

What is required to future-proof clinical research through the use of adjunct routine data?

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Prosperity for All:

- People at the heart of service delivery
- Population-based approach

Social Care Research strategy:

- Involving the public in social care research
- Using existing and routinely collected data

and what is routine linked data?

Routine Data: Information collected routinely for day to day administrative purposes

Linked Data: Data brought together from two different records considered to belong to the same person

Health: Birth, Mortality, Hospital (primary & secondary care), GP Practice, Maternity, Cancer registers and screening

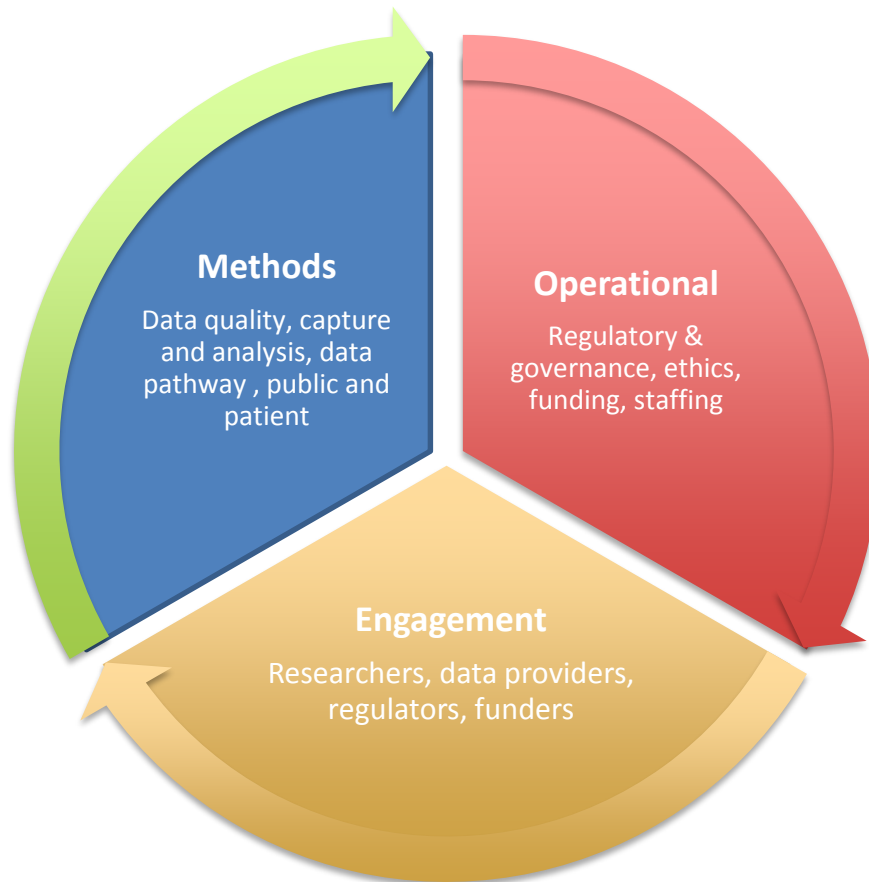
Education: Achievement, Attendance, Deprivation, Social care outcomes

Employment: Benefits, Salary

Census: Demographic, Ethnicity, Religion, Sex, Gender identification, Sexual orientation

Private Sector: Tesco clubcard

Our strategic approach



Questions

- New data sources
- New patient populations
- Acceptability of approaches
- Comparability to other data collection methods

Building capacity: staffing and skills

Centre for Trials Research

Dedicated role –
Routine data lead

Building capacity
across teams

Methods Sub-theme-
Routine data Strategy

Cardiff University

Data linkage network

Seminars and training

Invited speakers

Externally

Publications
(Methods)

Conferences

Workshops /
Seminars

Routine data projects

Centre for Trials Research



Building Blocks trial
Evaluation of FNP in England
Family Nurse Partnership



Building Blocks: 2-6
Longer term consequences of the
FNP programme using routine data



FNP Scotland
Evaluation of FNP in Scotland



STAR
Stemming the Tide of Antibiotic
Resistance



POOL
Establishing the safety of
waterbirth for mothers and babies

Cancer trials
utilising ONS
death data:

FRAGMATIC

FOLFERA

AML-15

AML-16

SCOPE 1

SCALOP



Division of Population Medicine Collaborations



LUCI Study

Long term follow-up of children
with UTI using routine data



HealthWise Wales

Welsh national cohort using
prospectively collected data
linked with NHS records

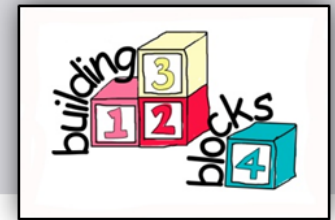


Investigating the pathway of type 1 diabetes
in childhood presenting in Primary Care

**Getting Animated
about Routine Data**

Why use routine data in trials?

- Accessibility of huge routinely collected datasets
- Objective assessments
- Reduces burden on participant | research nurse | GP
- Can reduce loss to follow-up
- Cheaper to obtain than self-report
- Reduces recall / selection bias
- Enhance / Validate collected trial data
- Longitudinal analysis



Outcome assessment by data source

Table 4.24 Number (%) of subsequent pregnancies within twenty four months of first birth, identified from each data source (N=1618)

Subsequent pregnancy?	Maternal self-report	Abortions	Inpatients	Outpatient	GP records	Overall
Yes	453 (52.2)	159 (9.8)	339 (21.0)	271 (16.8)	501 (52.7)	853 (66.2)
No	415 (47.8)	1459 (90.2)	1272 (79.0)	1340 (83.2)	450 (47.3)	436 (33.8)
Total	868	1618	1611	1611	951	1289
<i>Missing*</i>	750	0	7	7	667	329



Table 4.27 Percentage of participants with a subsequent pregnancies within twenty four months of first birth, by trial arm

		n	%	Adjusted OR* (97.5% CI)
HSCIC (Inpatients and Outpatients)	Intervention (N=450)	194	24.1	0.85 (0.63 to 1.15)
	Control (N=418)	211	26.1	
N=1611				
Maternal Self-report only	Intervention (N=450)	223	49.6	0.78 (0.58 to 1.07)
	Control (N=418)	230	55.0	
N=868				
GP records only	Intervention (N=471)	257	54.6	1.17 (0.87 to 1.57)
	Control (N=480)	244	50.8	
N=951				

* Intervention compared to Control. Analysis adjusted for stratification (site) and minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

A pathway to happy co-existence

Study set-up

Study work flows

Staff roles

Analysis

- Defining denominators
- Differing types of LTFU
 - Data quality
- Validation approaches
 - Timescales

Reporting

Archiving

Quality Management (SOPs!) & training

- small numbers
- De-identification
- Data destruction
- Asynchronous data access

Public involvement

- Practice
- Research

CARDIFF
UNIVERSITY

PRIFYSGOL
CAERDYDD

Centre for
Trials Research

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Ymchwil Treialon

Thank you for listening

Lugg-Widger et al. 2018. Challenges in accessing routinely collected data from multiple providers in the UK for primary studies: Managing the morass. IJPDS. 3 (3)



College of Biomedical and Life Sciences