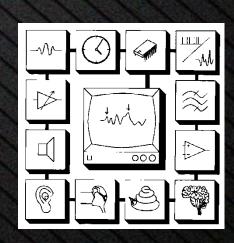
ANHSC 2015 conference

Remote professional training & support

Guy Lightfoot ERA Training & Consultancy

Email: admin@eratraining.co.uk www.eratraining.co.uk www.abrpeerreview.co.uk



Background

- Davis & Bamford report 1997
 - Made the case for universal newborn screening (OAE)
- Preparation of protocols
 - 1999 diagnostic ABR based on click ABR
- National programme roll-out 2001 2006
- 3-day ABR training course on ABR for all staff
- Development of suite of protocols (now "guidance")
 - Early Assessment overview
 - AC & BC frequency specific ABR & ASSR testing
 - ANSD & CM testing
 - Others, inc Tymp & VRA
 - Available at www.abrpeerreview.co.uk/resources.html

Background

- National database (eSP)
- Screen Includes:
 - Bilateral PCHI of moderate or greater degree
 (>=40dB averaged 0.5 to 4kHz)
 - ANSD in NICU/SCBU babies
- Screen Excludes
 - Unilateral PCHI (but will be detected)
 - Mild bilateral PCHI (some may be detected)
 - ANSD in well babies
- Referred babies should be assessed within 4 weeks
- Assessment to be completed by 8 weeks

Prevalence

PCHI Bilateral – 1.3 per 1000 births

- 1.1 Congenital
- 0.2 Acquired

PCHI Unilateral: - 0.8 per 1000

Progressive – inc CMV 1.65 per 1000 by age 9 yr

ANSD ~ 0.1 per 1000

Severity (NHSP data at 2011)

Moderate(40-69dB)	51%
Severe (70-94dB)	28%
Profound (>=95dB)	21%

Prevalence: 2/1000

Screened: 10000

	Normal	PCHI				
Pass	9681	2 969				
Refer	299	18	309			
	9980	20	10000			

Sensitivity: 90.0%

Specificity: 97.0%

Referral rate: 3.2%

PPV: 5.7%

Prevalence: 2/1000

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NNT:	17.6

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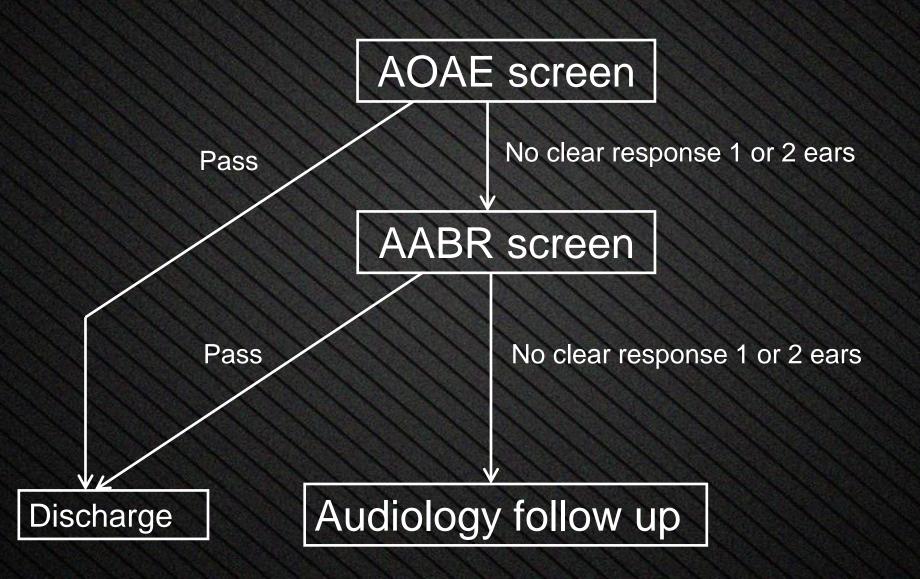
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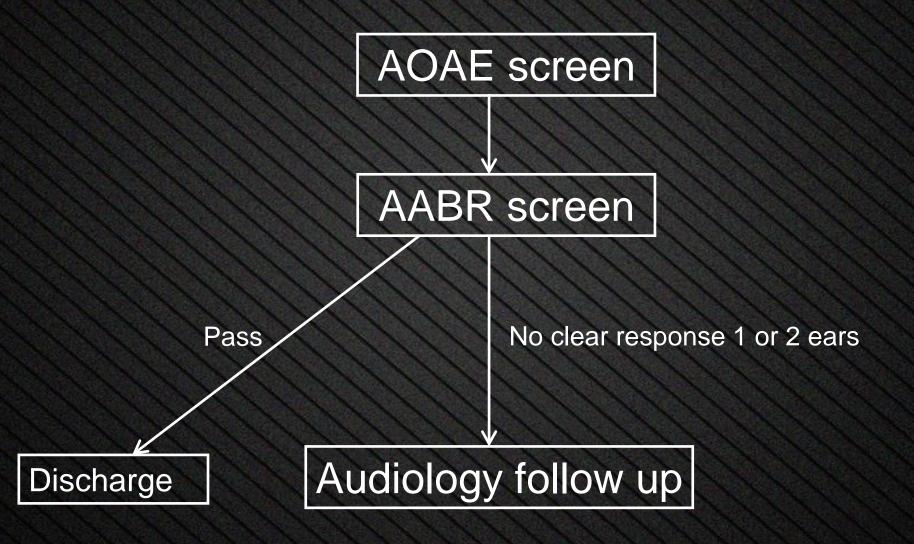
Referral rate: 3.2%

