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Power and sample size considerations for detecting deviations from secular trends in surveillance surveys

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SUMMARY

On-going public health surveillance is essential to the detection and monitoring of epidemics. We present statistical methods for determining the sample size that is required to detect unacceptable deviations from existing secular trends in prevalence with specified power. Between 1958 and 1969, a large study was conducted for providing surveillance of the prevalence of infection for a well-known disease. Data from this study indicated that the prevalence of infection in the mid-1960s increased significantly over previous secular trends among important demographic groups tested. These data are used to illustrate the statistical methods that we propose for detecting departures from existing temporal trends, estimating the year in which the changepoint occurred and specifying sample sizes for on-going active surveillance studies.

Keywords: Active surveillance; Age–period–cohort model; Changepoint; Generalized linear model; Non-central χ^2

1. Introduction

Epidemiologic surveillance is the on-going and systematic collection, analysis and interpretation of health data in the process of describing and monitoring a health event. This information is used in planning, implementing and evaluating public health interventions and programmes. Surveillance data are used both to determine the need for public health action and to assess the effectiveness of programmes (Centers for Disease Control, 1988).

Many of the published guidelines for active surveillance surveys have been concerned primarily with the difficulties in administering screening tests that are used in assessing health status. Statistical specifications for the design of these surveys are customarily simple and rarely linked to the objective of discerning deviations from existing trends in prevalence or incidence. Bleiker *et al.* (1988) provided one example of this type of approach.

The purpose of this paper is to provide statistical methods for specifying sample sizes that achieve the specified power for detecting deviations from existing secular trends estimated from independent cross-sectional surveys that are conducted regularly for conducting active epidemiologic surveillance. Within this context, cohort and period effects receive special scrutiny since a deviation from monotonic declines in prevalence and incidence over time in either effect signals the possibility of a growing public health problem. Surveillance methods based on tracking age, period and cohort (APC) effects have been popular since Frost (1939) employed them in his analysis of tuberculosis mortality rates. Excellent reviews providing a summary of the statistical literature on APC methods are given by Kupper *et al.* (1985) and Holford (1985, 1991). However, there is little guidance in the literature that enables researchers in public health to link the choice of sample sizes directly to the use of these models that are

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tailored for addressing the objective of discerning deviations from existing trends in prevalence.

Marschner (1994) provided methods for determining sample sizes for estimating incidence for a single, one-time survey. These methods are based on Keiding's (1991) models for incidence and prevalence. However, information from data obtained from a one-time survey is not sufficiently rich to distinguish cohort from period effects or period from age effects. Consequently, conclusions from such data must be interpreted carefully. In this regard, these methods are not entirely suitable for *on-going* active epidemiologic surveillance in which data are obtained from independent and serial cross-sectional surveys.

This paper is organized as follows. In Section 2, we sketch a cohort–period model for estimating prevalence. Also, we designate one type of departure from this model that is of particular interest in conducting surveillance. In Section 3, the power function is derived for specifying sample sizes that enable the departures from trends in cohort and period effects to be detected with specified probability. In Section 4, we illustrate our methods by using data from the survey of infection conducted between 1958 and 1969. The paper concludes in Section 5 with a brief discussion of the special statistical difficulties faced by designers of statistical surveillance systems.

2. Changepoint model for infection prevalence

Consider a hypothetical active surveillance programme that consists of serial and independent cross-sectional surveys that are conducted annually. Also, let us assume that people who are in the scope of the survey are within a specified age range. In this case, each annual wave of sampling is restricted to people who belong to specific birth cohorts. We shall assume that equal numbers of people are sampled from each of these birth cohorts in each year of the study. Further, we assume that interest focuses on trends in infection prevalence over the most recent T consecutive years of the surveillance programme. For convenience, we shall denote the years that are under study by $t = 1, \dots, T$ and the set and number of birth cohorts that are in the scope of the survey in year t by \mathcal{C}_t and $n_{\mathcal{C}_t}$ respectively.

