



HTA

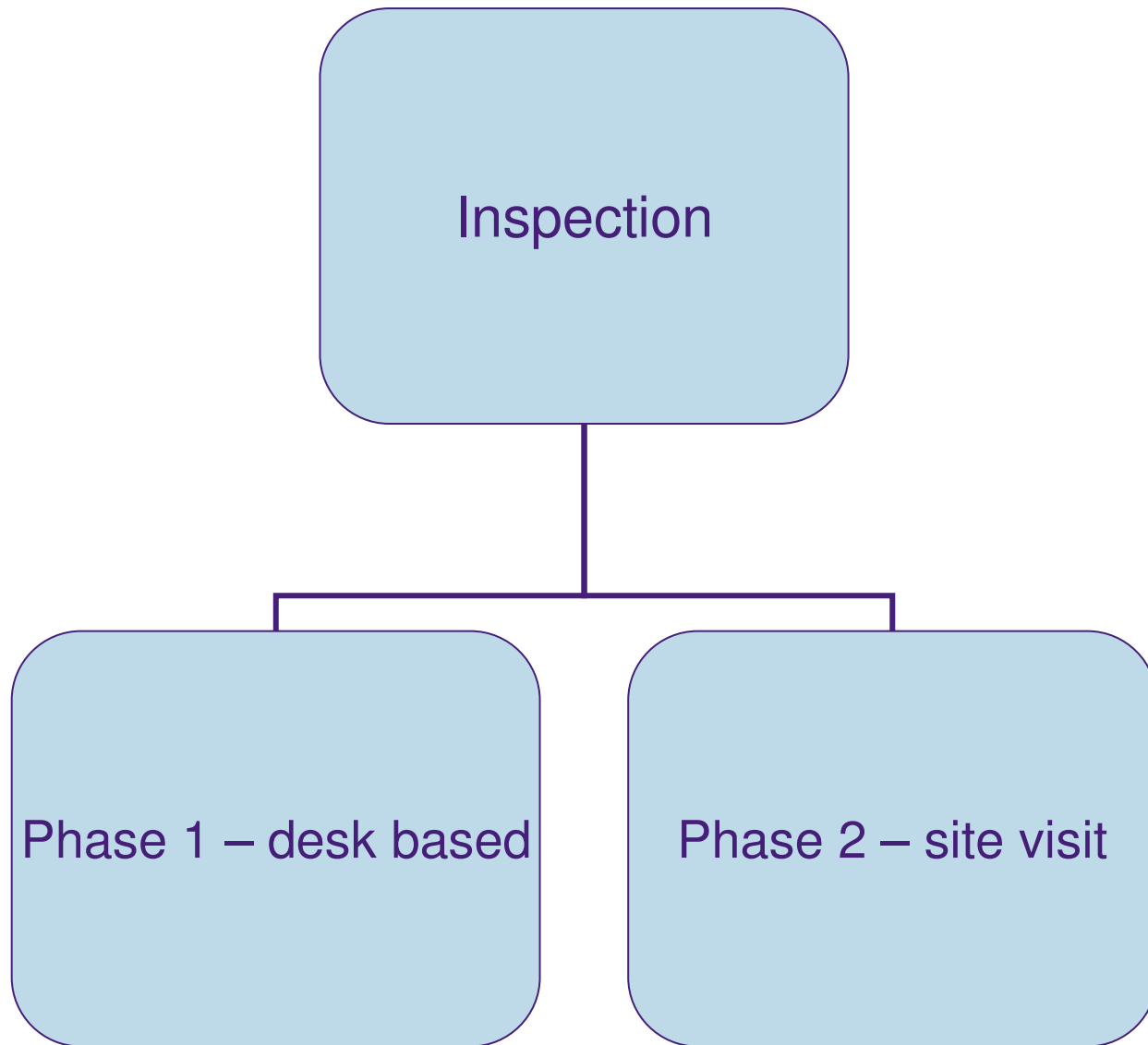
Human Tissue Authority

Preparing for an HTA Inspection

Chris Perrett
Regulation Manager

Inspection

- Desk based and site visits
- Leads to written and verbal advice and guidance
- Informs licensing decisions



Phase one and two inspections

- 636 phase one (desk based) inspections completed
 - 208 were of HA sector establishments.
- 129 risk based phase two (site visit) inspections completed
 - 47 were of HA sector establishments.

