Use of time to pregnancy in environmental epidemiology and surveillance

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ABSTRACT

Background Potential sources of environmental pollution, such as incinerators or landfill sites, can adversely affect reproduction and/or development. Time to pregnancy (TTP) is a validated measure of biological fertility that can be studied with relatively small populations.

Methods Pregnant local residents living within 3 km of a landfill site (‘exposed’ group, n = 200) or elsewhere in the Rhondda valleys (‘unexposed’ group, n = 400) were interviewed by health visitors or midwives. The response rate was 83%.

Results No difference was found in the TTP distributions between the exposed and unexposed groups. Relationships of TTP with covariates were consistent with the literature.

Conclusions In a context of public and scientific concern about possible reproductive toxicity, an interview study of TTP was highly acceptable to local women. A large enough sample to generate stable TTP distributions was readily achieved.

Keywords environmental epidemiology, fertility, fecundity, landfill, reproduction, time to pregnancy

Introduction

Human reproduction and embryonic development can be adversely affected by exposure to environmental agents,1,2 and because of this, clusters of miscarriages or congenital anomalies are often attributed by the public to recognisable potential sources of pollution, such as incinerators or landfill sites. In such cases, typically, there are too few adverse events to allow causal hypotheses to be tested rigorously. End points that are more frequent allow small populations to be investigated. In this paper, the use of ‘time to pregnancy’ is explored as an end point that may have utility for investigating population environmental exposures.

Time to pregnancy (TTP) is an outcome measure of biological fertility, defined as the number of months that a couple takes to conceive, given unprotected intercourse. TTP is a functional measure of couple fertility,3 and its use is complementary to more mechanistic research on specific biological pathways and medical conditions in both sexes, and to studies using biomarkers of semen quality. As well as being a sensitive measure of biological fertility in the true sense, TTP is also affected by embryotoxic agents that cause early loss before recognition of pregnancy.3 TTP is well suited to surveillance, and has been suggested as an useful overall indication of a reproductive hazard when no specific hypothesis can be formulated.4

Whilst prospective TTP studies beginning in women before they become pregnant are feasible5 and have methodological advantages in the study of aetiological factors,5–8 they are often not practicable as they are expensive to conduct. They also tend to suffer from methodological problems such as the absence of a sampling frame and low and selective participation rates, leading to bias.9 However, retrospective TTP studies are easy to conduct, require a relatively short questionnaire, and have been found to be acceptable in a wide variety of cultures.3

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Validation studies have demonstrated that women’s self-reports give an accurate representation of the true TTP distribution,\textsuperscript{10–13} even with duration of recall up to 20 y.\textsuperscript{13} Men can also provide apparently valid information, generating the same distributions and analytical results as women drawn from the same population,\textsuperscript{14,15} albeit with more digit preference and item non-response (typically 10–15\% compared with 5–10\% for women). TTP is a property of the couple, so the covariates for both partners are required. As the outcome is the number of months that it took to conceive and TTP values are constrained to be integers, the discrete-time analogue of the Cox model is recommended for analysis.\textsuperscript{9,16} Alternatively, regression models for ordinal responses such as the continuation-ratio model can be used.\textsuperscript{17}

The methodology of retrospective TTP-based research has evolved gradually since the mid-1980s, and the potential biases and other problems are now well understood. They can be effectively controlled if the studies are properly designed, conducted and analysed\textsuperscript{19,18} (see Discussion). Time trends\textsuperscript{14} and international differences\textsuperscript{19,20} have been studied, and risk factors for delay in TTP identified.\textsuperscript{15,21–23} Whilst there are many occupational studies of TTP, e.g.\textsuperscript{24,25} its potential for use in environmental epidemiology has not hitherto been realised. It is proposed that the following applications be considered:

(i) defined population studies in areas close to sources of emissions of agents that are perceived as possibly harmful;
(ii) surveys representative of the general population that are sufficiently large to allow spatial heterogeneity to be detected;
(iii) non-spatial studies that relate TTP to environmental agent exposure.