Let $m_{t,b}$ denote the number of subjects examined in year t that belong to birth cohort b and let $Y_{t,b}$ denote the number of people among these subjects who are found to be infected. We shall assume that $Y_{t,b}$ has a binomial distribution with mean $m_{t,b}\mu_{t,b}$ where $\mu_{t,b}$ denotes the prevalence of infection among these subjects. Further, we shall assume that $\mu_{t,b}$ is related to linear predictor $\eta_{t,b}$ by the logistic link function.

Clayton and Schiffers (1987a,b) described models that allow the secular trend to be easily modelled as a regression on cohort and period effects. This model includes p - and q -order polynomial effects for cohort and period effects respectively and is given by

$$\eta_{t,b} = X_{t,b}^T \lambda. \quad (1)$$

Here, $X_{t,b} = (1, b, b^2, \dots, b^p, t, t^2, \dots, t^q)^T$ and λ is a vector of regression coefficients that can be interpreted as how the logit of the probability of infection is modified by changes in $X_{t,b}$.

To investigate whether there is a change in the period effect immediately after year \mathcal{T} that deviates from trends existing before year $\mathcal{T} + 1$, let e_t be a binary indicator that defines the time periods following and preceding time \mathcal{T} , i.e.

$$e_t = \begin{cases} 1 & \text{if } t > \mathcal{T}, \\ 0 & \text{otherwise.} \end{cases}$$

Then, a model that accounts for a deviation from existing period trends immediately after year \mathcal{T} is

$$\eta_{t,b} = X_{t,b}^T \lambda + Z_t^T \psi \quad (2)$$

where $Z_t = (e_t, e_t \times t, e_t \times t^2, \dots, e_t \times t^q)^T$ and ψ is a vector of regression coefficients. We shall refer to equation (2) as the ‘changepoint’ model. Zacks (1983) provided a survey of classical and Bayesian statistical approaches to the changepoint problem. Also, Simkin and Downham (1988), Zaidi *et al.* (1989), Stroup *et al.* (1989), Yao (1993), Frisén and De Maré (1991) and Nobre and Stroup (1994) have provided other statistical methods that are tailored for identifying changepoints for passive epidemiologic surveillance studies in which data consist of counts without denominators.

In the next section we give the power function for detecting a deviation from the existing secular trend.

3. Power function for detecting changes in period trend

We wish to investigate the plausibility of a deviation from an existing secular trend by testing the null hypothesis $\psi = \psi_0$. Within this context the null value ψ_0 is usually 0 (denoting no deviation from existing trend) and it is of interest to choose a sample size such that it is possible to detect a specified alternative value of ψ with prescribed probability.

The log-likelihood ratio statistic is given by

$$2\{l_{n\psi}(\hat{\psi}, \hat{\lambda}) - l_{n\psi}(\psi_0, \hat{\lambda}_0)\} = 2\{l_{n\psi}(\hat{\psi}, \hat{\lambda}) - l_{n\psi}(\psi, \lambda)\} - 2\{l_{n\psi}(\psi_0, \hat{\lambda}_0) - l_{n\psi}(\psi_0, \lambda_0^*)\} + 2\{l_{n\psi}(\psi, \lambda) - l_{n\psi}(\psi_0, \lambda_0^*)\} \tag{3}$$

where $l_{n\psi}$ denotes the log-likelihood function based on a sample of size n , and $(\hat{\psi}, \hat{\lambda})$ and $(\psi_0, \hat{\lambda}_0)$ denote the maximum likelihood estimators of (ψ, λ) under the alternative and null hypotheses respectively, and λ_0^* denotes the limiting value of $\hat{\lambda}_0$ as described by Self and Mauritsen (1988). The statistical test for investigating a deviation from an existing trend in the period effect is obtained by comparing the log-likelihood ratio statistic to its asymptotic distribution under the null hypothesis, which is a central χ^2 -distribution with $q + 1$ degrees of freedom.

For a specified alternative value of ψ , say ψ' , the power function of the test may be approximated by a non-central χ^2 -distribution on $q + 1$ degrees of freedom. For statistical models belonging to the class of generalized linear models, Self *et al.* (1992) have provided an approximation to the non-centrality parameter by equating the expected value of a non-central χ^2 random variable to the expected values of lead terms in the asymptotic expansions for each of the three terms on the right-hand side of equation (3).

