Achieving the IGT for Hosted Secondary Use Teams

Rhian Hughes
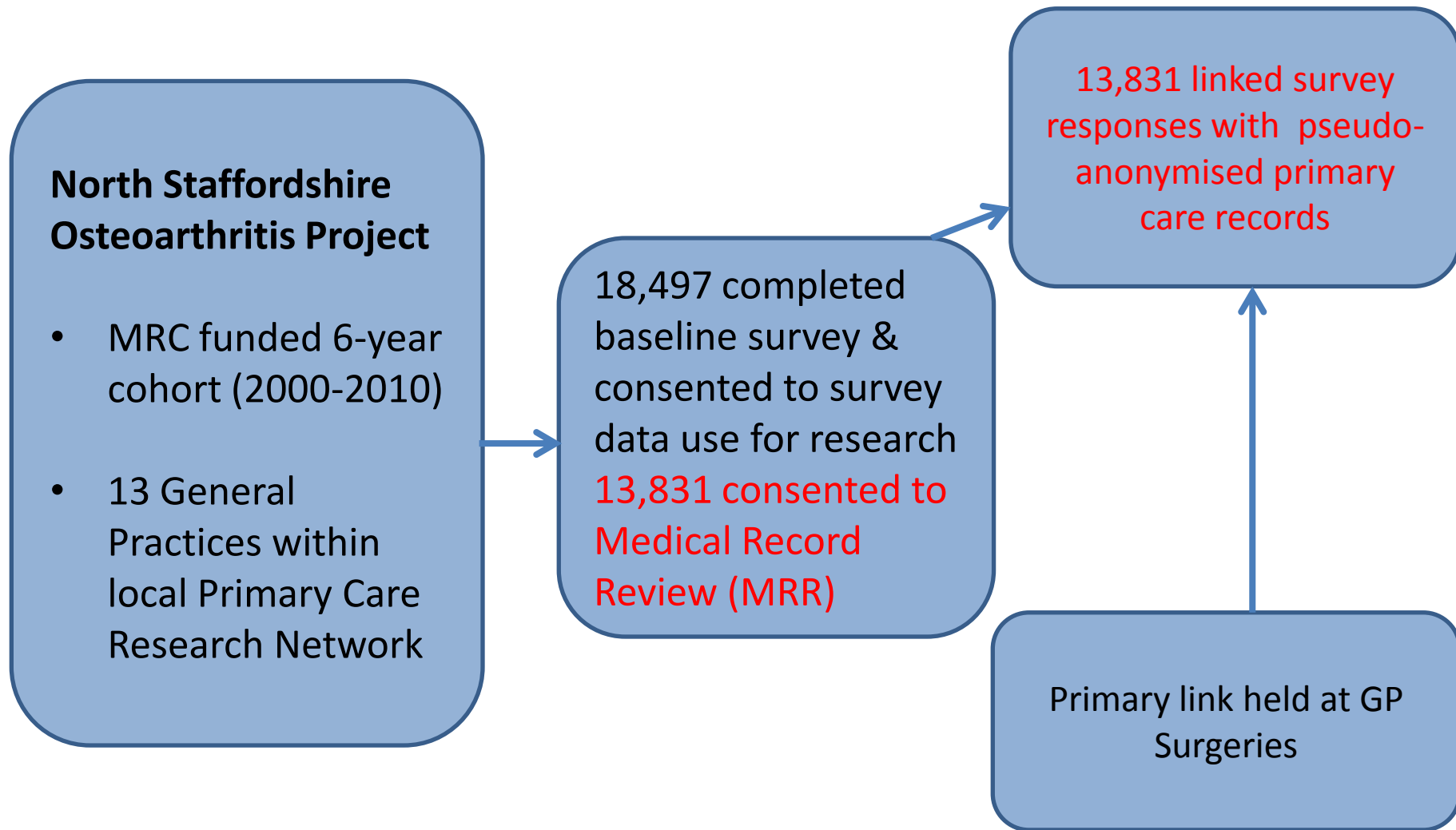
Victoria Welsh

Contents

- Context
- New policies
- The Keele approach
- Completing the IGT
- Summary

Context – the Research Question

- NIHR Doctoral Research Fellowship
  - September '11 – August '14
  - Multisite pain and falls in older people
- Research requiring linked data

Existing data-set	New data-sets
- Cohort survey responses - Primary care electronic records	-HES -ONS Mortality

Existing data-set: Background

North Staffordshire Osteoarthritis Project

- MRC funded 6-year cohort (2000-2010)