PPV: 5.7%

NHSP- well baby simplified



NHSP - NICU/SCBU baby simplified



NHSP Standards

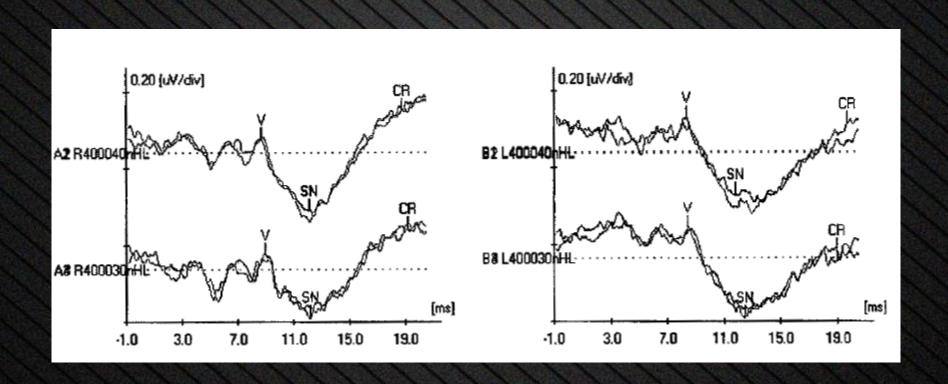
Coverage	≥ 95%
Diag follow-up within 4wk	≥ 90%
Ref rate (bilateral)	≤ 3%
Yield (bilateral)	Mean ≈ 1/1000

The need for protocols

- Without prescriptive guidance:
 - Variable (sometimes dangerous) practice
 - Inconsistent standards of diagnosis & management
 - Poor recognition of tester's own limitations
 - Practice is "stuck in the past"
 - Testers (& their employers) may be legally vulnerable
- NHSP guidance documents have been developed:
 - Using current scientific evidence & best practice
 - Based on high but clinically realistic standards
 - Drafts open to consultation
 - Subject to periodic review as new evidence emerges
 - Supported by experts to give testers clinical / practical advice

Example of a discharge ABR

"Clear Responses" at discharge level & 10dB above in both ears at 4kHz

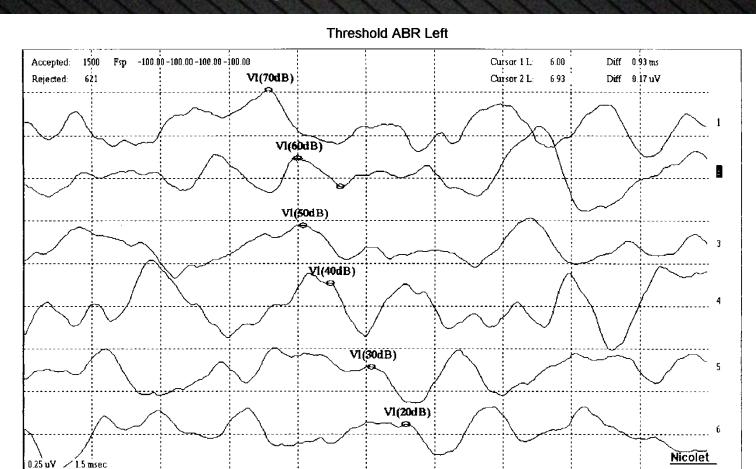


ABR Quality issues

- Despite comprehensive prescriptive guidance, several "serious untoward incidents" still occurred
- Out of court settlements typically £1.5M (AU\$2.8M)
- Series of QA audits were initiated from 2009
- Audits have revealed:
 - National guidance sometimes ignored or misunderstood
 - Errors of test parameters
 - Errors of waveform interpretation
 - Errors of test strategy
 - Errors of reporting
 - Errors of case management