Let n denote the size of the sample obtained during the T years that are under investigation and let π_t denote the fraction of the sample that is obtained in year t . Also, let λ denote the vector of values of the logistic regression coefficients describing the birth cohort and period effects before year $\mathcal{T} + 1$. Further, let ψ' denote a specified alternative value of ψ . Then,

$$\eta_{t,b} = X_{t,b}^T \lambda + Z_t^T \psi', \tag{4}$$

$$\mu_{t,b} = \exp\{\eta_{t,b}\} / (1 + \exp\{\eta_{t,b}\}) \tag{5}$$

and

$$\theta_{t,b} = \text{logit}\{\mu_{t,b}\} \tag{6}$$

denote the associated values of the linear predictors, prevalences and logits of the prevalences of the alternative model that we would like to detect with designated statistical power. Further, let $\mu_{t,b}^*$ and $\eta_{t,b}^*$ be the fitted mean and linear predictor respectively that are obtained from the logistic regression of $\mu_{t,b}$ on $X_{t,b}$ with prior weight $\pi_t/n_{\mathcal{T},t}$, and let $\theta_{t,b}^* = \text{logit}\{\mu_{t,b}^*\}$. The values $\mu_{t,b}^*$, $\eta_{t,b}^*$ and $\theta_{t,b}^*$ correspond to the limiting values under the null hypothesis $\psi = 0$ discussed by Self and Mauritsen (1988).

4. Surveillance for 1958–69 survey

Tables 1 and 2 list the numbers of people tested and the numbers determined to be infected for each birth cohort sampled between 1958 and 1969.

In Fig. 1 we show a plot of the smoothed secular trends of the prevalence of infection estimated for selected birth cohorts. These smoothed trends are estimated using the change-point model (2) when the polynomial birth and period effects are of the order $p = 1$ and $q = 2$ respectively. Plots for all birth cohorts show that after 1966 (i.e. 1967 and thereafter) the observed prevalence exceeds the expected trend in 20 cases out of 27 (74.1%). This systematic lack of fit is confirmed by a sign test that yields a p -value of 0.006 and lends evidence that the trend in rates after 1966 deviate from the earlier trend. Fig. 2 shows a plot of the scaled deviance (11) from which we infer that a 95% profile confidence interval for the time of the change in trend is between 1963 and 1967. Our findings of increased prevalence in the mid-1960s agree with other independent reports by Hanzel (1967) of outbreaks and increased incidence of the disease experienced in the mid-1960s in the population under study.

A deviance test comparing the null model (1) with the changepoint model (2) incorporating a changepoint after 1966 yields a deviance change of $\chi_3^2 = 33.56$. This test statistic corresponds to a p -value less than 0.001 and provides little evidence in favour of the null hypothesis that there was no deviation in the secular trend of the prevalence of infection after 1966.

