



Quality Donor System™ 2004

Talisman Medical Systems Limited
Vienna, VA

Supported in part by National Heart Lung & Blood Institute (NHLBI) grants HL61111 & HL072635
Quality Donor System is a trademark of Talisman Limited

Quality Donor System 2004

- Donor self-interview module
- Staff review module
- Intuitive touch-screen
- Auditable paper donor history card
- AABB Uniform Donor History Questionnaire
- Scientifically proven to reduce errors

Quality Donor System 2004

- 510(k) cleared
- English and Spanish interviews
- Communicates to BECS
- Over 200,000 donor interviews completed at 4 blood centers (as of 7/04)
- New UDHQ available November 2004

Scientifically Proven Benefits

- Donor satisfaction increased by factor ≥ 7
- Donors 14 times more likely to repeat
- Staff prefer 4 times more than face-to-face
- 60+% reduction in FDA-reportable errors
- Self-report of risky behavior – 9 times more frequent

Scientifically Proven Benefits

- Staff time savings of up to 5 minutes/donor
- Proven ability to update new CBER questions in 7 days
- No donor training
- 2-3 hours staff training
- Improved ability to handle donor surges and control queues
- 2nd *Transfusion* article in January 2005


Proven Reliability

- 2001 – First production line installation (MVRBC)
- 2003 – Changes for CBER-mandated questions reduced to 1 week
- 2003 – First RBC using QDS for 100% of donations (West TN RBC)
- 2004 – Second RBC using QDS for 100% of donations (Mid-South RBC)

Proven Reliability

- 2004 – Over 200,000 donors screened (July)
- No QDS bugs reported in over 2 years
- 3 more blood centers expected to be at 100% QDS screening by year end
- On target to screen 7,000 donors/week

Implementation

- 510(k) clearance  **NEW!**
- Installs with CBE-30 as standalone, wired and wireless LANs, WANS
- Changes require only Annual Report
- Operational in 4 blood centers in fixed sites, vans and setups

QDS Users

Mississippi Valley Regional Blood Center
Davenport, IA
(2001)



QDS Users

Lifeline – West Tennessee Regional Blood Center
Jackson, TN
(2003)



QDS Users

Lifeblood – Mid-South Regional Blood Center
Memphis, TN
(2003)



QDS Users

LifeShare Blood Centers
Shreveport, LA
(2004)



QDS Users

Dartmouth-Hitchcock Medical Center
Lebanon, NH
(2004)



Technology

- Software built with Web technology
 - Power
 - Flexibility
 - Scalability
- Touch-screen workstations
 - Estimated \$2,000 each
 - \$0.13/interview (100/week for 3 years)

Investment

- Supported in part by National Heart Lung & Blood Institute (NHLBI) competitive grants HL61111 & HL072635.
- To date more than \$3M has been invested in QDS R&D over 10+ years

Donor Self-Interview


- Audio-visual touch screen computer aided self interview – *AVT-CASI*
 - Text + Audio + Picture
- No donor training required
- Addresses medical illiteracy
- Pictures aid recall
- Greater perceived privacy

Donor Self Interview


Medical History

Question 30A

Were you born in, have you lived in, or have you traveled to any African country since 1977?



Laurie Rogenski, RN



Africa Since 1977?

Back **Yes** **???** **No** **Next**

Staff Review

Donor Name: Daniel A Donor
 Gender: Male
 Reviewer Login: admin
 Questionnaire: UDHQ

