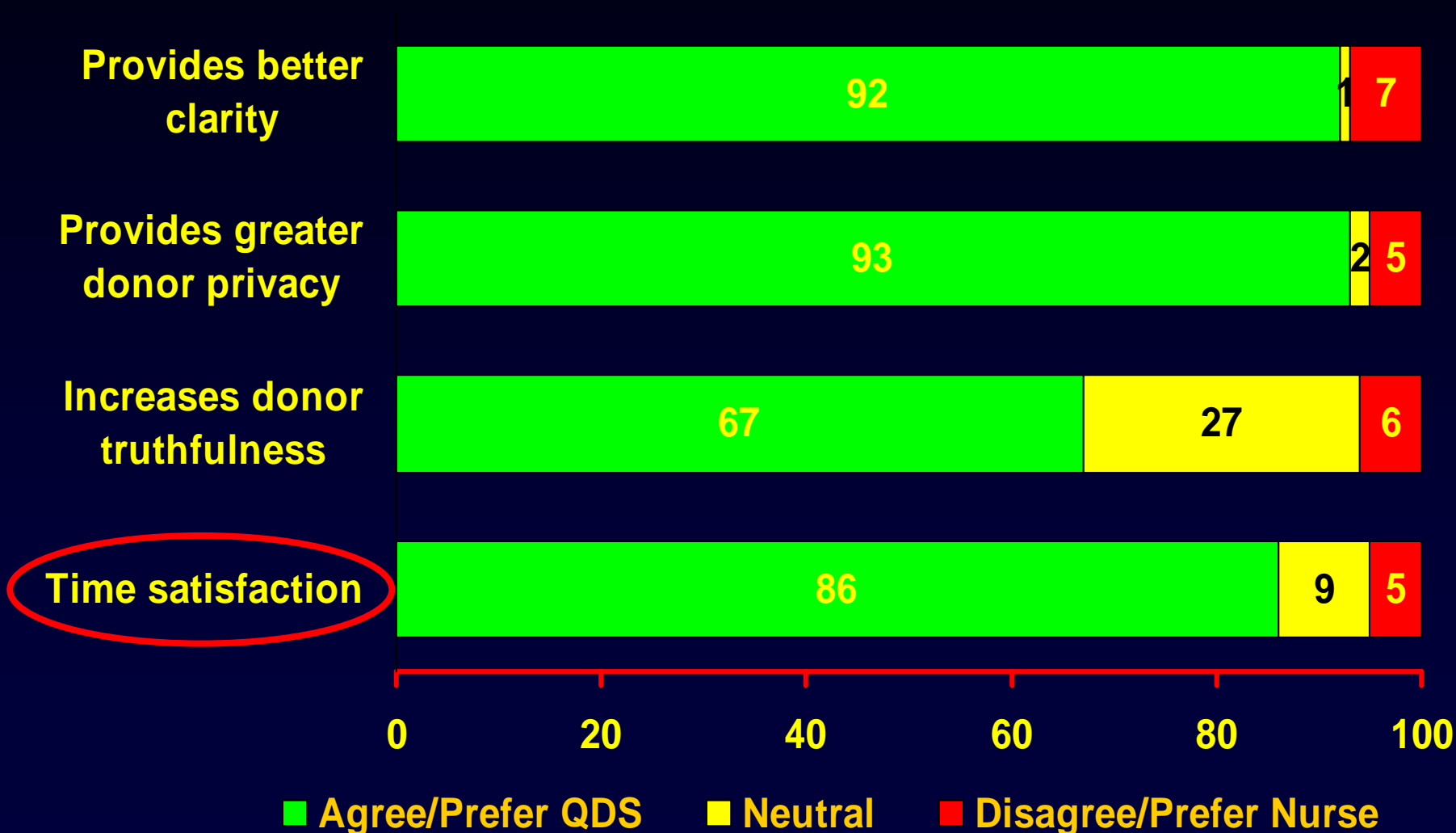
Overall

Donation Comments: Accepted for the donation

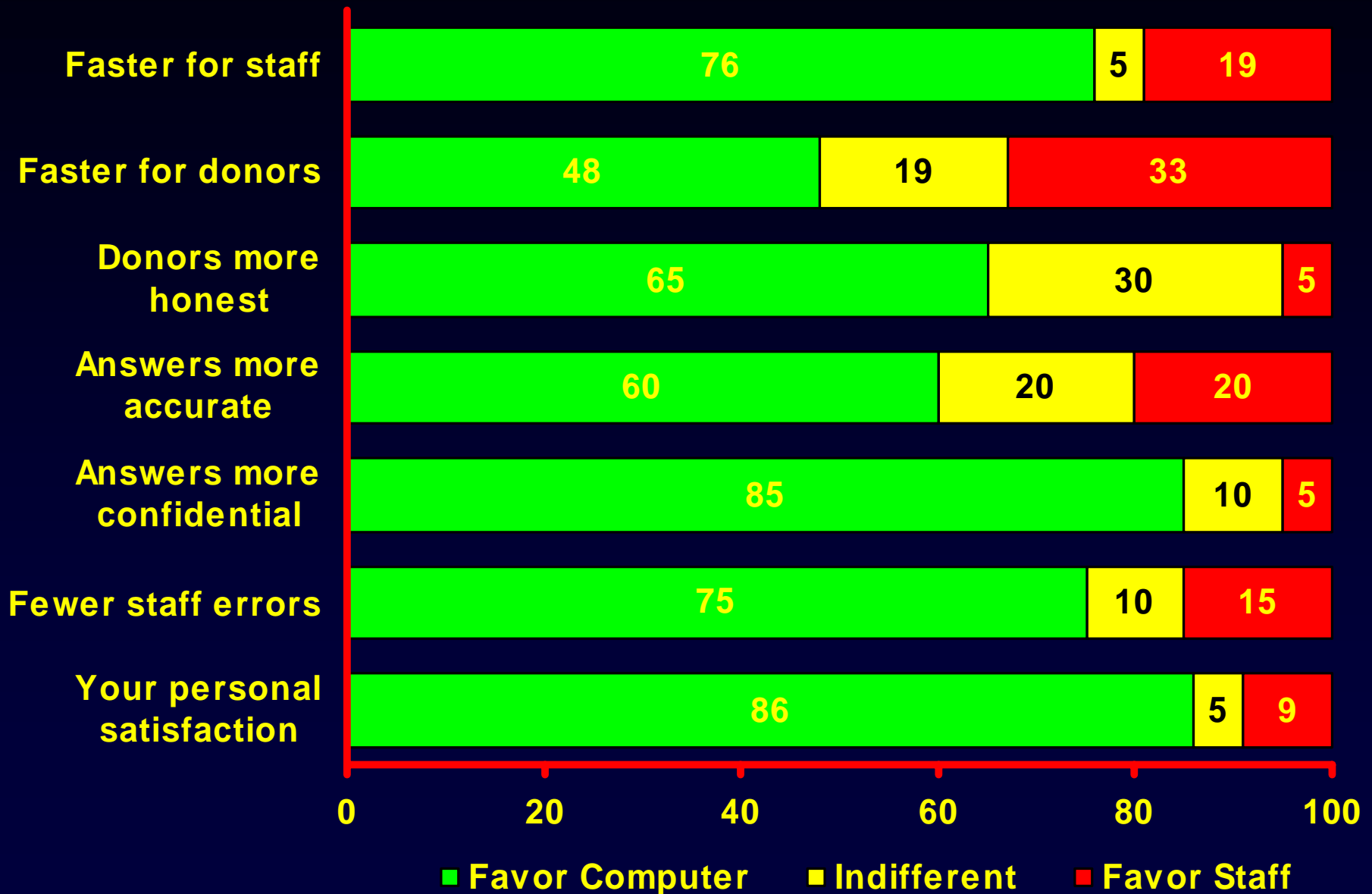
Post-Donation Survey of Donor Reactions to Quality Donor System™ Interview (Davenport Center Summer 2001 (N =532))