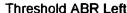
Simulated example from legal case

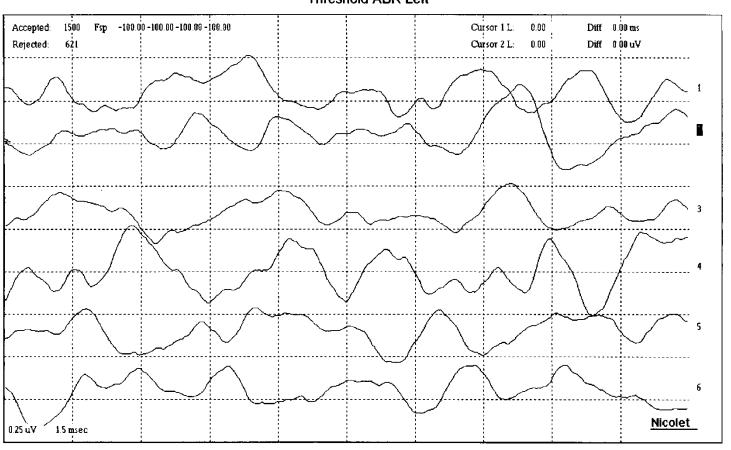
"Hearing within normal limits"



Simulated example from legal case

"Hearing within normal limits"





Sensitivity and Sweep Time Per Division

3 |0.25 uV | 1.5 msec

5 | 0.25 uV 1.5 msec

6 |0.25 uV

1.5 msec

1 |0.25 uV 1.5 msec

2 |0.25 uV 1.5 msec

"QA4" ABR audit (2012 / 13)

- Each centre required to submit 4 cases
 - 2 discharge & 2 PCHI
 - Cases selected by NHSP, not the centre
- Single national assessor (me!) rated each centre, moderated by another assessor
- Feedback given via NHSP, including:
 - Identification of issues
 - Suggestions for improvement
- Audit results (all aspects of post-screening service) available to the public
- This ensured pressure for improvement from parents and service commissioners

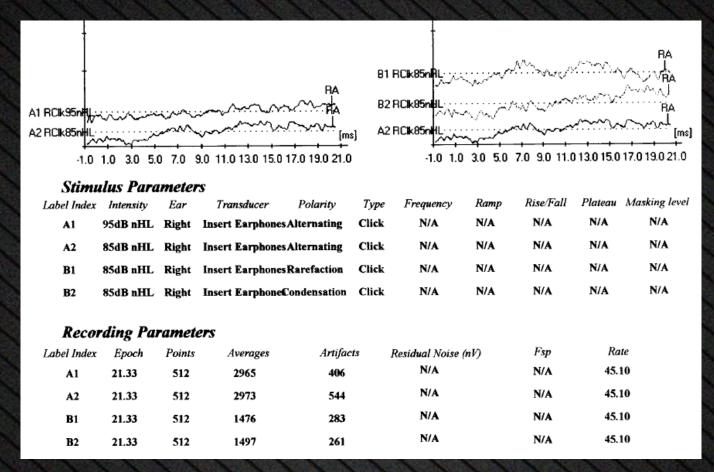
"QA4" ABR audit outcomes

	1 (best)	All cases are satisfactory with no (or only minor) issues	12%
	2	All cases are generally satisfactory but with some improvement indicators	35%
	3	Discharge cases are generally satisfactory with or without improvement indicators. PCHI cases have more significant shortcomings	48%
	4	Both discharge and PCHI cases have significant shortcomings	5%
•	5 (worst)	Serious shortcomings (suspend service?)	0%
		ne 3 sites had phone call from assessor to estand to decide whether to initiate mento	

NHSP ABR interpretation

- "Old school" approach:
 a response is either there or it is not
- NHSP approach: not 2 but 3 possible outcomes
 - Response is present, with a high degree of certainty (NHSP terminology "Clear Response", CR)
 - Response is absent, with a high degree of certainty (NHSP terminology "Response Absent", RA)
 - Recording conditions too poor to tell (NHSP terminology "Inconclusive", Inc)
- Inconclusive levels cannot contribute to the definition of threshold

QA4 Example: spot the issue!