- 13 General Practices within local Primary Care Research Network

18,497 completed baseline survey & consented to survey data use for research
13,831 consented to Medical Record Review (MRR)

13,831 linked survey responses with pseudo-anonymised primary care records

Primary link held at GP Surgeries

Existing data-set: Robust Governance Arrangements

- Individual patient consent recorded

  - to use survey and medical record data for research

  - to link survey and medical record data-sets

- Full pseudo-anonymisation achieved

- Secure databases and established SOPs

- Data custodian (senior statistician)

- Primary key held by established 'Research GP Practices'

- Practice leaflets and posters highlighting research use of anonymised data

New data-sets

- Linking existing survey and GP record data with:
  - HES
  - ONS Mortality

- Existing consent deemed insufficient to allow pseudo-anonymised linkage of HES and ONS data

→ NHS Act 2006 Section 251 required to access participant data without consent

- Request for linkage via pseudo-anonymisation equivalent to personal identifiable data

Patient and Public Involvement

- ***Is the use of participant information without consent acceptable?***

" the benefits outweigh the risks and this is what is most important"

"if it is going to help prevent falls in the future it is for the good of everyone and worth doing"

"[the research] should be allowed to go ahead"

- Acceptable proposal - including using data from survey participants that declined Medical Record Review

Achieving the linkage

- Secondary host (Keele):
  - EMIS ID, Research ID, DoB, Sex

Pseudo-anonymised identifiers provided via NHS.net encrypted link to:

- Primary Key Holder:
  - EMIS ID, DoB, Sex: matched to provide NHS number & post code

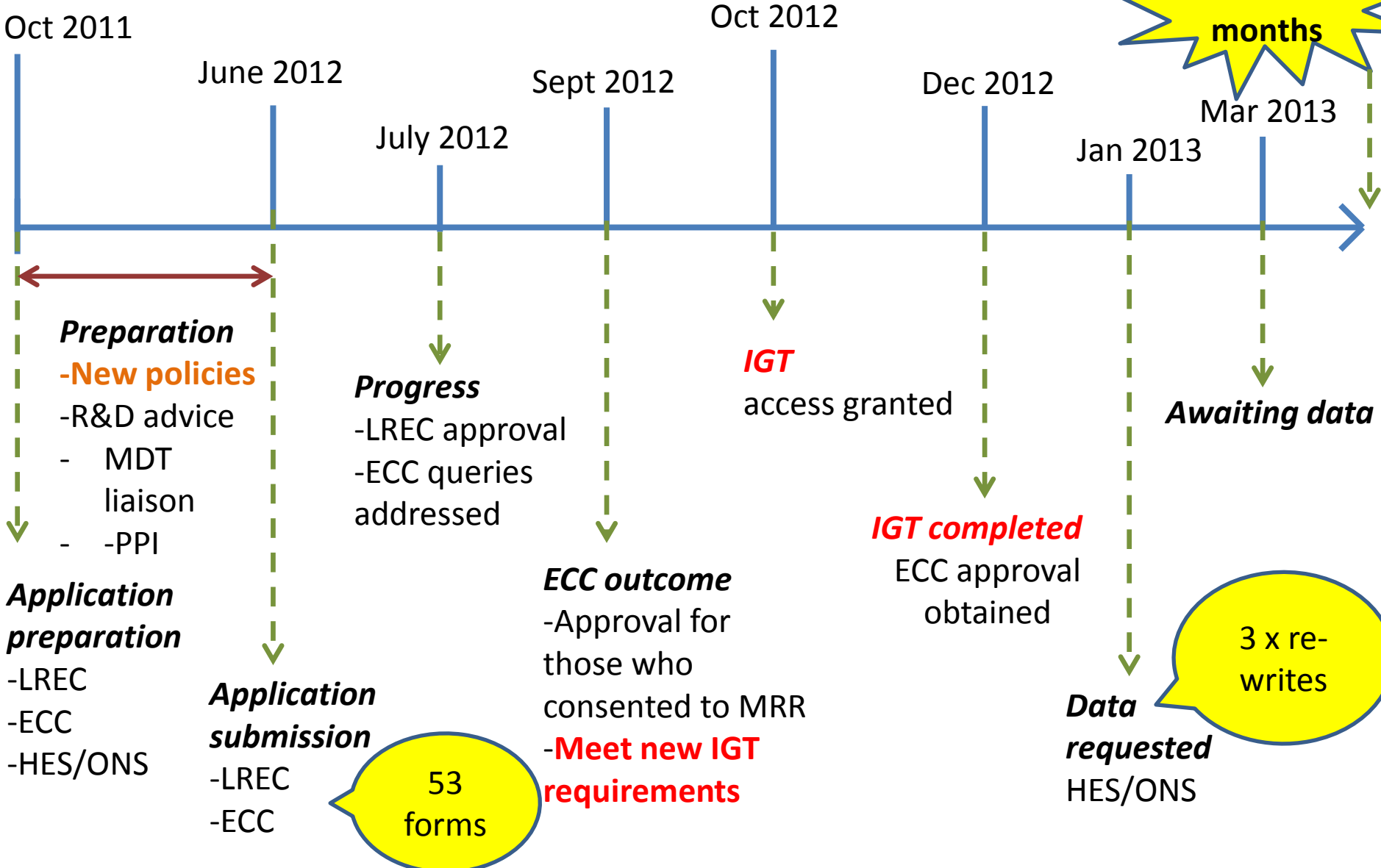*Identifiers provided via NHS.net encrypted link to:*