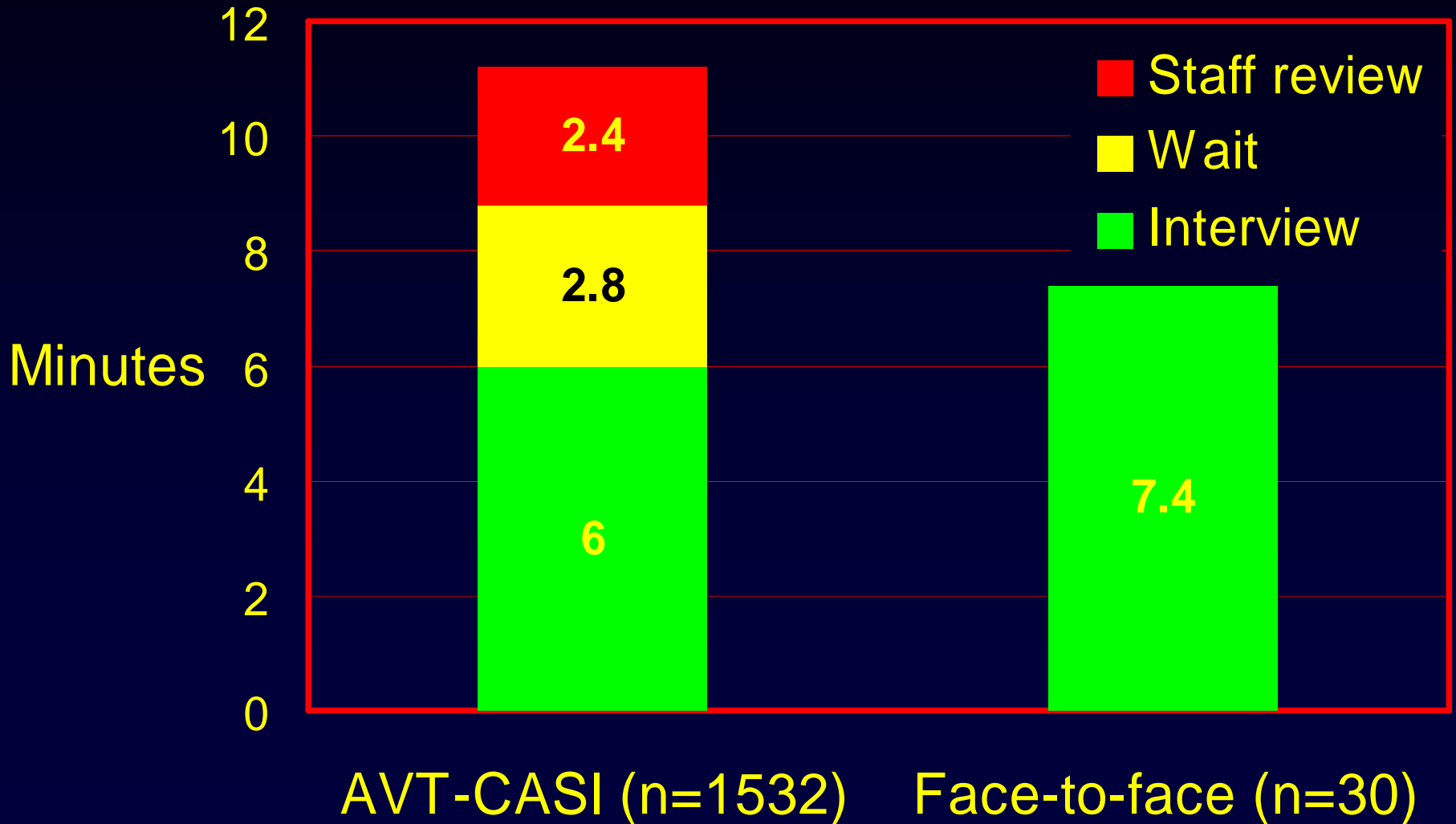
Post-Donation Survey of Donor Reactions to Quality Donor System™ Interview (Davenport Center Summer 2001 (N =532)



MVRBC Staff Survey (N=21)