- There are two, but which is most important?
 - "RA" claimed but no estimation of residual noise
 - Maximum safe stimulus level exceeded with inserts

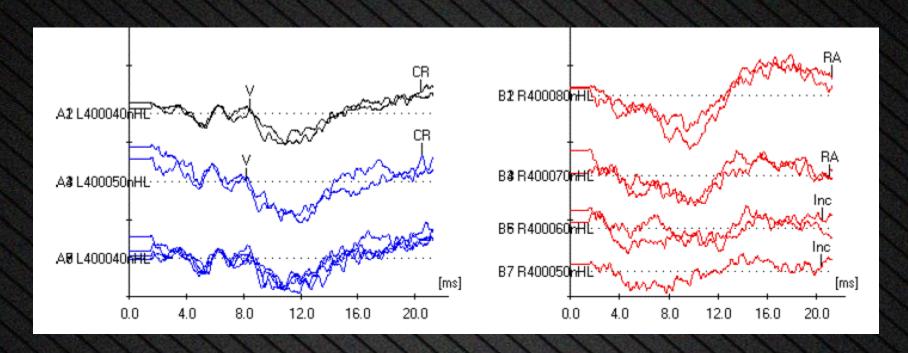
Tubal insert phones - Warning!

- All calibration data is derived from adults
- Unlike supra-aural phones, the enclosed volume of inserts depends on just the canal size
- In a neonate, this is much smaller than in an adult
- Physics: +6dB per halving of volume
- The actual stimulus will be 10-20dB higher in a newborn so "100" dBnHL is really 110-120dBnHL and that is about 140-150dB peak SPL!

(From Sininger et al, 1997, Hear Res 104; 27-38 Voss & Herrman 2006 Ear & Hearing, 26, 636-650)

- Beware delivering highest intensities via inserts EVEN WHEN THERE IS NO ABR!
 - the baby's hair cells might be normal!
 - Never test >85dB

QA4 Example: what's going on here?



- Lt is fine (4 runs at 40dB, weighted add)
- Rt labelled "RA" because it doesn't look "quite right"
- Presumed to be artifactual (a clamped run would help)
- Electrode misconnection has inverted the waveforms

So, there is a problem – Solutions?

- Available options include:
 - Require ABR testers to undergo certification (driving test)
 - Free "refresher" courses for all ABR testers
 - On-site visits to identify issues and initiate re-training
 - Close monitoring / mentoring of worst performing sites
 - Suspend service of sites resistant to change
 - Promote the development of regional peer review groups, with national moderation & support
 - Introduce remote "tele-audiometry" ABR or on-line expert
 - Continue QA audits to monitor quality
- So what did NHSP do?

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Tester certification

- If starting from scratch, is a viable option
- Particularly attractive if one ABR system specified
- Expensive: involves both training & examination
- Long lead-time and resource dependent
- Rejected by NHSP as a solution for England

On-site visits for struggling sites

- Implemented, post QA4 (5 sites)
- 1-day visit by an ABR expert (AM clinic, PM talk)
- Non-obvious issues occasionally revealed
 - e.g. sources of electrical interference
 - e.g. poor electrode technique
- Areas of misunderstanding quickly revealed
- Springboard to a period of mentorship
 - The visit fosters relationship of trust (& obligation to engage?) with mentor
- Testers were initially apprehensive but visits very effective in initiating change

Remote mentoring of worst performing sites

- Typically 12-15 sites at any one time
- Follow up on issues exposed by QA audit
- Every ABR (waveforms & report) sent to mentor by email within 2 days of testing
- Mentor emailed back with review and suggestions
- Issues logged by mentor
- Case selection was eased as progress was made
 - e.g. changed to bilateral referrals only or PCHI only
- Site released when standards were acceptable
- Efficient but a few sites wouldn't engage in process
 - maybe seen as "punishment" for poor performance

Peer Review- what's involved?

