

Project to Enhance ALSPAC through Record Linkage (PEARL)

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Avon Longitudinal Study
of Parents and Children

Supported by
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Today's Presentation

A summary of our data linkage activities in ALSPAC

1. Background to ALSPAC
2. Information Governance
3. Linkage to Administrative Records
4. Linkage to Health Records
5. Conclusions

Background – Avon Longitudinal Study of Parents and Children (ALSPAC)

The ALSPAC study

- Recruited >15,000 women; who were pregnant, while living in the Bristol area, with a delivery due date between 1st April 1991 and 31st December 1992
- Follow-up of the young people through 59 questionnaires and 9 clinical assessment visits
- Mothers & Fathers/partners clinical assessments started in 2008
- Recruitment being extended to fathers/partners, grandparents, siblings and the 3rd generation children (i.e. the children of the index child)
- A hypothesis-free study; remit to collect life course information on the family, allowing investigation of the environmental and genetic determinants of health and development
- More information in the study cohort profiles:
Boyd et al (2012) & Fraser et al (2012)

Background – Project to Enhance ALSPAC through Record Linkage (PEARL)

Informing the use of linkage in observational studies

- Increase use of linkage to routine health and administrative databases
- Increase the understanding of the secondary use of routine data in an observational study
- Demonstrate the potential of linkage in this context:
 - ALSPAC as an exemplar setting
 - Generalisable methods to establish linkages
 - Exemplar projects to demonstrate the value of linkages

PEARL – Wellcome Trust £1.7 million, 2009-2014

PI – John Macleod



Information Governance

Legislative and Governance Requirements

Main legislation includes:

- Data Protection Act (1998); EU Data Protection Directive (95/46/EC)
- European Convention on Human Rights
- Departmental legislation (e.g. NHS Act (1996))

Implications for observational research:

- Requirement to notify and seek consent for use of personal information
- Requirement to ensure the security of the data and that it is used in a consistent manner with the information provided to participants
- Implications differ depending on department

Participant Consent



Participant Consent



Participant Consent

Consent Campaign*

- 13,136 consent packs sent
- 3,622 packs returned (28%)

*figures correct June 2013

Category	Sub-Category	n consented	% consented
ALSPAC		3,393	93.7%
Of those who consented to ALSPAC:			
Health		3,222	95.0%
Education	School	3,271	96.4%
	FE	3,246	95.7%
	HE	3,217	94.8%
Economic	DWP	2,958	87.2%
	HMRC	2,964	87.4%
Criminal	Criminal Convictions & Cautions	3,112	91.7%

Participant Consent

Linkage Consent Summary:

- 3,393 ALSPAC consenters
- Of these
 - 2,754 consented to all linkages (81.2%)
 - 584 varied their consent decisions (17.2%)
 - 55 refused all linkages (1.6%)
- Respondents typically supportive of research use of their records
- High rates of non-response; response biased in similar manner to general participation in ALSPAC

PEARL Research:

1. Patterns in consent decisions
2. Qualitative research to understand factors that contribute to participants declining consent to linkage

Alternative legal routes to accessing records?

Legal access to health records for medical research (from a DPA perspective) depends on:

- a. consent, b. anonymity or c. issuing a privacy notice

Privacy Notice

- Informing individuals that the study will use their personal information (and providing a means of opting out)
- ALSPAC have received approval to use this for health and education records

But,

- Uncertainty as to whether it can be used to access criminal records and cannot be used to access DWP records due to other legislation
- Questions exist as to the compatibility of seeking consent and justifying access on the grounds of issuing a privacy notice
- Potential difficulties in arranging the release of data on this basis

Alternative legal routes to accessing records?

Section 251 Support

- Only applicable to NHS records
- Secretary of State has given Section 251 support to ALSPAC to access the records of non-responders
- Excludes routine access to mental and sexual health data

Anonymised Records

- Consensus that researchers can access/use anonymised records without consent
- Requires greater levels of infrastructure and support/technical ability within departments

Information Security

- ALSPAC has been awarded ISO/IEC 27001 Information Security accreditation
- Working towards NHS Information Governance Toolkit assessment and possibly HMG Security Framework standard
- The ALSPAC Data Linkage Safe Haven; a demarcated team and working environment (both physical and IT server space). Safe Haven staff manage the linkages and pseudonymise all incoming identifiable data

BABIES TO
BIRTH
CARING IN
LEARNING
TOGETHER
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CARING IN

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They Glass SK 507

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Linking to ALSPAC participants
Administrative Records

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Administrative Records: Education Records

- School (state maintained establishments) records are held in the National Pupil Database (Dept. for Education)
- ALSPAC linked ~85% of cases to the NPD, excludes those outside of England and in private establishments
- Provides access to:
 - Attainment (Key Stage results)
 - School & Pupil census data
 - Attendance & Exclusion Data
- FE & HE data held by the Dept. Business, Innovations & Skills, but this is mappable through NPD.
 - Individual Learner Record, FE and work based learning records
 - Higher Education Statistics Agency (HESA), HE records