Data should be obtained from special surveys with a well-defined source population. Clinical samples (drawn from fertility clinics, for example) are unsuitable, due to strong selection and self-selection biases, and studies based on volunteer samples are also difficult to interpret and should be avoided. Two types of sampling frame are suitable for retrospective environmental studies of TTP:

(i) Pregnancy based studies: A sample of women who are pregnant or have recently had a baby are asked about TTP relating to that pregnancy. The advantage is that it is easy to define and contact the women and, as they are asked about a current or recent pregnancy, recall bias is minimal. Disadvantages include that sterile couples are excluded and subfecund couples are underrepresented.
(ii) Cross-sectional studies: Couples are selected randomly from the general population, and asked about TTP either for all previous pregnancies or for just one, e.g. the first; it is also possible to enquire about unsuccessful attempts and sterility (see below). For many of them, the pregnancy(ies)/attempt(s) may have been some years ago, which can be an advantage in certain circumstances, for example with a landfill site that has been operating for years, when pre-operational observations are valuable. As the focus is on previous exposures, this design approximates to a retrospective cohort study. The disadvantage is long recall with possible recall bias, especially for variables relating to exposure and for covariates (as also occurs e.g. in case control studies of cancer).

In its literal sense, the term ‘time to pregnancy’ refers only to the period of unprotected intercourse that leads to conception, but TTP studies should also collect information on contraceptive failures (see Discussion). In addition, it is possible also to include unsuccessful attempts (infertile phases and long-term infertility) if the study design is not pregnancy based. This is preferable, as stronger inferences can then be made: selection bias from including only fertile couples is avoided, and regression estimates are not conditional on achieved conception as they are with pregnancy based studies.\textsuperscript{26} The length of the unsuccessful attempt generally has to be at least six months for the couple to remember these attempts and provide valid information about them. Use of a cross-sectional sample rather than pregnancies may also allow study of a larger number of conceptions, by extending the number of years of observation.

We report here a study of TTP in the neighbourhood of the Nant-y-Gwyddon landfill site in the Rhondda valleys in South Wales, which can be regarded as a pilot study for the use of this approach in environmental epidemiology. Studies of residents had shown that women living nearby were at increased risk of giving birth to a child with a congenital anomaly. Rates were also increased for the years leading up to the opening of the site,\textsuperscript{27} and this raised concerns about the other local environmental exposures that could possibly explain the increased rate of congenital abnormalities in this area, requiring further investigation. However, as only up to four babies with congenital anomalies are born each year to families living within 3 km of the site, the statistical power was lacking to explore increases in risk over a short period of time. A follow-up study was therefore undertaken to explore this issue further, using TTP as an outcome.
measure. The aim of this study was to determine whether the distribution of TTP varied between residents living close to the landfill site and those further away.

Methods

Following approval by the Bro Taf Local Research Ethics Committee, women were identified from the local midwifery records. They were eligible for the study if they had achieved a pregnancy of at least 24 weeks and were resident in the Rhondda valleys. The first 600 consecutive pregnant women after July 1999 who satisfied these criteria comprised the study group, including 200 living in the five wards within 3 km of the landfill site (‘exposed’ group) and 400 in the other 10 wards, as experience has shown that approximately 200 pregnancies with TTP values are required to generate a stable distribution.3

A questionnaire, based on that used in the Asclepios project24,25 was administered by health visitors or midwives in face-to-face interviews. It documented demographic details, previous contraceptive method, TTP and self-reported environmental exposures. Reported covariates since stopping contraception included smoking habits of both partners, mother’s alcohol consumption and use of medication (prescribed and over-the-counter), recreational drugs, use of hair colorants and exposure to solvents in paint. Personal educational level and current employment were also recorded, as was a ward-based deprivation score (Townsend Index of Material Deprivation). The questionnaire was pre-piloted to assess its acceptability. All interviewers were trained to administer the questionnaire.

Statistical analysis was carried out using STATA version 8.2. Relative risks and 95% confidence intervals (CI) were calculated. Differences in proportions were tested using Chi squared test for heterogeneity. A continuation-ratio model was fitted17 to estimate the odds ratio of becoming pregnant within the next month at a given time, comparing the exposed and unexposed groups.

