

Ante-mortem Testing for Blood Transfusion

The creation of a panel of samples to be used in assessing tests for
vCJD in donor blood.

NHSBT Test Assessment Facility.

Belinda Pelle

Manchester Blood Centre.

vCJD

- First described 1996 (deaths 1994=0, 1995=3, 1996=10)
- Atypical clinical features
- Neuro-psychiatric symptoms
- Age at presentation 12 - 74 years

- Onset of symptoms to diagnosis - 9 months
- Diagnosis to death ; 6 - 24 months
- No known cure
- Same strain of disease as Bovine Spongiform Encephalopathy (BSE)

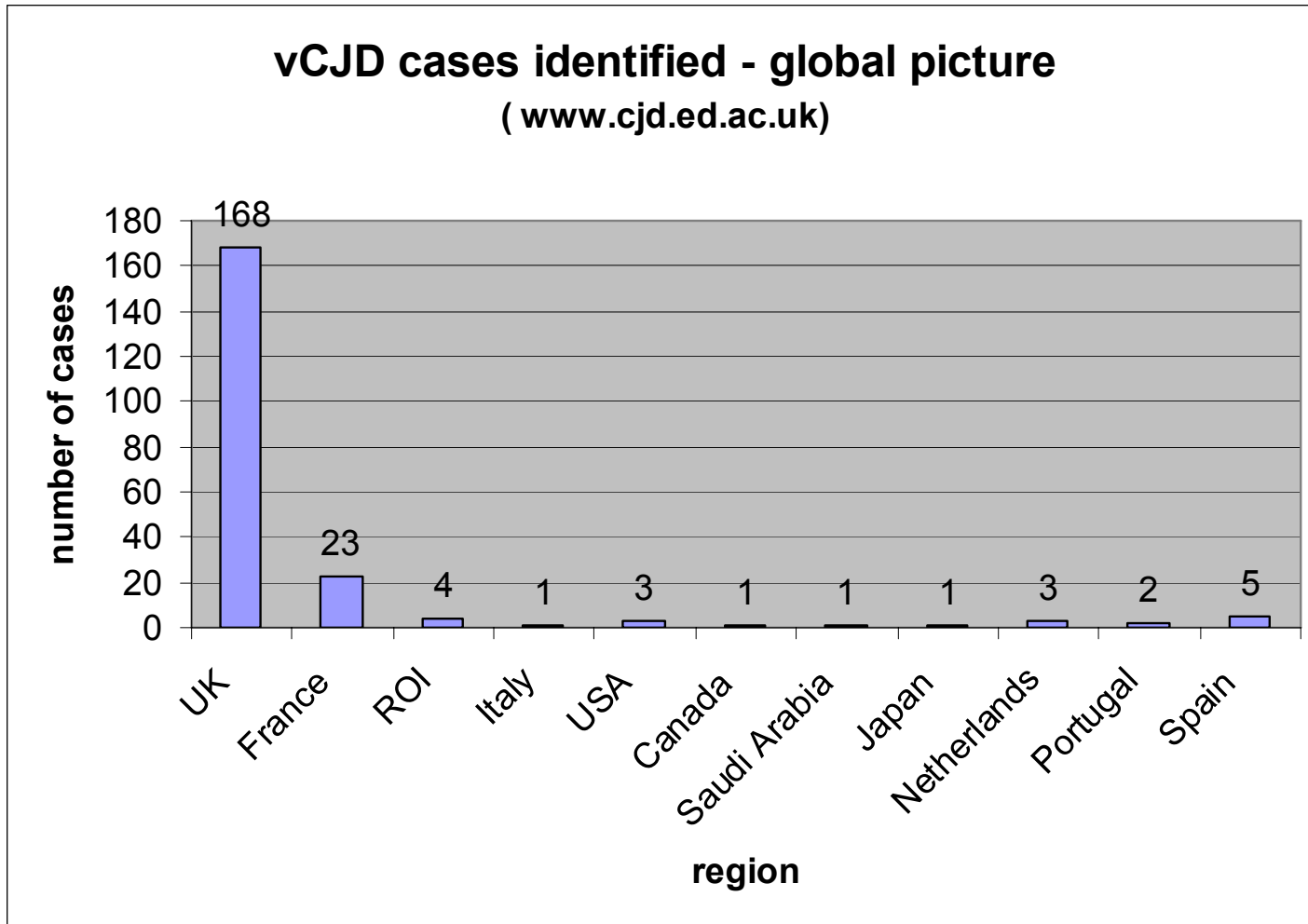
- SACTTI position statement

vCJD in the UK

deaths from definite (confirmed) vCJD	115
deaths from probable vCJD (no neuropathology)	49
total	164

cases still alive	4
deaths 1996	10
deaths 2000	28
deaths 2004	9
deaths 2008	1

- Unknown incidence in population
- 3 cases associated with receipt of blood components
- UK CJD surveillance unit (www.cjd.ed.ac.uk)
- N.J.Andrews, Centre for Infections, HPA.



