Reflections on Research
Past, present and future

John Williams
Health and Care Research
Wales Conference
5th October 2017
Overview

• Look back at my research career
• Pick out some observations
• Share my vision for the future
• Focus on patients, healthcare and data
• Emphasis on impact, and pragmatism
My career

• Trained at Cambridge University & St Thomas’ 1964-70
• Royal Naval Medical Officer 1967-88
  – Trained as a gastroenterologist
  – Professor of Naval Medicine 1984-88
• Established Swansea Postgraduate Medical School in 1988
• Chair in Health Services Research in Swansea University Medical school since 2001
• Director of R&D at WORD 2002-7
• Founding Director of Health Informatics Unit, Royal College of Physicians since 2001
Health Services Research

• may include research from any healthcare discipline including: medical sociology, medical statistics and biostatistics, health psychology, clinical psychology, health economics, modelling, clinical trial methodology and organisation, community-based clinical trials, medical anthropology, medical geography, medical ethics, medical education, healthcare policy evaluation, health service organisation and management, health technology assessment, patient experience, clinical epidemiology and decision analysis, methodologies for complex interventions and health informatics.

http://www.rae.ac.uk/panels/main/b/health
The Navy Days – sea time

• 1972/3 Ships Medical Officer HMS Plymouth
  On hurricane patrol in the Caribbean


No Good Clinical Practice
No Ethics infrastructure
No Clinical Trials Units
Back on dry land – RNH Plymouth

– Explored the clinical pharmacology and efficacy of H2-receptor antagonists – metiamide and cimetidine
– First compounds to suppress gastric acid secretion
– Revolutionised the management of acid-peptic disorders

Inhibition of food-stimulated gastric acid secretion by cimetidine


Summary

The effect of cimetidine, a new histamine H2-receptor antagonist, on gastric acid secretion stimulated by a homogenised meal was studied in six normal volunteers using an in vitro intragastric titration technique. The subjects were studied twice, no more than 48 h apart, receiving

Relief of Duodenal Ulcer Symptoms by Oral Metiamide

R. E. Pounder, J. G. Williams, G. J. Milton-Thompson, and J. J. Misiewicz

Summary

Thirty patients with symptoms of duodenal ulceration were treated for five to eight weeks in a double-blind trial with either metiamide 1 g daily by mouth or a placebo. In the 15 patients receiving metiamide there were significant reductions in nocturnal pain and acid consumption. Daytime pain was diminished. The results suggest that histamine H2-receptor antagonists are likely to be useful in the medical management of the symptoms of duodenal ulceration.
1982 Falklands Islands

• Led a Surgical Support Team
• Converted SS Canberra from troop ship to hospital
• Prepared for mass casualties
Preparing for mass casualties

• Devised a very simple resuscitation approach
• Documented the outcome

Rapid evacuation and resuscitation saves lives. Observational studies can have a big impact.
Williams JG  A disposable proctoscope Lancet 1982;ii:1228
Swansea Postgraduate Medical School (1988-2001)

- Established the Postgraduate School
- Consultant at Neath General Hospital
  - Built up a clinical service in gastroenterology
  - Supported by in-house EPR
  - Pragmatic trials in service delivery

Impact:
Informed both policy and practice. Basis for a 4* impact case study in REF 2012
Swansea University Medical School (2001 – now)

- Pragmatic trials - health records & gastroenterology
- Validation of PROMS:
  - UK Inflammatory Bowel Disease Questionnaire
  - Gastrointestinal Endoscopy Satisfaction Questionnaire
  - Gastrointestinal Symptom Rating Questionnaire
  - Crohns and Ulcerative Colitis Questionnaire
- Use of operational data for RCTs
- Health records and data provenance
Use of HES and PEDW data for research

- WORD (2002-7) – forerunner of NISCHR and HCRW
  - Clinical Research Collaboration Cymru (CRCCymru)
  - Health Information Research Unit
- Explore the use of routinely collected data for research
- Established the SAIL database – research using data linkage
What causes the ‘weekend effect’?

- The weekend effect by GI diagnosis:
  - Severe liver disease
  - GI malignancy

- The weekend effect in relation to % reduction in admissions at weekends:
Analysable patient data

• **Operational** data captured and coded at the point of care

• **Routine** data – collected as a by-product of care, using a secondary extraction and coding process from paper or electronic records – eg PEDW or HES

• **Designed** data – bespoke for audit or research and other specific purposes
Data requirements

- Patient care
- Audit
- Research
- Commissioning
Can operational electronic data support randomised controlled trials?

• In 2000, we repeated the analysis of four completed RCT’s using data extracted from local PAS, Pathology, Radiology and Clinical systems, and PEDW

• Studies were small multi-centre trials addressing four different technologies:
  – open access to outpatients
  – investigation of sleep apnoea
  – autologous blood transfusion
  – surgery for incontinence

• Funded by the HTA Programme
We concluded:

• Routinely collected data can support RCT’s
• If clinically rich enough, and held in electronic form (ie in patient focused electronic records, as well as patient administration systems)
• Costs would be less, and larger trials could be run
• The quality of electronic data needs to improve

• Williams JG et al The value of routine data in health technology assessment: can randomised trials rely on existing electronic data? Health Technology Assessment 2003;vol 7:no 6
Why does data quality matter?

