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DATA PAPER

Data from the PALS (Pregnancy and Lifestyle Study), a Community-Based Study of Lifestyle on Fertility and Reproductive Outcome

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In order to assess the possible effects of lifestyle on fertility and pregnancy outcome, the PALS (Pregnancy and Lifestyle study) collected extensive data on a broad range of parameters termed 'lifestyle' from couples who were planning a natural (non-assisted) pregnancy in the coming months. There was no intervention. Participants were recruited over a six year period from 1988 to 1993 in response to extensive promotion in the local media. Male and female partners were interviewed independently and all interviews were conducted prospectively before the couple attempted to conceive. The result of each month of 'trying' was recorded and pregnancies were confirmed by urine tests and by ultrasound. The length of gestation of each pregnancy was recorded and pregnancies at term were classified with respect to weight. Multiple pregnancies and/or babies with congenital abnormalities have been excluded from the dataset. The data is stored as an xls file and each variable has a codename. For each of 582 couples there are 355 variables, the codes for which are described in a separate metadata file. The questionnaire based data includes information about households, occupation, chemical exposures at work and home, diet, smoking, alcohol use, hobbies, exercise and health. Recorded observations include monthly pregnancy tests and pregnancy outcomes.

Funding statement: NH&MRC (Australia) Project grant (1988–1990) awarded to Dr Judith H Ford and Professor AJ McMichael as chief investigators.
Keywords: Fertility; reproduction; lifestyle; maternal age; paternal age; occupational exposure; spontaneous abortion; miscarriage; small for gestational age

1. Overview

Introduction/Study Description

This study was funded by a grant from the National Health & Medical Research Council of Australia. Our goal was to obtain accurate information about fertility rates and the environmental factors that influenced fertility from people who were not undertaking any clinical treatment. Furthermore, we wanted to obtain this data prospectively as no such information was available at the time. Prior to undertaking the study JHF had directed a clinical cytogenetics laboratory for many years and was particularly interested in identifying factors other than maternal age that might significantly contribute to spontaneous abortion (miscarriage) and infertility.

2. Context

Spatial coverage

The whole of the state of South Australia, Australia.

Temporal coverage

Couples completed their interviews between June 1988 and August 1993. Data on attempted conceptions, urine tests and pregnancy outcome data was collected until all interviewed couples had completed nine months of attempted conceptions.

Species

Homo sapiens

3. Methods

Steps

Study participants were sought through general promotion in the media including a 'Community' (i.e. non-commercial) TV advertisement, radio interviews and newspaper articles. Because it was important that the participants represented the normal population i.e. there was not an over-representation of couples with pre-existing problems, the focus of the promotion was on the joy of pregnancy and prevention of problems. One particular aspect of the promotion that encouraged this was a monthly prize (random draw) of a romantic candle-lit dinner for two at an excellent restaurant. Participants were not otherwise paid or reimbursed for their participation.

Once couples were recruited they were assigned an ID and an appointment for each of the male and female interviews, which were conducted face to face or by telephone

by one of three interviewers, two female and one male. Participants were asked if they had a preference for the gender of the interviewer and if so, they were assigned an interviewer of that gender. Where it was not possible to complete a telephone interview, the participant was sent a paper questionnaire by mail with pre-paid return postage. All data was recorded on paper and an A4 Lever-arched file was set-up for each couple. These paper records have since been shredded. Two separate record systems were established. The first, which was called 'Profiles', assigned an ID and recorded the names and addresses of participants and their ongoing appointments, results of tests and other checklists. Couples had matching IDs e.g. P0001F and P0001M. The identifiable records were retained in the computer program Dbase and in print-outs. The ID and coded responses to interview questions were entered into the first version of SPSS in Windows however because of the large number of questions and the relatively low operating capacity of computers at the time, the male and female data were initially retained in separate databases. These have since been merged and the coded data is available as an Excel file and the codes for all the variables as a pdf file.

Each month that the couple attempted to conceive, they contacted the team on the morning that the female's menstrual bleeding would usually commence or the following Monday (if on a Saturday or Sunday). If bleeding had already commenced then it was noted that an attempt had been made but that pregnancy had not occurred this time. If, however, bleeding had not commenced then the female would collect an early morning urine specimen, which she then arranged to send to our laboratory. All pregnancy tests were available by the end of the day of receipt and where a test was positive an appointment for an ultrasound scan was made at about the seventh day. Where pregnancy tests were equivocal, a second and occasionally third urine sample was tested.

Follow-up was conducted at regular intervals but couples were asked to contact the study group immediately should a pregnancy spontaneously abort or if any other unforeseen event should occur. If pregnancies proceeded normally then both the couples and their doctors were contacted six weeks before the expected date of birth. Doctors, usually obstetricians, were given a simple form to complete that summarised the outcome of the pregnancy, e.g. singleton birth or other, birth weight group, gender, any congenital abnormalities.

