



Centre for  
Trials Research

Canolfan  
Ymchwil Treialon

Pride & Pragmatism  
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# Randomised Trials and Routine Data: the promise, the reality and the potential

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## Issue...

- Randomised trials are getting increasingly expensive
- Selection bias of participants
- Burden of data collection on staff in a stretched health service
- Co-intervention effects from data collection
- Loss to follow-up is reasonably large in most trials
- Challenge with modelling real life impact of interventions
- Challenge with very long term follow-up

## Promise...

- Single patient electronic record
  - Accessible wherever they need care
  - Accessible by whoever is delivering care
  - Complete and accurate data on the whole health of a patient
  - Accessible to researchers
  - Linkable to research data collected
  - Potential to be patient held

# Reality... 10 years ago



BMJ

BMJ 2012;344:d8173 doi: 10.1136/bmj.d8173 (Published 2 February 2012)

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## RESEARCH

### Effectiveness of multifaceted educational programme to reduce antibiotic dispensing in primary care: practice based randomised controlled trial

OPEN ACCESS

Christopher C Butler *professor of primary care medicine*<sup>1</sup>, Sharon A Simpson *senior research fellow*<sup>1,2</sup>, Frank Dunstan *professor of medical statistics*<sup>1</sup>, Stephen Rollnick *professor of healthcare communication*<sup>1</sup>, David Cohen *professor of health economics*<sup>3</sup>, David Gillespie *statistician*<sup>1,2</sup>, Meirion R Evans <sup>1</sup>, senior lecturer in epidemiology and public health, M Fasihul Alam *research fellow*<sup>3</sup>, Marie-Jet Bekkers *research associate*<sup>1,2</sup>, John Evans *information manager*<sup>1,2</sup>, Laurence Moore *professor of public health improvement*<sup>4</sup>, Robin Howe *consultant microbiologist*<sup>5</sup>, Jamie Hayes *director, Welsh medicines resource centre*<sup>6</sup>, Monika Hare *trial manager*<sup>1,2</sup>, Kerenza Hood *professor and director*<sup>1,2</sup>

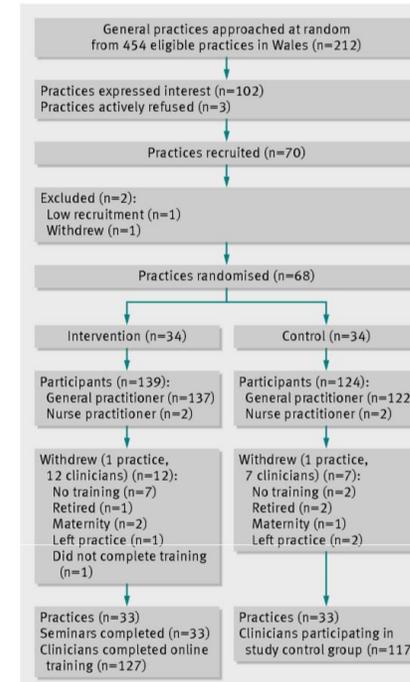


Fig 4 Participant flow diagram

## Reality... 10 years ago



PARC  
Prescribing data by  
practice

Antibiotic prescribing rates

PEDW  
Hospitalisations by  
practice

Hospitalisation rates

WHICSU  
Practice list sizes

Prescribing rates for RTIs  
Reconsultation rates for RTIs

Practice systems  
Consultation coding  
Reconsultation

## Reality... 10 years ago



Practice systems  
Consultation coding  
Reconsultation

- Wrote a program to interrogate their system to produce summary information
- Could only integrate into Vision & Ganymede systems (n = 37)
- Practices could not manage to undertake this themselves so we sent staff into the practice
- Only data to leave the practice was the summary table (no individual level data)
- Challenge to separate out contacts from face to face consultations

## Reality... 10 years ago



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But

- data were relatively limited and potentially over simplified
- Still challenging to do long term follow up in resource terms
- Need to consider intervention effects on coding behaviour
- Could only get a proportion of practices

## Reality...5 years ago



- Participants:** N=1,645 first time mothers aged  $\leq 19$  years from 18 PCTs in England
- Intervention:** Family Nurse Partnership (FNP) Programme (+ usual care)
- Comparison:** Usual Care (midwives, GP, health visitor)
- Outcomes:** **Maternal:** Subsequent pregnancy within 2yrs, Smoking in pregnancy,  
**Child:** Birthweight, Emergency attendances /admissions by 2yrs