- Quality of patient care
- Patient safety
- Integrated records
- Rigour of data linkage studies
- Detailed phenotyping for precision medicine
Weaknesses of HES & PEDW data

- **Timeliness:**
  - Delay in availability

- **Content**
  - **Quality:** Diagnosis and procedures are inaccurate in up to 20% of cases
    - **Breadth:** no data on presenting complaint or medication; poor data on co-morbidities
    - **Depth:** Diagnosis terms and codes lack attributes such as disease extent; behaviour; severity; evidence
For example: Inflammatory Bowel Disease

- Diagnosis: Crohn’s, Ulcerative Colitis or Indeterminate?
- Diagnosis attributes
  - Anatomical distribution
  - Severity
  - Behaviour – inflammation/fistulisation/stenosis
  - Evidence (?history, imaging, histology)
- Lifestyle (smoking; diet)
- Family history
- Treatment
- Response to treatment
- Patient recorded outcomes
Weaknesses of source data

- **Timeliness**: Delay in availability of data
- **Content of clinical returns from hospitals** (HES in England, PEDW in Wales)
  - **Quality**: Diagnosis and procedures are inaccurate in up to 20% of cases
  - **Breadth**: No data on presenting complaint or medication; poor data on co-morbidities
  - **Depth**: Diagnosis terms and codes lack attributes such as disease extent; behaviour; severity; evidence

- **Operational clinical systems** do not meet Good Clinical Practice requirements applicable to research systems
Multicentre, pragmatic RCT, using mixed methods in 62 sites

Compared the clinical effectiveness and cost-effectiveness of infliximab and ciclosporin in steroid-resistant acute severe colitis

Primary outcome HRQoL @ two years

Secondary outcomes: colectomy; readmissions; adverse events; mortality

Used an operational clinical system to record and manage the data (GeneCIS)

Survived a 3 day inspection by the MHRA
Standards for electronic records

- **GCP** - for data
- **Technical** – operating systems, networking, interfaces
- **Information** – terminology (SNOMED-CT), drugs (dm+d), communication (HL7; FIHR), NHS & professional number
- **Professional** – structure and content
  - National standards for structure and content of electronic patient records - endorsed by the Academy of Medical Royal Colleges, Professional Record Standards Body and NHS Digital
  - Information models have been developed to facilitate their incorporation in clinical systems

Making it happen....

- Promote professional culture change

Hospital episode statistics: time for clinicians to get involved?

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Standards in medical record keeping

Robin Mann and John Williams

Abstract – Medical records serve many functions but their primary purpose is to support patient care. The RCP Health Informatics Unit (HIU) has found variability in the quality of records and discharge summaries in England and Wales. There is currently a major drive to computerise medical records across the NHS, but without improvement in the quality of paper records the full benefits of computerisation are unlikely to be realised.

The onus for improving records lies with individual health professionals. Structuring the record can bring direct benefits to patients by improving patient outcomes and doctors’ performance.

At the Mayo Clinic in Minnesota kept all their patients’ records in a personal leather-bound ledger. This was replaced in 1907 with patient-based records, and this method of record-keeping is still used today by some domiciliary health visitors.

The first major attempt to standardise medical records in the UK came in 1958 with the publication of the Tunbridge report. This produced some of the standard hospital medical records forms we use today (Box 1). In his report, Tunbridge also described the problems of extracting information from records for secondary purposes. He proposed that medical...
IT infrastructure to support patient care and research

Hospitals

Study team

NHS Network

SU network

VPN

Patient records

Data Repository

Hospital 1
Hospital 2
Hospital 3
...
Hospital 40

Study Data

Data Warehouse

Pseudo-anonymised

Other Sources (HES, ONS, etc)
Symptoms
Diagnoses
Tests/results
Treatment/procedures

Data linkage studies
Stratified Medicine

Research data

Health record

Guidelines
Technology appraisals
Quality standards

Performance monitoring
Audit
Registries
Appraisal
Pharmacovigilance

Stratified Medicine

Pharmaco-
Policy

- **NHS Digital** *Transfer of care initiative* [http://systems.hscic.gov.uk/interop/tci](http://systems.hscic.gov.uk/interop/tci)
- **SNOMED CT** [http://systems.hscic.gov.uk/data/uktc/snomed](http://systems.hscic.gov.uk/data/uktc/snomed)

**Impact:**
Basis for a 4* impact case study in REF 2012

- **Practice is now up to the practitioners!**
In summary.....

• Practitioners – explore and evaluate everything you do
• Observational studies have impact
• Data is the new currency
• Clinical trial methodology is changing
• Operational data will feed multiple purposes in the future
• But the depth and quality of routinely recorded digital clinical data must improve
Thank you

for listening...

...and to all those with whom I have worked over the last 45 years.
Too many to list, but you know who you are. I am very grateful.