



The research commercialisation office of the University of Oxford, previously called **Isis Innovation**, has been renamed **Oxford University Innovation**

All documents and other materials will be updated accordingly.
In the meantime the remaining content of this Isis Innovation document is still valid.

URLs beginning www.isis-innovation.com/... are automatically redirected to our new domain, www.innovation.ox.ac.uk/...

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eHealth & Big Data



Isis Innovation & Oxford AHSN Technology Showcase

Why do we need a National Data Guardian?

Fiona Caldicott

OUHT

30 June 2015

IIGOP

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Background Information Governance Review 2012-13

Key finding; 'should ensure the right balance between sharing and protecting information'.

What does this mean for;

- **IG in the increasingly linked health care and social care sectors**
- **Data security and protection**
- **Much greater awareness of the citizen about these issues**

Key Message – ‘*The culture must be changed*’

- **New duty to share**
- **Reduce the harm caused by not sharing**
- **Clinicians to use their clinical judgement on sharing decisions**
- **Greater trust between Health and Social Care**

The Caldicott Principles

The new 7th Principle...

‘The duty to share information can be as important as the duty to protect patient confidentiality.’

Health and Social care professionals should have the confidence to share information in the best interest of their patients/service users within the framework set out by these principles. They should be supported by the policies of their employers, regulators and professional bodies.

No surprises – Review recommendations

- **All health and social care organisations must publish in a prominent and accessible form, information about disclosure of personal confidential data**
- **People must have access to all the electronic care records about them, across the whole health and social care system, without charge.**
- **An audit trail of everyone who has accessed PID should be made available to patients, and carers with the patient's consent, including both in the trail. This will take time to implement.**

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The Independent IG Oversight Panel

Established in September 2013 to have:-

- **Oversight of IG in the Health and Social Care system**
- **To be independent**
- **To provide advice and challenge**

**To report directly to the Secretary of State for Health
Progress on implementing the Caldicott
Recommendations**

IIGOP's Key Areas of Focus through 2013-14

- **Developing an IG knowledge and information service (established as the Information Governance Alliance)**
- **Commissioning**
- **Legislation development (EU Data Protection Regulations and Law Commission Review)**
- **Consent Management, now often called preferences (IT system consent flags to record sharing decisions and opt outs)**
- **Accredited Safe Havens**
- **Care.data**

There is no silver bullet

- **There must be a legitimate [legal] relationship**
- **‘To care appropriately, you must share appropriately’**
- **A culture of anxiety amongst staff must be changed to one of confidence**
- **IG has become a barrier to sharing, and**
- **n.b. Nice Guideline 138 [2012] on Patient Experiences in adult NHS services**

National Information Board established 2014

- **Personalised Health and Social Care 2020**
- **Using Data and Technology to transform outcomes for patients and citizens**
- **Published November 2014**
- **10 work streams**
- **Digital access to health and care information and transactions**
- **Access to recommended NHS and social care apps**

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Work stream 4

- **Build and sustain public trust**
- **Roadmap to consent based information sharing and assurance of safeguards**
- **Health and social care data as rich resource for UK citizens**
- **Access to newest and most effective treatments including earlier diagnosis, e.g. 100,000 genome**

Another Key Message - Trust

- **Build and sustain public trust**
- **Who is trustworthy**
- **Role of National Data Guardian**

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Stop Press ...

Caldicott becomes first government health data tsar and National Data Guardian

‘Appointed to oversee safeguards for schemes like care.data as NIB publishes new framework for integrated NHS patient records strategy’

**Kable - Government Computing
Published 13 November 2014**

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Europe's Data Guardian or Data Protection Supervisor

- Greater effort to protect health data
- collected by mobile devices
- Though great potential to improve healthcare and lives
- Both app designers and legislators should do more to enhance security in 'complicated' market
- May 2015

Medical Devices

- **Rapidly expanding range**
- **Record data about patient in absence clinician**
- **Data available to patient, professional, or both**
- **? How certain is the identity patient**
- **? Effective use device so that data is reliable**
- **? Awareness that monitoring is creating a personal record, so all duties must conform to legislation. Is patient informed about this?**

Medical Devices continued....

- **If patients decide on their own initiative to use a monitoring device, are they made aware of the terms and conditions, especially PCD?**

Consent

- Approval or agreement for something to happen after consideration
- *Explicit* – informed, has capacity, gives consent voluntarily
- Is required for sharing with staff who are not part of team
- Needed if is for a use other than that for which information originally collected
- *Implied* – only acceptable in context direct care.
No action needed on part of patient. But lawyers...

Consent post Lanarkshire judgement

- **Or Nadine Montgomery v Lanarkshire H Board**
- **from paternalistic practice or ‘doctor knows best’**
- **to transparency and choice**
- **comparison to patient having more rights over the information they give a clinician**

2013-2015 care.data

- **Publicity campaign fails**
- **BMA and RCGP withdraw support in February 2014**
- **care.data paused**
- **NDG and IIGOP to inform Secretary of State when appropriate for data to be extracted from GP practices, November 2014.**

What will make the difference?

- **The Review recommended**
 - **Improved training and on-going education for all staff not just IG staff**
 - **Better information for all patients and service users**
 - **Stronger oversight for IG at board level**
- **Much of this has been said before – what will make a real difference this time?**

Where We Are...

- **The Review of IG was published in March 2013.**
- **Government accepted the report recommendations that summer**
- **HSCIC Guidance on Confidentiality and Code of Practice have now been published**

Where We Are continued...

- **IIGOP report to care.data Programme Board
Published 18 December 2014**
- **IIGOP's first Annual Report to Secretary of
State for Health published January 2015.**
- **Cross party support for National Data
Guardian.**

National Data Guardian

- **Consultation on powers to commence – when?**
- **Statutory footing – what will legal vehicle be?**
- **[No new health and social care legislation]**
- **Meanwhile hosted by HSCIC – independent status recognised.**
- **Essential that is independent.**

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References

Information: to share or not to share? The Information Governance Review

Published 26 April 2013

<https://www.gov.uk/government/publications/the-information-governance-review>

Caldicott information governance review: Department of Health response

Published 12 September 2013

<https://www.gov.uk/government/publications/caldicott-information-governance-review-department-of-health-response>

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References

IIGOP Terms of Reference

[https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/269528/IIGOP Terms-of-reference-V1_0.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/269528/IIGOP_Terms-of-reference-V1_0.pdf)

House of Lords debate on Care Bill

7th May 2014

<http://www.publications.parliament.uk/pa/ld201314/ldhansrd/text/140507-0002.htm>

References

**IIGOP report to care.data Programme Board Published
18 December 2014**

<https://www.gov.uk/government/publications/iigop-report-on-caredata>

**IIGOP Annual Report to Secretary of State for Health
Published 2 January 2015**

<https://www.gov.uk/government/publications/iigop-annual-report-2014>

References

National Information Board

<https://www.gov.uk/government/organisations/national-information-board>

Thank You

Your questions are welcome

**For any other queries
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