HTA approach to phase 2 inspections

- Proportionate
- Risk-based
- Focused
- Effective in our use of resources

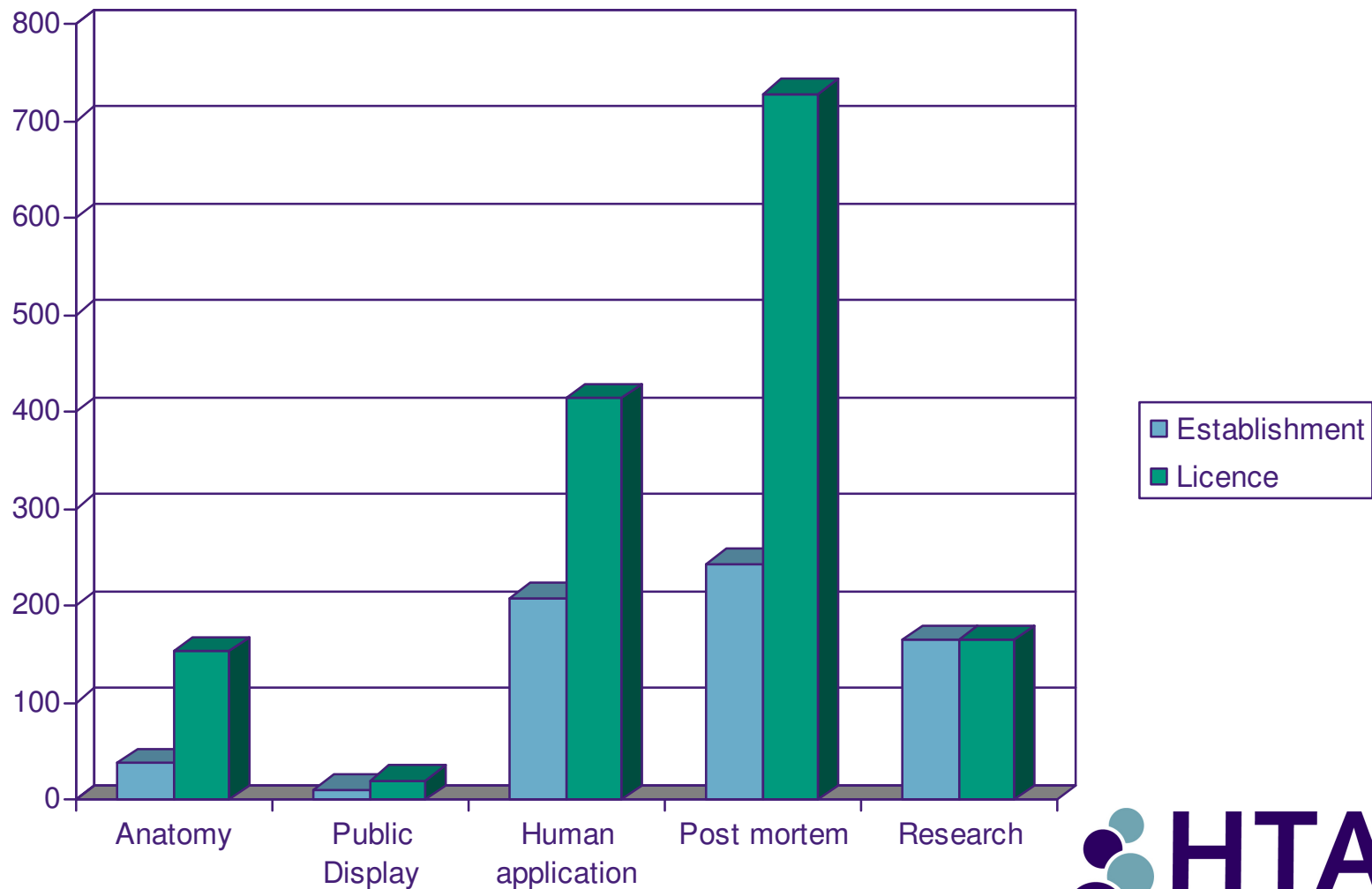
Prioritisation by risk

- Conditions
- Accreditation
- Complexity of service
- Critical assessment

Phase two inspections

- Risk based
- Random
- Thematic
- Unannounced

Number of establishments and licences in each sector



HTA inspection team

- HTA professional inspectors
- Specialist Advisors

Phase two inspections

- Site visits
 - gather additional visual and aural evidence
 - test evidence provided and compliance with standards
 - test validity of HTA's risk assessment
- Risk based, thematic, unannounced

Preparing for inspection

- Inspection Programme Planning Officer
- Agree date
- Assign Specialist Advisor
- Allocate inspection team
- Produce timetable
- DI, LH and PD review compliance report
- Prepare documentation

Inspection Timetable

- Preliminary meeting
- Visual inspection
- Documentation review
- Audit of the traceability of stored material
- Interviews
- De-brief meetings
- Feedback meeting

Inspection Timetable

Inspection details	
Establishment Name and no.	
Inspection date	
Inspection focus	Personnel, premises, practices and additional condition
Inspection team	Lead Inspector, Regulation Manager
	Inspector, Regulation Manager
	Observer, Regulation Manager
Proposed timetable	
Time	Activity
09:00	Inspection team arrive at establishment
09:00 – 09:30	Introductory meeting: Inspection team and DI, LH representative and other staff
09:30 – 11:00	Tour of premises and audit trail
11:00 – 12:30	1-2-1 meetings with staff
12:30 – 14:00	Working lunch: Debrief and documentation review
14:00 – 15:00	1-2-1 meetings with staff
15:00 – 15:30	Completion of audit trail and documentation review
15:30 – 16:30	Collation of notes
16:30 – 17:00	Feedback to establishment
17:00	Inspection team leave establishment

Documentation to be available on site

- Organisational chart
- **Self-assessed compliance report**
- Clinical notes for audit trail
- Policies (e.g. consent, disposal)
- Standard Operating Procedures
- Training records
- Internal audit schedule/s and audit reports
- Risk assessments