Primary aim of TAF - overview

- Currently no large scale routine blood screening test for vCJD in humans - in development stages
- DoH requirement for Blood Services to assess and report findings as soon as possible
- **Readiness** - determine if emerging tests are operationally 'fit for purpose' – sensitivity, specificity, impact assessment
- **Test Assessment Facility** – panel of samples ready for use

Required profile of panel

- 5,000 U.K. and 5,000 U.S. donations (comparison)
- Consenting donors
- Mix of male : female
- Variety of ages
- Variety of geographical areas
- Not 'actively selected '

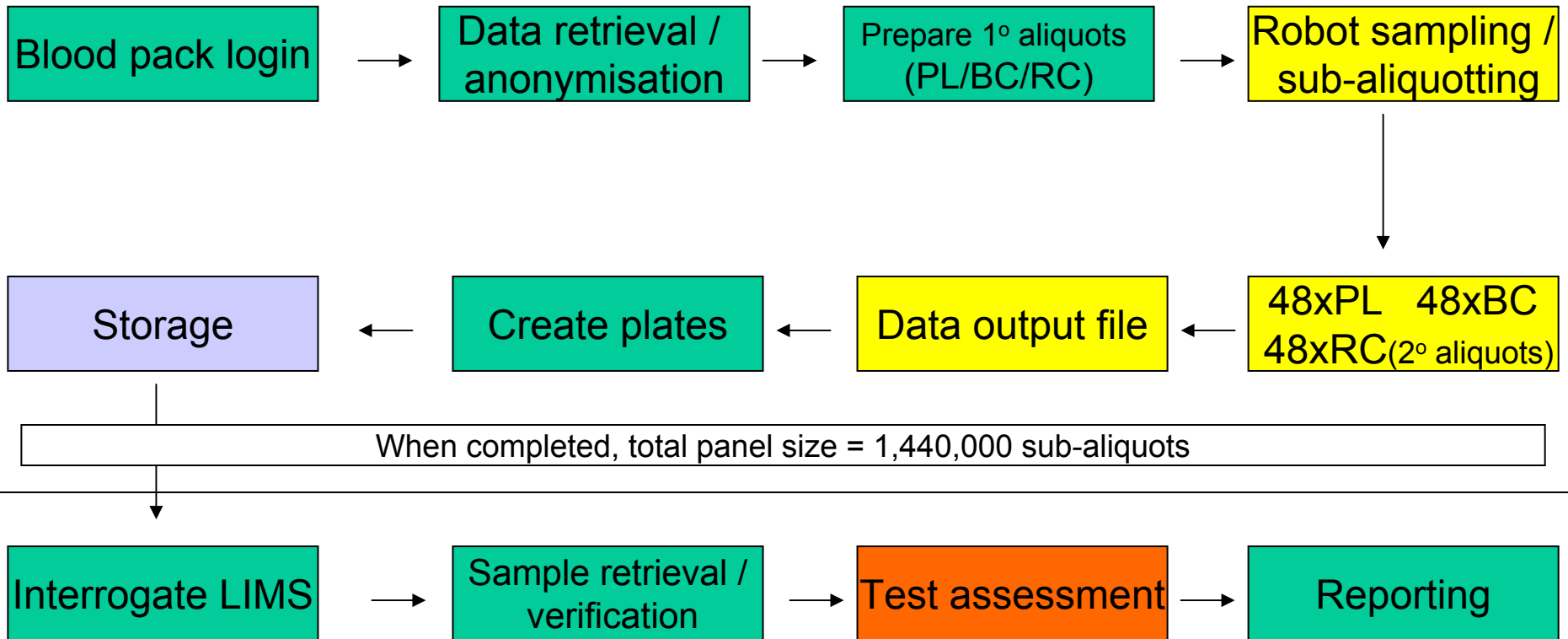
- Irreversibly anonymised

- Completed by end 2007

System requirements

- Pack login - anonymisation
- Processing facilities
- Robotic sample handlers with integral cameras
- Highly configurable LIMS- Manage database / irreversible anonymisation
- Wireless technology - for storage and retrieval requirements
- GMP + GAMP compliant
- Transport / logistics / consent