Results

Questionnaires were completed from interviews with 499 out of 600 women identified as giving birth to a child from the midwifery register between July 1999 and June 2000, a response rate of 83%. Of those not interviewed, there was no response from 77 women despite three attempts by the health visitor to contact them; nine women did not achieve a pregnancy of 24 weeks; eight women refused to participate; three women had moved out of the area with no forwarding address; two were not interviewed because of illness; and two were found not to be residents of Rhondda. The electoral ward of residence for 481 of the 499 respondents were able to be identified, 326 in unexposed and 155 in exposed wards. Of the 499 pregnancies, 362 (73%) were eligible for a TTP value as they did not result from a contraceptive failure, and reported TTP values were available for 329 (91%) of these.

The mean ages of the 155 women living in the exposed wards (26.3 y) and their partners (28.0 y) were similar to the mean of the 326 women and partners in the unexposed wards (26.8 and 28.3 y, respectively) (Table 1). A higher proportion of women in the exposed group (45%) compared with the unexposed group (12%) were within the lowest quintile of the distribution of Townsend score for material deprivation.

Women in the exposed wards were less likely to have used birth control prior to pregnancy, and were more likely to have planned the pregnancy, and to have taken prescribed medicines (Table 2). There was no significant difference in the proportion of women taking fertility treatment, folic acid supplements or other medicines, or tablets or sprays bought from a pharmacy. Medication for asthma was more commonly reported in the exposed wards (RR 4.21, 95% CI 1.29–13.76) although the numbers were small (eight cases and four controls). The results were similar when use of bronchodilator and steroid inhaler were analysed separately.

The cumulative TTP distributions (Figure 1) were very similar for residents of exposed and unexposed areas. There was no difference in fertility for those in the exposed group

<table>
<thead>
<tr>
<th>Table 1 Demographic characteristics of women in exposed and unexposed groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal age</td>
</tr>
<tr>
<td>---------------</td>
</tr>
<tr>
<td>&lt;20</td>
</tr>
<tr>
<td>20–24</td>
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<tr>
<td>25–29</td>
</tr>
<tr>
<td>30–34</td>
</tr>
<tr>
<td>35–40</td>
</tr>
<tr>
<td>Deprivation quintile</td>
</tr>
<tr>
<td>1(most deprived)</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>4</td>
</tr>
<tr>
<td>5(least deprived)</td>
</tr>
</tbody>
</table>

*Chi squared test for heterogeneity.
compared to those in the unexposed group [OR 1.02 (95% CI 0.78, 1.33)] (Table 3). Women younger than 25 y were more fertile. Fertility was significantly increased among women educated beyond the age of 16 y. It was also increased among women who had previously used contraception, as expected. Following adjustment for all maternal and paternal characteristics, there was still no significant difference in fertility between the exposed and unexposed groups. However, education level was more strongly associated with increased fertility (Table 3).

Although there was a lower proportion of accidental pregnancies in the exposed group (16.4%) compared with (27.4%), this difference was not significant following adjustment for all maternal and paternal characteristics [adjusted OR 0.48 (95% CI 0.20, 1.15)]. Nevertheless it was considered important to explore whether this could have affected the findings, because accidental pregnancies are ineligible for a TTP value and are treated as missing values in the main analysis. A sensitivity