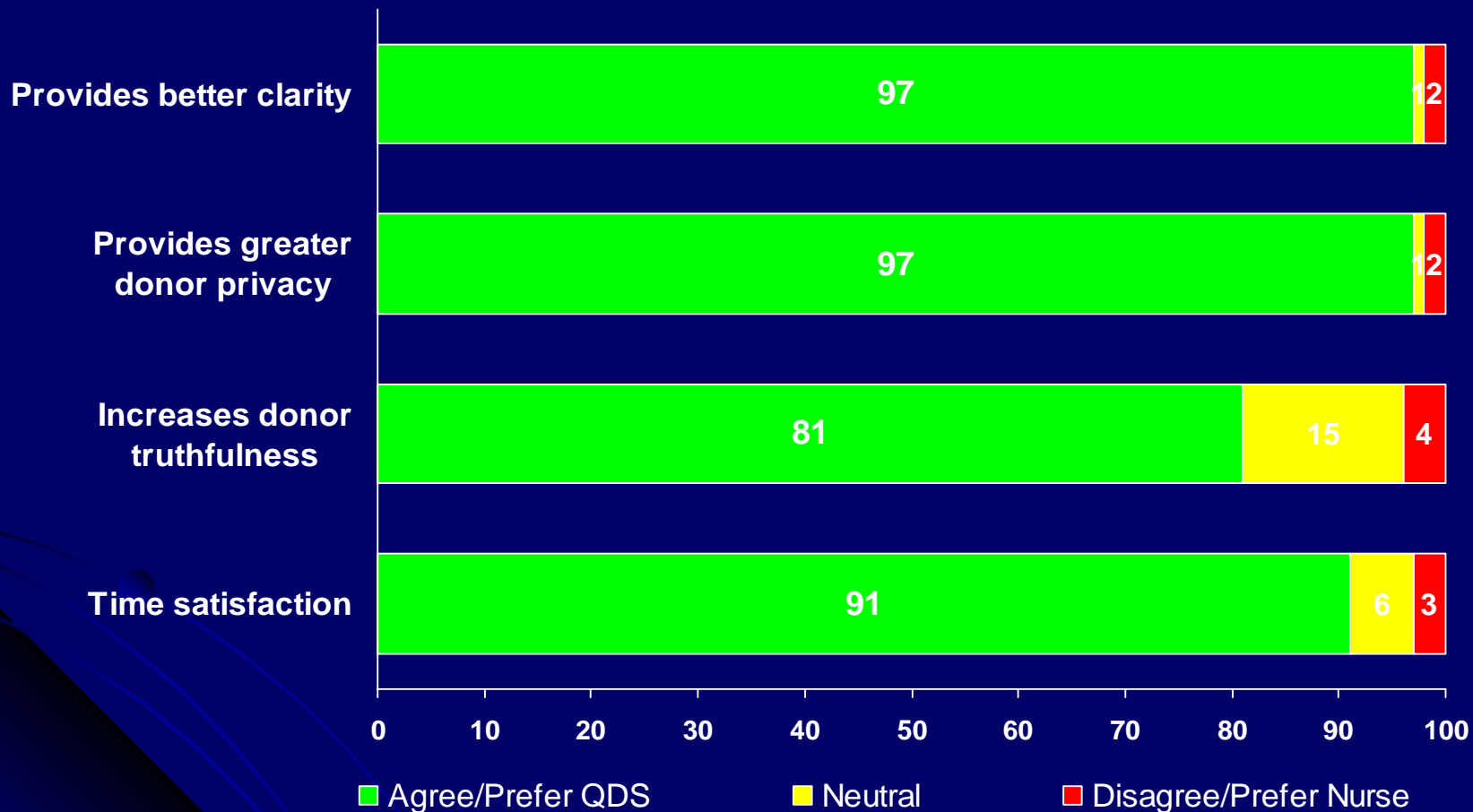
- ▼ -Needs Review
- ▼✓ -Acceptable After Review by Staff
- ⚠ -Aberrant After Staff Review
- ✓ -Answer Acceptable
- ✗ -Donor Deferred Black-N/A

✓ Question 1	✓ Question 10D	Question 14C	✓ Question 24
✓ Question 2	✓ Question 10E	Question 14C1	Question 25
▼✓ Question 3	✓ Question 10E1	Question 14C2	✓ Question 26A
⚠ Question 4	✓ Question 11	✓ Question 15A	✓ Question 26B
✓ Question 4A	✓ Question 11A	✓ Question 15B	✓ Question 27A
✓ Question 4B	Question 11A1	✓ Question 15C	✓ Question 27B
✓ Question 4C	Question 11A2	✓ Question 16	✓ Question 28
✓ Question 5	✓ Question 11B	✓ Question 18	✓ Question 29
✓ Question 5A	Question 11B1	✓ Question 19	✓ Question 30A
✓ Question 6	▼✓ Question 12	✓ Question 20A	Question 30B
✓ Question 7	Question 13	✓ Question 20B	✗ Question 30C

Donor Satisfaction Survey

3 Blood Centers*

March-May 2004 (N=2,188)