Administrative Records: DWP & HMRC

- DWP hold individuals benefit records
 - Linked via National Insurance ID
 - Departmental legislation explicitly requires consent for data access (but anonymous access is OK in theory)
 - Complicated 'ownership', Child record remains the property of parent/carer
 - ALSPAC have made limited progress in agreeing linkage & data access with the DWP
- HMRC hold tax and employment records
 - Linked via National Insurance ID
 - Access route, via HMRC datalab, becoming established
 - ALSPAC have not yet applied for this access

Administrative Records: Criminal Convictions & Cautions

- Records maintained in the Police National Computer system (PNC)
 - Requires PNC Information Access Panel (PIAP) authorisation to access records
 - Linkage conducted by Ministry of Justice using deterministic process (using Name, Date of Birth, Gender)
 - Records consist of multiple 'event' tiers, linking individuals, convictions and crimes into a longitudinal sequence.
- ALSPAC linked a pilot sample in May 2013
- Currently held on an anonymous basis
- Outcome of our application to access on an identifiable basis due shortly

Administrative Records: Criminal Convictions & Cautions

Pilot sample of 7,361 consenters and consent non-responders (who were advised of the implications of non-response in the privacy notice)

- 885 (12%) linked to a conviction or caution record
- 4,000 records in total (66% convictions), with individuals having between 1 and 63 separate records.

PEARL Research:

1. Study variations in study/clinical reporting of criminal/anti-social activity and criminal record
2. Associations between criminal record/self-reporting criminality and study participation & consent
3. Exemplar research into the relationship between early life course and subsequent criminality

Linking to ALSPAC participants Health Records



Linkage to the NHS Central Demographics Spine

- HSCIC conduct linkage using deterministic matching
- 99% linkage match rate
- ‘Vital events’ notifications provide:
 - Tracing information
 - Cancer registrations
 - Death notifications
 - Onward linkage to other NHS databases

PEARL Research:

1. Investigating elevated risk of breast cancer following pregnancy

Secondary Care Records

Well established, centralised, national resource (HES)

- Identification of records through existing links to NHS ID, and for early records a deterministic process using a range of personal identifiers (date of birth, gender, postcode)
- Linkage undertaken by HSCIC Data Linkage Service
- ALSPAC linked our consenting sample (~3,200) to HES in May 2013
- Linkage to consent non-responders scheduled for Autumn 2013

PEARL Research:

1. Study variation between clinical/study reporting of self-harm
2. Linkage methodology

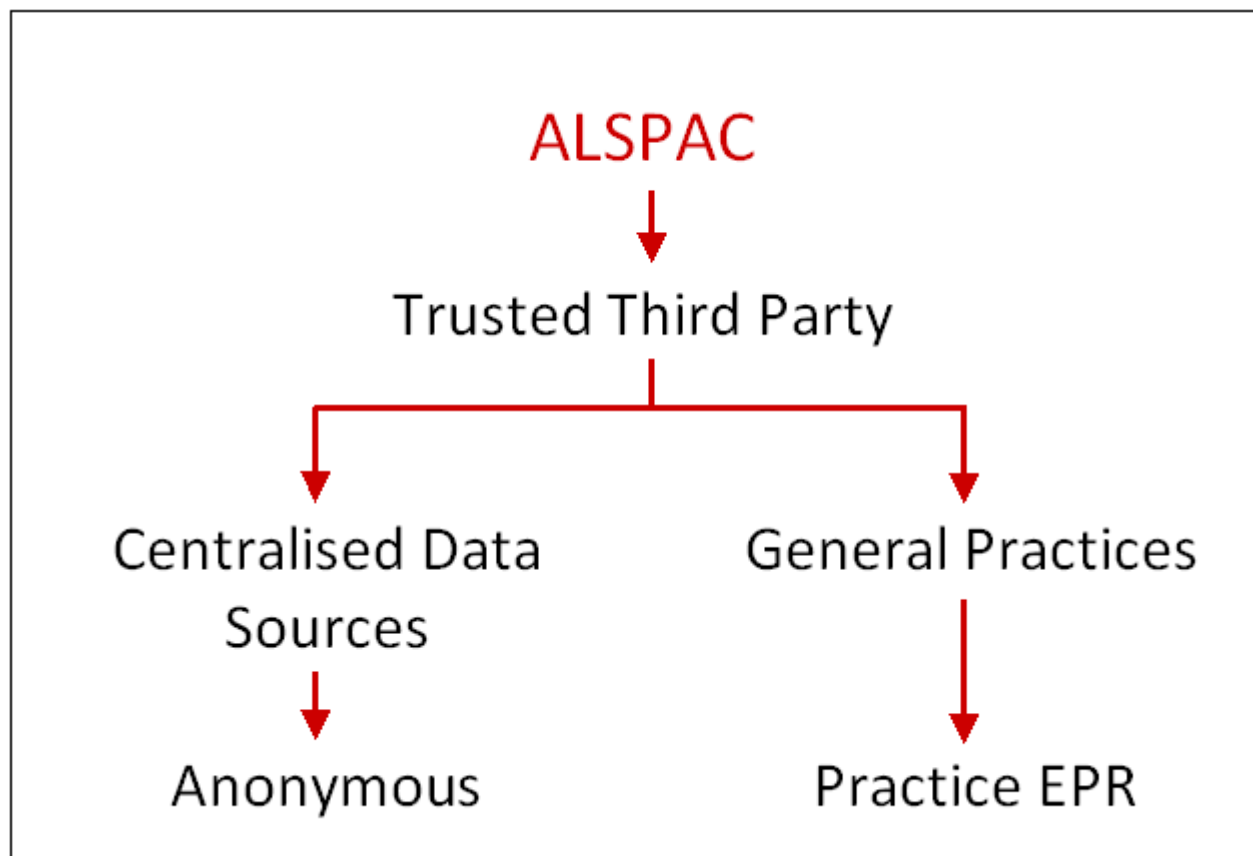
Primary Care Records

- Information on ~90% patient consultations with NHS are held in the Electronic Patient Record (EPR)
- The majority of EPRs are held within General Practices
- Currently there is no national EPR database, although data on sub-samples of the population are available
- Recent advances in the General Practice Extraction System (GPES) suggests a greater potential for centralised records.

EPRs: Scale of potential and challenges

- ~14,000 General Practices in England and Wales
- ~65,000 registered practitioners
- At a local level the EPR is held in a variety of systems
- Patient movement between practices and systems
- Clinical data is presented as structured and unstructured data
 - ~100,000 clinical 'Read' codes (diagnoses, symptoms, administrative and demographic)
 - ~40,000 drug and devices codes
 - Important information is contained within free text
 - Can contain embedded data (e.g. letters, x-rays)

PEARL: Generalisable methods for accessing primary care data



Anonymous Centralised Databases

- E.g. Clinical Practice Research Datalink (CPRD)
- Anonymised data access linked at the individual level
- Linkage facilitated through Trusted Third Parties

Strengths

- Ability to analyse individual level data without consent (dissent respected)
- Services under development to improve coverage

Weaknesses

- Currently limited population coverage

PEARL Research:

1. 'validate' self-reported asthma data
2. study variations in study/clinical reporting of psychosis like symptoms
3. Investigate association between health status and study participation / linkage consent

EPR Extraction from General Practices

- PEARL have developed a generalisable method to extract participant EPRs
- Working with partners in the Secure Anonymised Infrastructure for Linkage (SAIL)
 - University of Swansea
 - NHS Wales Informatics Service (NWIS)
- NHS Information Centre (NHS IC)
- Practice software providers
 - Apollo Medical Systems Ltd
 - Egton Medical Information Systems Ltd

Practice level authorisation

The practice 'own' the EPR, our access requires their authorisation

- Currently extracting a pilot sample of 2,808 consenting participants
- Registered in 533 practices, across England & Wales

GP Authorisation Status*	Practices	%	Patients	%
No response to date	241	45.2	710	25.3
Declined Authorisation	22	4.1	66	2.4
Authorised	270	50.7	2,032	72.4
Total	533	100	2,808	100

*30th June 2013

Automated data extraction from practice software

- EMIS; largest coverage of any system in England
- Apollo; interacts with multiple software databases, >80% coverage
- Developed ALSPAC software components that identify and extract individual EPRs
- The extracts are split into a demographic file and a clinical data file by the software company
- Data extraction successfully started; rolling process during 2013

PEARL Exemplar Research:

1. Linkage methodology & outcomes (nature of the records extracted)
2. Expand our asthma/mental health to this data set

Conclusions

Information Governance: ALSPAC making good progress in addressing legal, ethical and security concerns of data owners, but a long and resource intensive process. We are exploring alternatives to consent based models of accessing participant data.

Linkage to administrative records: Access to education records is well established, access to other records hindered by internal uncertainties regarding data sharing and/or only available via specific, localised solutions

Linkage to health records: Access to centralised records is well established, although application process can be onerous. Methods to access linked EPRs are emerging, both at a national level (CPRD) and at a study level (PEARL)

Linkage & research: high profile and investment in infrastructure making a difference. PEARL aims to contribute through our generalisable methods and exemplar research

Thank You, Any Questions?

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Background - ALSPAC Data Linkages

Established prior to PEARL

Category	Data Set	Status	Data Owner
Health	Maternity and birth records	Established	Local NHS
	Death and Cancer Registries	Established	NHS HSCIC
Education	School (ages 5-16)	Established	Dept. for Education
	FE (ages 16+)	Established	Dept. Business Innovations and skills
	HE (Ages 18+)	Established	

PEARL

Health	Primary Care EPR	Established	National DBs and GP records
	Secondary Care	Established	HES
Economic	Tax and Earnings	Negotiating	HM Revenue & Customs
	Benefits	Negotiating	Dept. Work & Pensions
Criminal	Convictions and Cautions	Approved	Ministry of Justice