Process



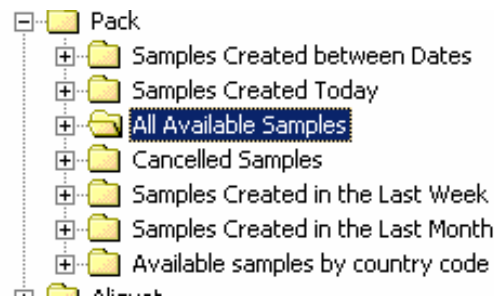
Irreversible anonymisation

- Demographic data imported by LIMS at pack log-in
- Retrieves (age band, gender, sector code)
- Overwrites donation ID with new sample name

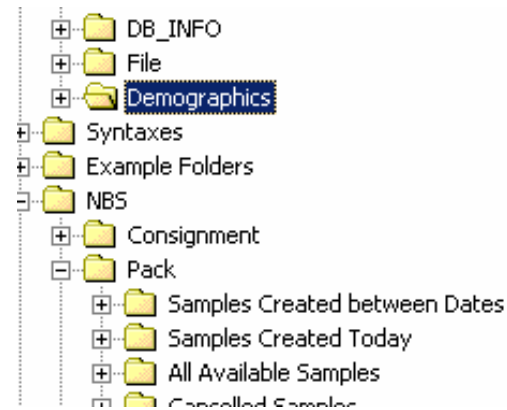
- Demographics onto separate data table
- Rows populated in random order
- Unique entries, no link back

- Data table acts as a monitor

Blood and Transplant



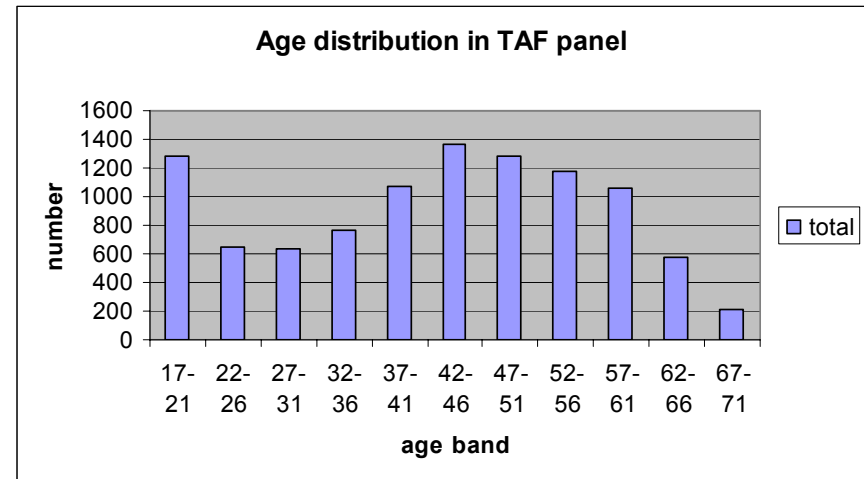
09347	10590	10590	U.K.	Grun0002	18/10/2007 08:27:38
09348	10591	10591	U.K.	Grun0002	18/10/2007 08:28:23
09349	10592	10592	U.K.	Grun0002	18/10/2007 08:29:09
09350	10593	10593	U.K.	Grun0002	18/10/2007 08:29:55
09352	10595	10595	U.S.	jone0095	18/10/2007 11:20:23
09353	10596	10596	U.S.	jone0095	18/10/2007 11:21:52
09354	10597	10597	U.S.	jone0095	18/10/2007 11:22:55
09355	10598	10598	U.S.	jone0095	18/10/2007 11:24:17