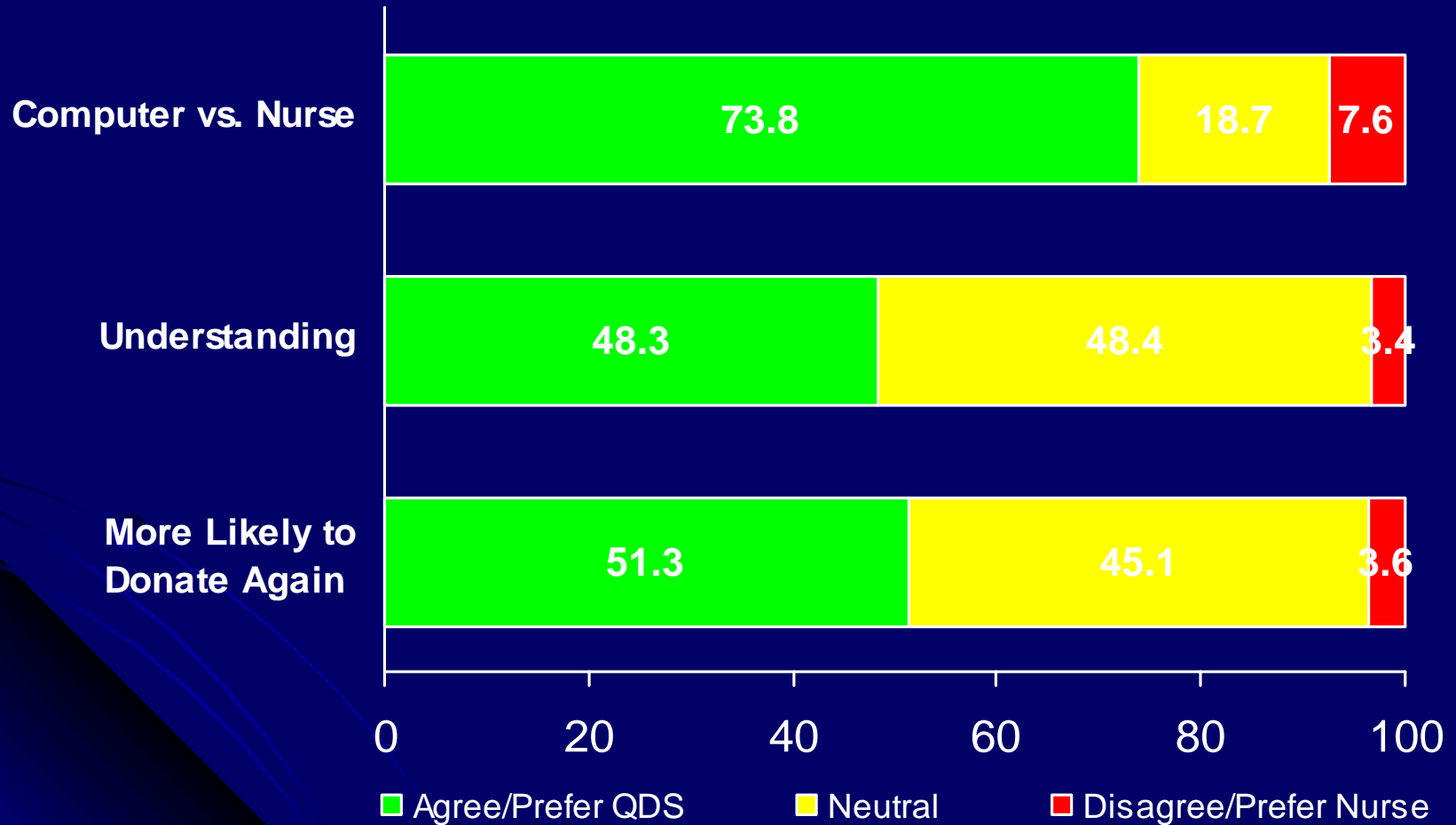


*Preliminary data

Donor Satisfaction Survey

3 Blood Centers*

March-May 2004 (N=2,188)



*Preliminary data

Replicative donor satisfaction surveys

Comparison of responses to interview questions by donors exposed to QDS at 2 locations for first time vs. repeat QDS users MVRBC (2001)