- NHS Information Centre (IC):
  - NHS number, DoB, Sex, Postcode
  - IC link identifiers to provide HES and ONS Mortality

Identifiers plus data provided via NHS.net encrypted link to:

- Keele – who strip out NHS number and convert post code to deprivation code
- Pseudo-anonymised full data-set achieved

The application process

Oct 2011

June 2012

July 2012

Sept 2012

Oct 2012

Dec 2012

Jan 2013

Mar 2013

17 months

Preparation
-**New policies**
-R&D advice
- MDT liaison
- -PPI

Application preparation
-LREC
-ECC
-HES/ONS

Application submission
-LREC
-ECC

53 forms

Progress
-LREC approval
-ECC queries addressed

ECC outcome
-Approval for those who consented to MRR
-**Meet new IGT requirements**

IGT access granted

IGT completed
ECC approval obtained

Data requested
HES/ONS

3 x re-writes

Awaiting data

New policies

- Requirement for a "Systems Level Security Policy"
- Took the opportunity to review all policies relating to data security, data processing and storage
- NIHR CTU Registration
- Review affected all aspects of our activities:
  - Policies – local and central
  - Standard Operating Procedures
  - Local and Central IT
  - HR policies

PhD Project required Institution-level review of procedures

The Keele Approach

- Whole systems approach – CTU SOPs
- Helpful prompts in Systems Level Security Policy template
- Required explicit accountabilities between the Research Centre and:
  - Central IT: *full check of equivalence of UCISA information security toolkit to BS 7799 and ISO29001*
  - HR: *contractual duty of confidentiality*
  - University Registrar: *Data Protection and delegation of authority to hold and process sensitive data*

From Systems Security Policy ….

- Physical, electronic & paper data security measures
- N3 connection, NHS.net and encryption (including laptops and data sticks)
- Network security, firewalls, segregation
- Access controls (on-site only) and management
- Anonymisation, archiving, fair processing (from paper to electronic) and destroying identifiers
- Explicit procedures for personal, coded but identifiable, pseudo-anonymised and fully anonymised data

More Explicit Data Policies ….

- Revised Systems Security Policy and Handling of Sensitive data

- Implemented changes in IT and HR

- Incorporated revised procedures into all aspects of SOPs and linked working documents

To SOPs ….

SOP revision was extensive!

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SOP Compliance	Initial Concept to Funding and Contracts	Project Development to Approvals	Site Initiation and Study Implementation	Analysis and Dissemination	Archiving

Development and Management of SOP Training — SOP 18

Developing & Submitting Grant Proposals and Contract Sign-off — SOP 3

Project Management — SOP 4

Site Initiation — SOP 5

Writing and Revising SOPs — SOP 1

Study Master File — SOP 6

The Set-up of Study Administrative Procedures — SOP 13

Document Control — SOP 2

Document Design and Development — SOP 7

Recruitment, Intervention and Data Collection — SOP 8

Database Design and Development — SOP 9

Monitoring, Audit, Inspection & Serious Adverse Events — SOP 14

Service Level Agreements and Study Costings — SOP 10

Study Closure — SOP 15

Analysis and Dissemination — SOP 16

Archiving and Storage — SOP 17

Regulatory Submission - Internal & External — SOP 11

Research Passports and NHS-to-NHS Agreements, Honorary Contracts and Letters of Access — SOP 12

Timescales

- Policy review to ECC submission:
  - 8 months
- ECC submission to outcome
  - 6 months
- ECC decision
  - Complete IGT

  "it should only take a few hours"

Completing the IGT

- Completely unexpected hurdle
- Content / requirement unknown
- Took **a month** to gain access
- Needed additional data manager time to complete
- Little guidance on requirements