The obvious:

- Technical issues / test parameters
- Waveform interpretation
- Result reporting

The less obvious:

- Practical arrangements (age of baby; timing of clinics)
- Test strategy (doing the correct tests, correct order)
- Case management (follow-up / referral when necessary)
- BSA ABR peer review document:
 - www.thebsa.org.uk/bsa-groups/electrophysiology-group/ ep-additional-resources/

Models of ABR Peer Review

Periodic get-togethers to discuss "interesting" cases

- Good for bonding working relationships with colleagues
- Some improvement in skills
- Only as good as the best member
- Process is too slow to help individual patients
- No training in reviewing skills
- Embarrassing cases not selected

Poor

Models of ABR Peer Review

NHSP Generic scheme

- Data is transferred by secure email in < 48 hours ✓
- Cases selected systematically
- Consistent review result format (Excel spreadsheet)
- Good for bonding working relationships with colleagues
- Reviewers receive training & are accredited
- Fast turn-round time: advice can inform next session on the same baby
- Doesn't require IT investment / costs
- Doesn't integrate with English ABR national database
- Reviewer is known to tester

Better

Peer Review Spreadsheet

	A	and the second second by the second second	C	D	E	F	G	Н	100	J	К	L	М	
							ester re background / results / plans for further tests etc. (Do not exceed cell width)							
3		Tester		Well baby. ABR at 1 week corrected age suggested severe bilateral loss but had considerable										
4		Case ID	Example	interference issues so results uncertain.										
5		Reason for test	Newborn screen referral	Today bilateral flat loss confirmed. Tymps flat R & L. Impressions taken.										
6		Newborn Screen outcome	NCR bilateral											
7	For Tester Use	Date of test (dd/mm/yyyy)												
Corrected Age at test (weeks) 6 Aids fitted - for F/U at 8/12. Over 48 hr in NICU/SCBU - yes/no No														
10		ABR AC Transducer / Stim Type	Insert / Pips											
11	Outcome of ABR/any further action PCHI management													
12		Date of next appt if any												
13		Date sent for review												
14		Reviewer name		Comments from Reviewer (Do not exceed cell width; use separate rows)										
15		neviewer name												
16			Good that you got 2 frequencies but RA requires replication, with noise <25nV. It is important to know if this baby has a conductive or sensorineural loss so I would urge you to											
17	For Reviewer use	Date review returned to site						need to aid t						
18	. or neviewer use	Discussed with tester? yes/no	No	consider	Jimging	Dack IOI	TA DC. II I	rocu to aid t	and date v	van nung i	as AC IIII	condida (Journ De	
19		ABR quality judgement	Improvement indicators	Note to a	eviewor	there are	6 rows	above for yo	ur commo	nte Limitu	what wou	enter in o	ach call so	
20			ABR repeat					above for yo), as in this						
21		Action required beyond planned?	явк repeat	паст са	ii ue read	TX91 OII)	is maden	, as at this	скаттрте. Т	nese ceils	do not W	rap me te	SAL.	
22		ABR THRESHOLDS in dBnHL				RIGHT E	A D				LEFT EA	n		
23		ADK THRESHULDS IN OBURL		and the same of th							ir Conduc			
	N-4					Air Conduc			ELLO OF STORY				011 1 (014	
THE COURSE	Notes:			0.5k	1k	2k	4k	Click/CM	0.5k	1k	2k	4k	Click/CM	
	Use =, <=, or > prefix		tester - result:		=80		=75			=75		=70		
		idd (M) after the result e.g. =40(M)	Gold standard?		Yes		Yes			Yes		Yes		
	By convention,		reviewer - result:		<=80		<=75			<=75		<=75		
		eing within 10dB' with =50 but	reviewer - agree within 10dB?											
		n as not agreeing with =55 (or more)		Bone Conduction			property and	Maria de la como		ne Condu				
		o requires agreement with standard		0.5k	1k	2k	4k	Click	0.5k	1k	2k	4k	Click	
	Gold std requires = so	me threshold (or <=30eHL AC4kHz)	tester - result:											
32			Gold standard?											
		s may be added as comments -	reviewer - result:											
	Hover mouse over cell	Is with red corner to view comment	reviewer - agree within 10dB?											
35														
36		Category	Indicator		Details (Do not exceed cell width)									
37	Improvement	Interpretation	Labelled RA but unreplicated v	ed waveform 4k Rt 70, 4k Lt 60, 1k Rt 75, 1k Lt 70. These do not qualify for RA.							A.			
38	Improvement	Interpretation	Threshold recorded as = when		<=		All, With	out valid RA	these mus	t be report	ed as <=			
39	Improvement	Interpretation	Reported as Gold Standard but	t is not			All. Gold	standard th	resholds >	30dBeHL re	equire an	RA 5-10d8	3 below	
40	Improvement	Interpretation	Mismatch between chart and	eSP entry			4k Lt 70	marked Inc (correct) bu	t reported	as though	n it was CF	₹	
41	Improvement	Interpretation	More than 2 traces overlaid					- makes esti						
42	Improvement	Test Strategy	A further 2 waveforms, added	pairwise	needed to	resolve	Addition	al traces for	Lt 4k at 70	to resolve				
43	Improvement	Test Strategy	BC would be helpful					se conducti						
	Improvement													
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1000000	Improvement													
20000000	Improvement													
	Improvement													
200000000	General / other	This are can also be used for further o	omments by the reviewer if ne	eded										
- 100,000	Reviewer comments	and the same of th	and of mercines and											
49														
50														
51	Number of improvemen	nt indicators in each category		Outcom	ne meas	ures		1						
III CONTRACTOR OF THE PERSON O	Admin	n ndicators in each category		Outcome measures										
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	Parameters	0		reviewer 0 4 0%										
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58		0												
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Models of ABR Peer Review