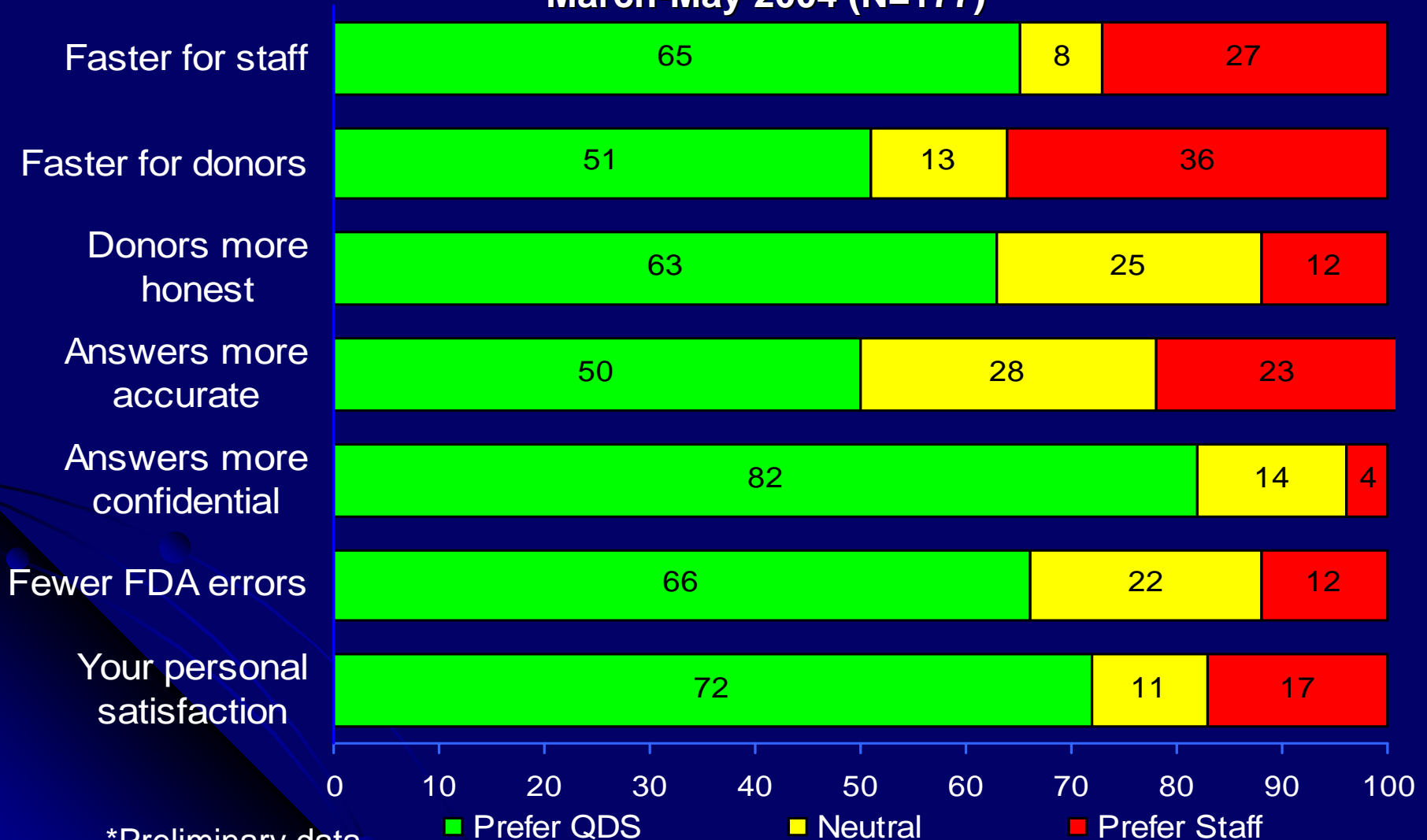
Ratios of Numbers of QDS-favorable to QDS-unfavorable Donors (1+2) to (4+5)

	First exposure	Prior exposure	Prior - First
A. All donors			
Clarity	12.4	17.2	4.8
Privacy	14.5	17.9	3.4
Truthfulness	7.5	10.3	2.8
Time involved	13.5	20.6	6.9
B Repeat donors only			
QDS vs. staff	5.5	7.9	2.4
Understanding	8.0	11.9	3.9
Likelihood of return	8.4	14.3	5.9

Staff Satisfaction Survey

Three Blood Centers*

March-May 2004 (N=177)



*Preliminary data

10/19/2004

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Time Studies

Face-to-face (FTF) and QDS donor interviewing

MVRBC Davenport Center (2001)

Average Elapsed Time (minutes)

Interview mode	N	Self-interview	Wait for staff	Staff review	Total donor time	Total staff time
QDS	1532	6.0	2.8	2.4	11.2	2.4
FTF	30	–	–	–	7.4	7.4
Time Difference					+3.8	-5.0

**QDS reduces errors and omissions by > 60%
compared to FTF screening
MVRBC (2000-2002)**

	QDS	FTF	Total
Error or omission	20	250	270
No error or omission	13542	65934	79476
Total	13562	66184	79746
Error rate/1000 Int.	1.475	3.777	3.386
Decline in error rate	61%		

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

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

Source: CBER/NIH Best Practices Presentation 2002

Deferral of first time donors for high risk behaviors: MVRBC single fixed site*

	Face-to-face <u>5/21/00-5/20/01</u>	QDS <u>5/21/01-12/30/02</u>
High-risk deferrals	1	19
Total first time donors	890	1849
Rate per 1000 donors	1.12	10.28
Ratio of rates		9.2

* Deferrals for HIV & STD, excluding tattoos, body piercing & other blood exposure

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

L Katz, MD - *FDA and the Changing Paradigm for Blood Regulation*, Jan 2003