### Table 2

<table>
<thead>
<tr>
<th>Variables</th>
<th>Unexposed, n (%)</th>
<th>Exposed, n (%)</th>
<th>Unadjusted relative risk (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Using birth control</td>
<td>90 (28)</td>
<td>29 (19)</td>
<td>0.67 (0.46, 0.98)</td>
<td>0.03</td>
</tr>
<tr>
<td>Planned pregnancy</td>
<td>151 (47)</td>
<td>91 (59)</td>
<td>1.25 (1.06, 1.50)</td>
<td>0.01</td>
</tr>
<tr>
<td>Last type contraception</td>
<td>184 (57)</td>
<td>100 (66)</td>
<td>1.17 (1.00, 1.35)</td>
<td>0.05</td>
</tr>
<tr>
<td>Prescribed medicine</td>
<td>104 (32)</td>
<td>69 (45)</td>
<td>1.37 (1.08, 1.74)</td>
<td>0.01</td>
</tr>
<tr>
<td>Self-medication</td>
<td>90 (28)</td>
<td>52 (34)</td>
<td>1.18 (0.89, 1.56)</td>
<td>0.26</td>
</tr>
<tr>
<td>Folic acid</td>
<td>229 (71)</td>
<td>114 (74)</td>
<td>1.03 (0.92, 1.16)</td>
<td>0.58</td>
</tr>
<tr>
<td>Painted house</td>
<td>163 (51)</td>
<td>87 (57)</td>
<td>1.11 (0.93, 1.32)</td>
<td>0.26</td>
</tr>
<tr>
<td>Dyed hair</td>
<td>153 (48)</td>
<td>67 (44)</td>
<td>0.91 (0.74, 1.13)</td>
<td>0.41</td>
</tr>
<tr>
<td>Took holiday</td>
<td>72 (22)</td>
<td>39 (25)</td>
<td>1.14 (0.81, 1.59)</td>
<td>0.46</td>
</tr>
<tr>
<td>Educated after 16 y</td>
<td>141 (47)</td>
<td>59 (41)</td>
<td>0.88 (0.70, 1.11)</td>
<td>0.27</td>
</tr>
<tr>
<td>Took any alcohol</td>
<td>196 (64)</td>
<td>107 (71)</td>
<td>1.12 (0.98, 1.28)</td>
<td>0.10</td>
</tr>
<tr>
<td>Full-time paid work</td>
<td>125 (39)</td>
<td>73 (48)</td>
<td>1.22 (0.98, 1.51)</td>
<td>0.08</td>
</tr>
<tr>
<td>Mother smokes</td>
<td>143 (44)</td>
<td>60 (39)</td>
<td>0.88 (0.70, 1.11)</td>
<td>0.28</td>
</tr>
<tr>
<td>Partner smokes</td>
<td>161 (49)</td>
<td>62 (40)</td>
<td>0.81 (0.71, 1.00)</td>
<td>0.05</td>
</tr>
</tbody>
</table>

### Table 3

<table>
<thead>
<tr>
<th>Variables</th>
<th>Unadjusted OR (95% CI)</th>
<th>Adjusted OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposed group</td>
<td>1.04 (0.80, 1.36)</td>
<td>1.17 (0.81, 1.68)</td>
</tr>
<tr>
<td>Maternal age &lt; 20 y</td>
<td>1.46 (0.93, 2.29)</td>
<td>1.43 (0.77, 2.66)</td>
</tr>
<tr>
<td>20–24</td>
<td>1.44 (1.01, 2.05)</td>
<td>1.27 (0.82, 1.98)</td>
</tr>
<tr>
<td>25–29</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>30–34</td>
<td>1.06 (0.74, 1.52)</td>
<td>1.14 (0.77, 1.70)</td>
</tr>
<tr>
<td>35–40</td>
<td>0.94 (0.48, 1.82)</td>
<td>1.01 (0.47, 2.20)</td>
</tr>
<tr>
<td>Deprivation fifths</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (most deprived)</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>2</td>
<td>0.88 (0.61, 1.27)</td>
<td>0.68 (0.43, 1.07)</td>
</tr>
<tr>
<td>3</td>
<td>0.98 (0.64, 1.50)</td>
<td>0.95 (0.55, 1.66)</td>
</tr>
<tr>
<td>4</td>
<td>1.45 (0.97, 2.17)</td>
<td>1.56 (0.95, 2.54)</td>
</tr>
<tr>
<td>5 (least deprived)</td>
<td>0.97 (0.64, 1.46)</td>
<td>1.10 (0.65, 1.86)</td>
</tr>
<tr>
<td>Using birth control</td>
<td>2.30 (1.38, 3.83)</td>
<td>1.90 (0.96, 3.76)</td>
</tr>
<tr>
<td>Planned pregnancy</td>
<td>0.87 (0.66, 1.16)</td>
<td>1.43 (0.94, 2.18)</td>
</tr>
<tr>
<td>Last type contraception</td>
<td>1.29 (0.99, 1.68)</td>
<td>1.27 (0.90, 1.80)</td>
</tr>
</tbody>
</table>

Values greater than 1.0 indicate higher fertility (shorter TTP).