Cloud-based structured scheme

- Good for bonding working relationships with colleagues
- Reviewers receive training & are accredited
- Data is secure & readily accessible ✓
- Integrates with English ABR national database
- Cases selected systematically
- Review is anonymous
- Requires IT investment / costs
- Review initiated only when all testing is complete

Best

Features of a good ABR PR scheme

- Cases for review must be selected systematically
 - e.g. all bilateral referrals
 - e.g. all PCHI cases + sample of discharge cases
- Reviewers trained and accredited to ensure standards
- Periodic moderation of reviewers to maintain standards
- Provision of independent Expert for advice & arbitration
- Evaluation of outcomes annual report of audit
- Timescale of reviews: <7 days (reviewer's advice used for the next test session for that case)

Advantages of a good ABR PR scheme

- Annual audits of PR scheme: evidence a reduction of errors
 - e.g. South London audit: Yr2 -v- Yr1 errors reduced p<0.001
- Lowers the risk of costly diagnostic & management errors
- Being a reviewer improves your own clinical practice
- Provides infrastructure of support for challenging cases
- Fosters professional pride in giving a good service
- Gives parents greater confidence in the service
- But...
 - must strike a balance between effectiveness and admin overhead

How are we doing in England? As a percentage of the live birth population (2014):

- One cloud-based PR scheme (East of England: 10%)
 - Being made available to other regions on a fee-paying basis
- Established regional "generic" email schemes (22%)
- Regional "generic" email schemes being developed (32%)
- No formal PR scheme (36%)
 - Seen as optional / avoidable; no penalty for non-engagement
- Is the English government addressing this?
- No: there has been a policy blunder!

"Public Health England"

- Created in April 2013 to oversee public health policy
- NHSP subsumed within PHE in April 2014
 - New mandate: limit all activity to the screen
 - NHSP's support & QA of diagnostic services stopped (now the responsibility of >130 individual hospitals)
- Standards are likely to fall now that QA is abandoned
- ERA Training & Consultancy Ltd offers
 - Training courses (as always) see www.eratraining.co.uk
 - Peer reviewer training & accreditation
 - "Support Voucher" scheme for advice on clinical cases
 - But never easy to sell services that were previously free!
 - Reluctant sites just look the other way
 - Would be far better if services were provided via NHSP

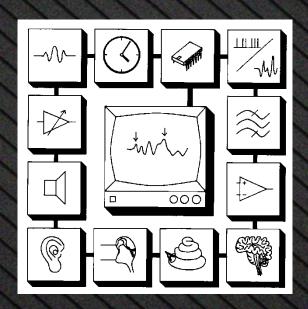


Take-home messages?

- Vital to establish & ensure use of national protocols
 - Need to be agreed & "owned" by testers
- Provide high quality training, specific to protocols
- Conduct regular QA audits
 - can't assume all testers adhere to protocols
- Provide technical/clinical support #
- Establish framework to facilitate quality improvements for struggling centres #
- Establish systematic ABR peer review scheme
 - Inc training & accreditation of reviewers #

can be remote

Many thanks for your attention!



www.eratraining.co.uk www.abrpeerreview.co.uk