Sampling strategy

Participants who had been previously referred to our department for a fertility related issue were excluded from the sample.

Quality Control

- The same three interviewers were employed throughout the study and all received intensive training before the study commenced.
- Consistency of responses was checked both by having many duplicate questions in the male and female questionnaires and by having some different questions that sought the same information. Where mismatches were found this was either followed up with the couple or the case was deleted.
- Accurate recording of the data and accurate transfer from written to computer files was checked through an extensive audit.

Constraints

No attempt has been made to verify the answers given to the questions hence responses on environmental exposures, diet, medical conditions etc should be regarded as the opinions of the participants rather than as verified facts.

Privacy

The records that contained identifiable information were kept separately from all other information and in a locked room. These were only accessible to the author, who was the Chief Investigator and Project's Administrative Leader. All specimens and interview data were referred to by codes P0001F and P0001M for couple 1 etc. These codes are used in the database and all potentially identifiable data such as dates of birth (ages are included) and postcodes of residence and/or work have been omitted.

Ethics

Before the commencement of the study, ethics approval was obtained from the Human Ethics Committee of The Queen Elizabeth Hospital and notice of approval was sent to the funding body, the National Health & Medical Research Council of Australia. Unfortunately, because computer records were not well developed at the time, the details of the application have not been retained.

Ethics approval has been sought for sharing the de-identified dataset from the study- Application title: "PALS Pregnancy & Lifestyle Study - Data Sharing". This has received approval from both the Human Research Ethics Committees of The Queen Elizabeth Hospital HREC/14/TQEHLMH/249 (approval 07/01/2015) and the Human Research Ethics Committee of the University of South Australia (Application ID: 0000034430) approved 27/05/2015).

4. Dataset description

Object name

File: PALS Data – Excel 1997–2003 workbook.

File: Variables in PALS Excel workbook – pdf file.

Occupational classifications (used in 1988–1993) – can be obtained as a pdf from the link: Australian Standard Classification of Occupations - ComLaw.

Data type

Primary Data.

Creation dates

01/06/1988 to 12/07/1994.

Dataset creators

Dr Judith Ford (Geneticist, Project leader).

Professor Janet Hiller (Epidemiologist and advisor).

Ms Leigh Kersnovske (Administrative Officer/Study Manager & Interviewer).

Ms Jenni Chappel (Administrative Officer/Interviewer).

Mr Jeff Suttle (Technical Assistant/Interviewer).

Language
English.

Programming language
Not included.

Licence
CCBY with attribution in any arising publications or presentations.

Accessibility criteria
Files are openly accessible.

Repository location
The 'collection' record on Research Data Australia: https://researchdata.ands.org.au/collection-pals-pregnancy-reproductive-outcome/617285

The digital object identifier for the PALS open data dataset: http://researchoutputs.unisa.edu.au/11541.1/9e222946e0bd4289bc8572b847b9abed

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5. Reuse potential
This dataset could have many applications especially as a control for comparison with fertility interventions. However, the dataset might also be useful for re-analysis to ask questions that have not been addressed in the publications below. For example, there were many questions asked about chemical exposures but as relatively few participants were exposed to any one chemical, most of this information has not been used to its fullest potential. Only three papers have been published thus far [1, 2 and 3]. Since the data was collected in the late 1980's it could also be useful to compare these data with a more recent collection.

Dr Judy Ford would be happy to be involved in future collaborations that involve these data but the dataset is available for researchers' individual use provided appropriate attribution is given.

Competing Interests
The author declares that they have no competing interests.

Acknowledgements
I would like to especially acknowledge my two colleagues Professor Tony McMichael, who helped me plan and fund the project but who moved to London soon after the funding was received and so didn't actually participate in the project, and Dr Brian Pridmore, an Obstetrician who was a leader in the use of ultrasound scan analysis, who oversaw the scans used to verify all the PALS pregnancies. Both Tony and Brian have sadly passed away but they are both remembered for their innovation and leadership in their fields.

References
1. **Ford, J H, MacCormac, L** and **Hiller, J** 1994 PALS (Pregnancy & Lifestyle Study): association between occupational and environmental exposure to chemicals and reproductive outcome. *Mutat Res,* 313(2–3): 153–164. DOI: http://dx.doi.org/10.1016/0165-1161(94)90045-0
2. **Ford, J H** and **MacCormac, L** 1995 Pregnancy & lifestyle study: the long-term use of the contraceptive pill & the risk of age-related miscarriage. *Hum Reprod,* 10(6): 1397–1402. DOI: http://dx.doi.org/10.1093/HUMREP/10.6.1397
3. **Ford, J H** 2011 Preconception risk factors and SGA babies: Papilloma virus, omega 3 and fat soluble vitamin deficiencies. DOI: http://dx.doi.org/10.1016/j.earlhumdev.2011.06.002

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