- Adverse incidents
- Quality Manual
- Maintenance contracts
- Contingency plans
- Meeting agendas and minutes

Aims of the preliminary meeting

- Meet the inspection team
- Explain the HTA ethos, principles and values
- Summarise the context for the inspection
- Outline the timetable
- Alleviate any concerns

Aims of the feedback meeting

- 'Highlights'
- Prepare the ground for the inspection report
- Explain what happens next
- Provide an opportunity to give advice and guidance

Post inspection

- Draft report sent to DI
- DI reviews for factual accuracy
- Finalised report sent to DI
- May lead to variation of the licence

Inspection Report

- Suitability of DI and LH
- Suitability of the premises
- Suitability of practices
- Summary comment
- Conditions – amend/add
- Adherence to SMART principles
- Advice and guidance

Conditions placed post inspection – human application sector

Category of standard	Number of conditions which refer to this standard
Consent	12
Governance and Quality	77
Premises, Facilities and Equipment	22
Disposal	5

Advice and guidance given post inspection - human application sector

- The majority of advice and guidance is related to governance and quality standards
- The advice centred upon ensuring establishments had a documented system of quality management and audit and that staff were appropriately trained in techniques relevant to their work and were continuously updating their skills.

Human Tissue Authority conference

Regulating tissues and cells for human application:
the past, the present, the future

Tuesday 25 March 2008

Venue: The Wellcome Collection Conference Centre,
183 Euston Road, London NW1 2BE

Time: 9.30 – 16.00



Regulating tissues and cells for human application: the past, the present, the future

- Presentations and seminars will cover issues such as:
 - European coding system
 - Quality management
 - Future use and regulation of human embryonic stem cells
- Speakers at the conference will include:
 - NHS Blood and Transplant
 - Medical Research Council
 - National Institute for Biological Standards and Control

To book your place: www.hta.gov.uk



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