Completing the IGT

- 14 requirements

- Each requirement had 3 sections

- Each section had 2 or 3 additional questions to complete

- Had absolutely no idea what commentary or level of evidence required to complete the IGT

- No idea what the different Tiers (1,2,3) signified to achieve the IGT

- Completion timescale driven by Vicki's need for data for her PhD project

IGT Requirements Booklet

- 107 pages long
- All the exemplars related to NHS processes
- Difficult to translate into University-equivalent evidence
- Applied our revised policies and SOPs to the requirements, and used these as evidence

Information Governance Management

10-120 Responsibility for Information Governance has been assigned to an appropriate member, or members, of staff

10-121 There is an information governance policy that addresses the overall requirements of information governance

10-122 All contracts (staff, contractor and third party) contain clauses that clearly identify information governance responsibilities.

10-123 All staff members are provided with appropriate training on information governance requirements.

10-120 Information Governance Management

- Responsibility assigned to a named individual
  - Yes / No
  - Details
  - Where recorded
  - Evidence - copy of the SSLP policy & Registrar delegation uploaded
- Named staff provided with training
  - Yes / No
  - Details – Training SOP and requirement to complete training log
  - Evidence - Copy of Training SOP uploaded
  - Exemplar asks for certificates of attendance, training reports, evidence on self-directed training – not provided
- IG Improvement plan: current level of compliance; target for improvements
  - Yes / No
  - Details – SSLP & SOP review process
  - Evidence – SSLP & Monitoring and Audit SOP uploaded

- https://www.igt.connectingforhealth.nhs.uk/home.aspx

Completing IGT
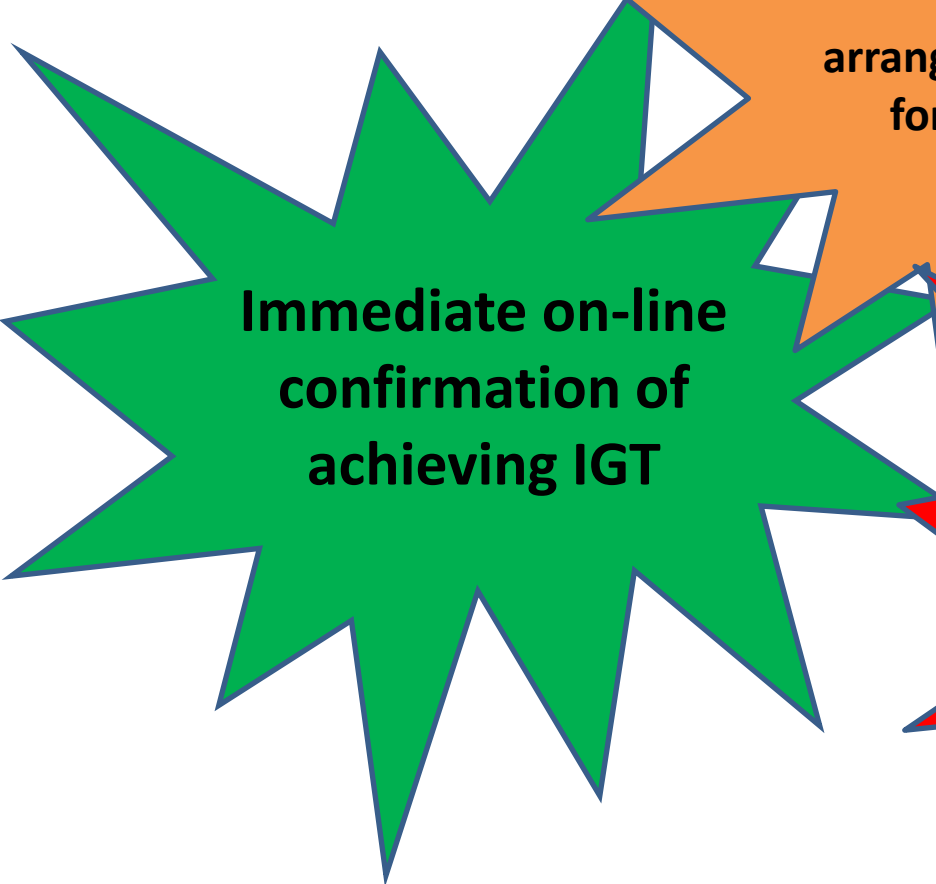
- Compliance equivalent to CTU registration or MHRA