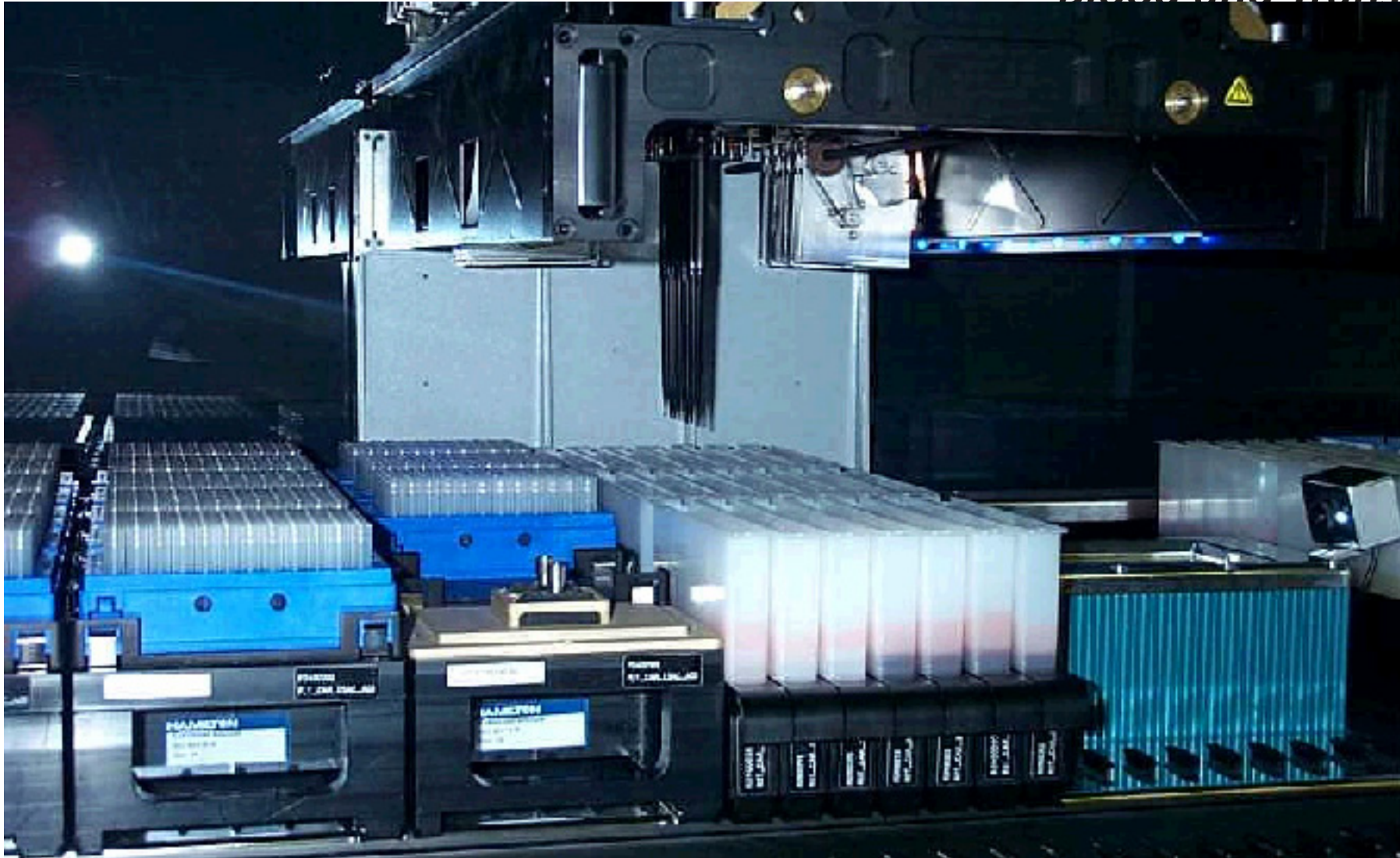
10022006100201476	32-36	F		6496
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10022006100201478	37-41	M	TA6	6498
10022006100201479	27-31	M	B523	6499
1002200610020148	62-66	M		6068
10022006100201480	22-26	M		6500
10022006100201481				6501
10022006100201482	57-61	F		6502
10022006100201483	62-66	F	YO62	6503
10022006100201484	42-46	M		6504
10022006100201485				6505

Status of completed panel (go-live Dec 2005)

- Completed 23/01/2008
- 316 deliveries from U.S., 263 from U.K (inc 21 Scotland)
- 10,053 packs logged in (> 100%)
- Male : female ratio = 47% : 53%
- 1009 postcode sectors
- Age bands show good distribution
- 15,201 plates









UK forum vCJD workshop - April 2007

- (HPA Populus Feb 2007)
- Assay development - CE marking, technical specification , sensitivity, specificity
- Validation protocols - procurement of high risk samples
- Insurance - assurances for donors / patients
- Donors and ethics - confirmation , counselling
- Supply planning - impact on donor database

Conclusion

- Panel complete
- NHSBT ready to assess available tests
- Extensive validation work to be undertaken
- Decisions to be made - Ethical / legal / clinical / supply chain
- Thank you for listening