### THE LANCET

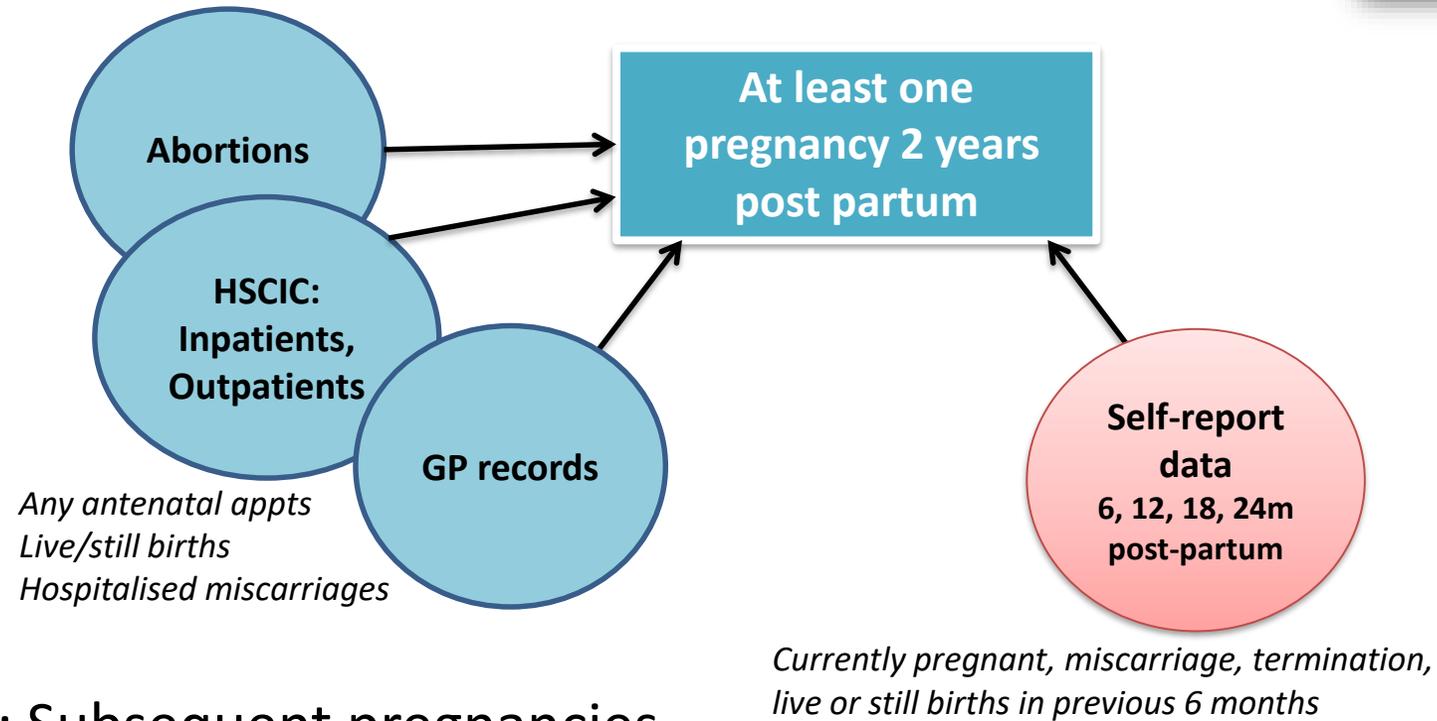
Effectiveness of a nurse-led intensive home-visitation programme for first-time teenage mothers (Building Blocks): a pragmatic randomised controlled trial







## Reality...5 years ago



Example: Subsequent pregnancies

## Reality...5 years ago



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)
<b>Total</b>	<b>868</b>	<b>1618</b>	<b>1611</b>	<b>1611</b>	<b>951</b>	<b>1289</b>
Missing*	750	0	7	7	667	329

# Reality...5 years ago



Table 4.25 Number (%) of participants with a subsequent pregnancy within twenty four months of first birth, by trial arm

	n	%	Adjusted* OR† (97.5% CI)	p-value
<b>Intervention (N=643)</b>	426	66.3	1.01 (0.77 to 1.33)	0.920
<b>Control (N=646)</b>	427	66.1		
<b>Total (N=1289)</b>	853	66.2		

\* Analysis adjusted for stratification (site) and minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

† Intervention compared to Control

Participants with a subsequent pregnancies within twenty four months of first birth, by

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

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

# PCTU