- One standard

- Even for secondary analysis of pseudo-anonymsied data

- Linkage requires identifiers – NHS number and post code

Some reflections
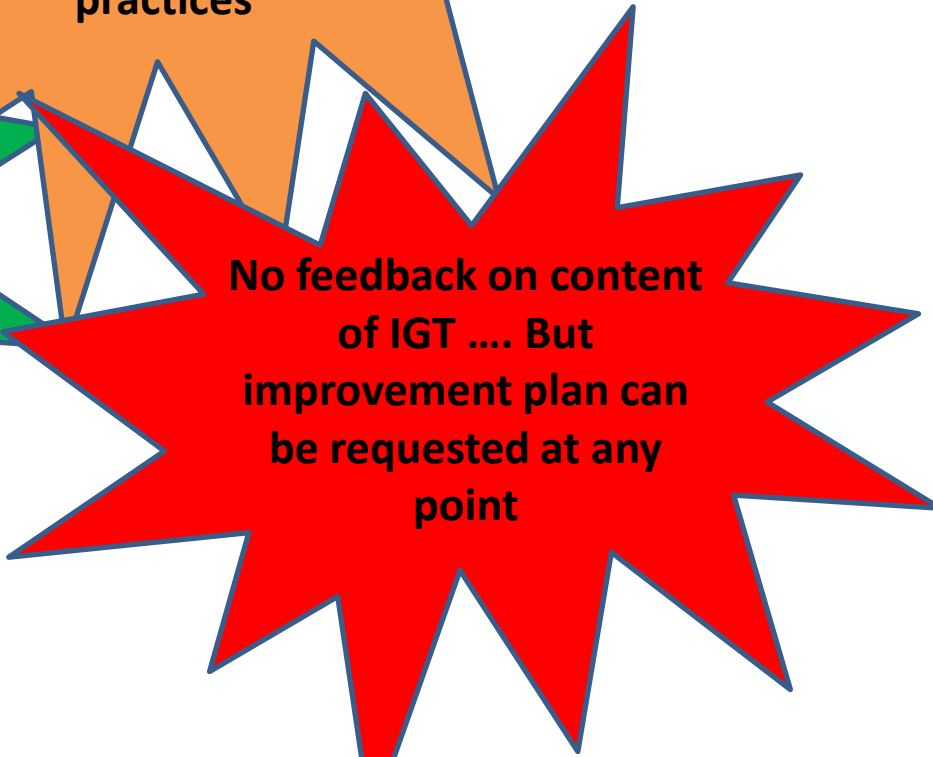
- Blind man's buff

- Self assessment ---- with no real sense of the assessment benchmark

- We provided brief descriptors plus evidence
  - Different approaches (no evidence) – same outcome

- Compliance with spirit of IGT requires serious investment
  - Writing / reviewing / updating procedures
  - Monitoring compliance

- Tick box?

- Confirmation of IGT happened in ….

14 days later, confirmation of satisfactory arrangements – request for new poster in practices

Immediate on-line confirmation of achieving IGT

No feedback on content of IGT …. But improvement plan can be requested at any point

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Final timeline?

- 29th November – IGT submitted --- and published on-line

- 11th December – NIGB confirmation of review and satisfactory arrangements in place

- 20th December – section 251 approval from ECC

- Application for data release submitted 17th January

- Identifiers now being prepared to enable linkage

Summary
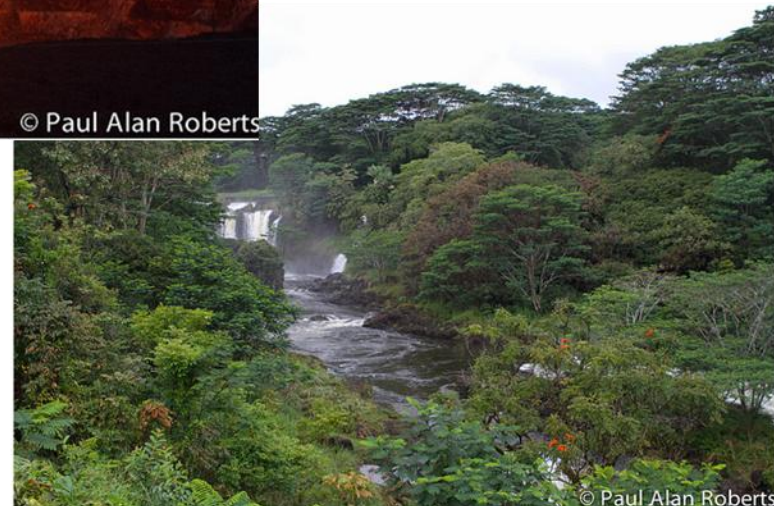
Acknowledgements

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