*Adjusted values were obtained from a multivariate model that included all the variables shown in this table.

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**Fig. 1** Cumulative distribution of time to pregnancy in exposed and unexposed wards.
analysis was therefore conducted in which pregnancies reported as accidental were included in the TTP analysis with an assigned value of zero, which would over-compensate any bias present, thereby providing upper and lower bounds for the magnitude of any association. The findings for the exposed/unexposed comparison were unchanged [adjusted OR 1.20 (95% CI 0.83, 1.73) compared with 1.17 (0.81, 1.68)]. The other findings were similarly robust, including the association with educational level, apart from ‘using birth control’ and ‘planned pregnancy’ which reversed in direction as expected (data available on request).

Discussion

Main finding of this study

The problems of small area studies to characterise risk precisely around a point source hazard are well recognised, and include a small study population, low levels of exposure that are difficult to define, and the possibility of migration reducing the stability of populations. Agencies responsible for protecting the public health need to use the most sensitive measures available to investigate adverse outcomes in communities.

This study showed no difference in TTP between residents of the Rhondda who lived close to the Nant-y-Gwiddon landfill site and those who lived some distance away. Although the power of the study was limited, it was sufficient to show the expected trends with age, previous contraception and educational level, although the confidence intervals included 1.0 after adjustment in the cases of previous contraception and age. The lack of association with living near to the landfill in 1999 provides some reassurance to couples living in the area. A more comprehensive study of risks to mothers living around landfill sites in Wales has shown that increased relative risks of congenital malformations after sites opened had declined to unity in 1998–2000.

What is already known on this topic

The TTP methodology is well established in descriptive studies, e.g. of national differences and of trends, and has also been widely used to study lifestyle behaviours and occupational exposures. However, to our knowledge it has not previously used in the context of environmental studies.

Evidence on the reproductive health effects of landfill sites is still rather limited. This is the first study of biological fertility in the neighbourhood of such a site.

What this study adds

Our experience shows that a pregnancy-based TTP study is readily acceptable in the context of local concern about possible toxic effects from a local landfill site. It is likely that this would be true of other such environmental sources of chemical exposure that could be regarded as potentially toxic, such as an incinerator or an industrial site. This accords with previous experience on the acceptability of TTP studies, but contrasts with the typical situation with factory studies, where experience has not always been so positive.

The negative findings in this study cannot necessarily be extrapolated to other landfill sites, due to the heterogeneity in chemical exposures from such sites. All we can say is that this particular site appears not to affect the biological processes that are measured by TTP, i.e. those leading to conception and to the successful maintenance of early pregnancy.

Limitations of this study

Potential biases need to be considered. The response rate of 83% suggests that response bias is unlikely to be a serious problem when this is the case.

As with any study that finds no association, we have to consider whether this could have been due to methodological shortcomings. The relevant issues are measurement error and statistical power. There is some measurement error associated with retrospective self-reports of TTP, but in this study, the lack of a precise exposure measurement is likely to have been far more important, because distance from a point source is a somewhat crude means of assessing exposure to chemical agents. In addition, the size of the study, with 117 in the exposed and 200 in the unexposed group, means that the statistical power was highly limited. The negative findings therefore need to be treated with some caution.

This study was carried out using a pregnancy-based sample. As previously stated, it is preferable to employ a cross-sectional population sample, and for the questionnaire to include items on infertile phases (unsuccessful attempts). The use of a pregnancy-based method here means that we cannot exclude the possibility that exposures from the landfill site can lead to severe infertility, manifest as inability to conceive, but without affecting the more minor degree of subfertility that TTP is able to measure; however, this appears to be biologically implausible. In the UK context, it would be feasible to carry out a study of this kind with a sampling frame based on age-sex registers in primary care. Such a cross-sectional survey design would allow a TTP study to be combined with other topics if desired.