Time studies AVT-CASI v. face-to-face



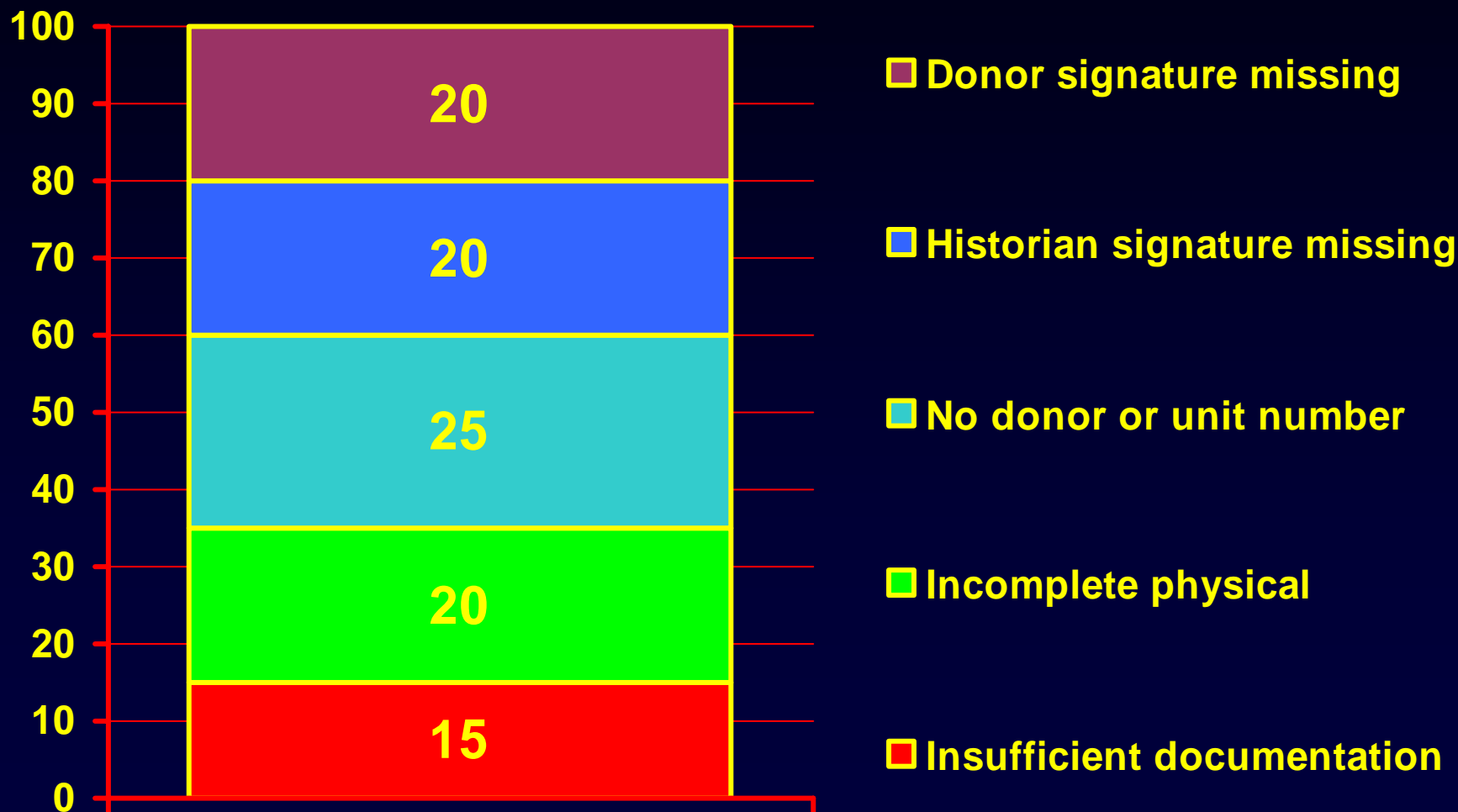
QDS reduces errors and omissions by >60% compared to verbal screening

	AVT-CASI	Face-to-face	Total
Error or omission	20	250	270
No error or omission	13542	65934	79476
Total	13562	66184	79746

Two-sided $p = 0.00004$ (Chi square). OR = 0.39, 95% CI: 0.24-0.63

* Errors/omissions include missed signatures, questions, vital signs, or documentation of responses or deferral codes.

85% of residual errors & omissions should be eliminated by planned upgrades



Impact of AVT-CASI on HIV and STD deferrals of FTD: single fixed site

Includes tattoos, body piercing, other blood exposure

Face-to-face
5/21/00-5/20/01

AVT-CASI
5/21/01-12/30/02

High-risk
deferrals
among FTD

9

43

Presenting
FTD

882

1825

Yates corrected chi-square (two-sided) $p=0.029$.
OR=2.3 (1.1-5.1).

Impact of AVT-CASI on HIV and STD deferrals of FTD: single fixed site

Excludes tattoos, body piercing, other blood exposure

Face-to-face
5/21/00-5/20/01

AVT-CASI
5/21/01-12/30/02

High-risk
deferrals
among FTD

1

19

Presenting
FTD

890

1849

Yates corrected chi-square (two-sided) $p=0.017$.
OR=9.15 (1.3-183.8).

Collaborators

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