The age range chosen would depend on which years are relevant to the exposure of concern. It would be possible to enquire about all pregnancies/attempts per couple, which is statistically efficient, or just one (e.g. the first). Only data on
groups and/or that their effect is small at the group level. This makes that they are equally distributed across the exposure participation. Similarly, information on illnesses, shift work and included in TTP surveys, as this would be likely to discourage information. For example, frequency of intercourse is not generally 40. This makes everybody equal at the starting time. If a woman starts trying to conceive at 35 y and only succeeds after 5 y, also analysed at the starting time. For example, if a woman classified as protective.9,34 Time variables, including age, are smoking after several months of trying to conceive, the relatively long TTP value would be associated with the non-smoking value, which could lead to smoking being wrongly classified as protective.9,34 Time variables, including age, are also analysed at the starting time. For example, if a woman starts trying to conceive at 35 y and only succeeds after 5 y, the value of 35 is associated with her TTP value rather than 40. This makes everybody equal at the starting time.

It is not necessary to ask for a great deal of detailed information. For example, frequency of intercourse is not generally included in TTP surveys, as this would be likely to discourage participation. Similarly, information on illnesses, shift work and travel during the TTP interval is omitted. The assumption is made that they are equally distributed across the exposure groups and/or that their effect is small at the group level.

**Conclusion**

Recommendations on the conduct of retrospective TTP studies are listed in Box 1. It is important to recognise that this type of study is unusually prone to bias if appropriate steps are not taken. To reduce the risk of bias, information on accidental pregnancies, and preferably also on unsuccessful attempts, should be regarded as an integral part of data collection and analysis. More detailed discussion of the methodological issues can be found in Joffe et al.,9 which has a suggested core questionnaire.

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**Box 1 Recommendations**

- **External generalisability requires that the study sample is representative of the underlying population.**
- **It is preferable to use a study design including periods of unsuccessful attempts, not only the couples who achieve a pregnancy.**
- **Questionnaire design is important:**
  - the criterion for eligibility of a TTP value is that no contraceptive method was being used;
  - TTP should be measured in months, ungrouped, and should include current pregnancies;
  - infertile phases of at least six months’ duration should be included, so that more complete inferences can be made about the whole population, and also to help avoid medical intervention bias and differential persistence;
  - ongoing attempts should be included, to ensure that the least fertile couples are not excluded and to help avoid truncation bias;
  - covariates should be measured not only for TTP but also for infertile phases and contraceptive failures, so that consistent analyses can be carried out for all three outcomes;
  - time-varying covariates should be measured at the starting time both for TTP and infertile phases, to reduce behaviour change bias.
- **Discrete-time survival analysis can be carried out using grouped-continuous models (for example, a grouped Cox model) or continuation ratio models. The two methods tend to produce qualitatively similar results, but continuation ratio models can be computationally easier to implement.**
- **Sensitivity to the choice of censoring time should be explored.**
- **The analysis should be confined to births, excluding non-birth outcomes such as miscarriages, to avoid bias due to differential recall.**
- **A parallel logistic regression analysis should be carried out using contraceptive failures as the outcome, to check whether the most fertile couples in certain exposure groups are being systematically excluded due to a higher propensity to have accidental pregnancies.**
- **A sensitivity analysis should be carried out that includes contraceptive failures, assigning them a TTP value of zero, to check for sensitivity to planning bias; this will over-compensate any bias that is present.**
Acknowledgments

The authors would like to thank Mrs Caroline Jones and Dr Sharon Hillier for their assistance with this study. The authors would also like to thank the health visitors and midwives in the Rhondda who administered the questionnaire; Mr Nathan Lester, National Public Health Service for Wales, for ascribing the ward codes and Townsend deprivation indices, and Mrs Bridie Sylvester and Mrs Andrea James for secretarial support. This project received funding from Bro Taf Health Authority. They approved the study design but made no amendments to the study design proposed, and had no involvement in the collection, analysis and interpretation of data, in the writing of the report or in the decision to submit the paper for publication.

The authors declare that they have no competing interests.

References