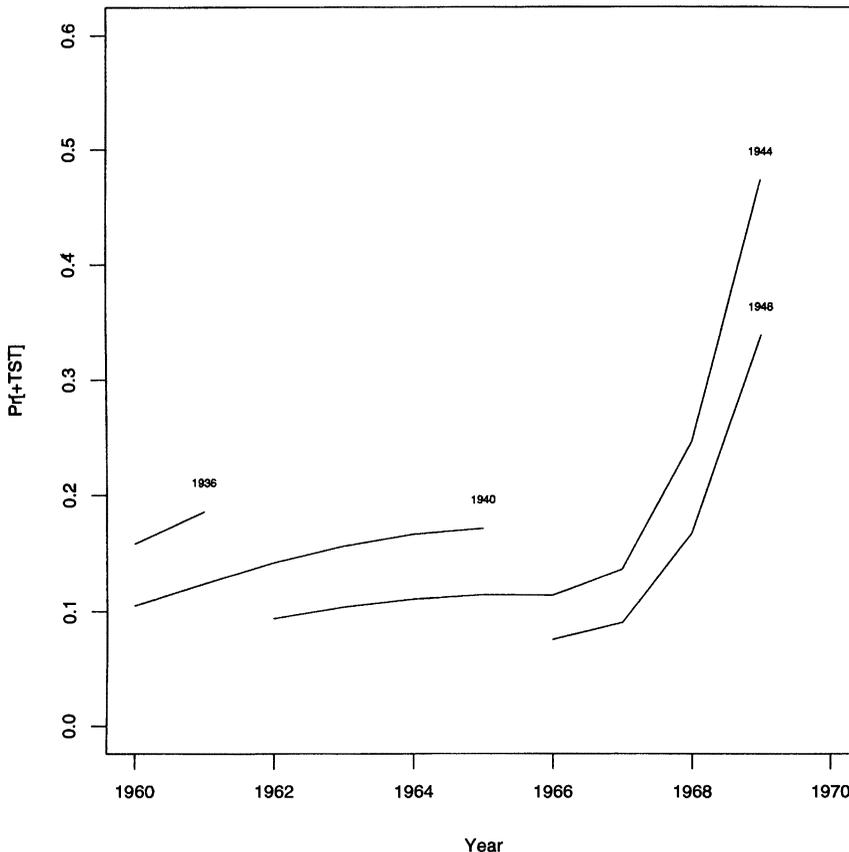


Fig. 1. Smoothed secular trend for selected birth cohorts

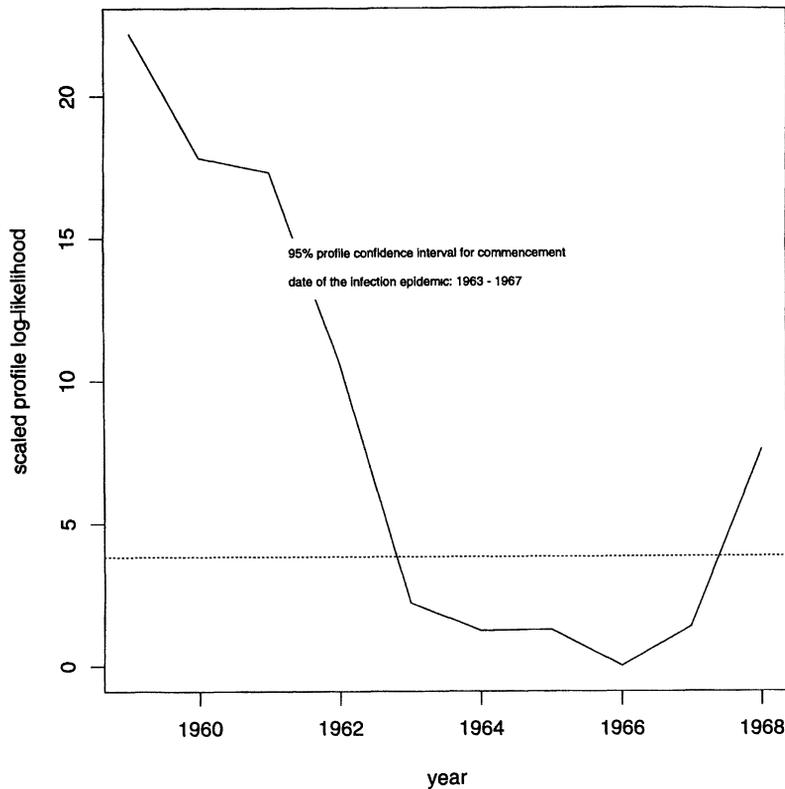


Fig. 2. Scaled deviance for estimation of the date of the start of the epidemic

4.1. Power calculations to detect similar epidemics

To determine the sample size required to detect similar epidemics as we have seen in the 1958–69 survey, we shall assume that annual surveillance is desired in the $T = 10$ years immediately preceding 1969 (i.e. 1960–69) for $n_{\varphi_i} = 8$ birth cohorts with ages between 18 and 25 years each year. In Table 3 we list the estimated logistic regression coefficients for the changepoint model (2) where the birth cohort effect is a linear effect and the period effect is given by an orthogonal polynomial of order $q = 2$. In particular, the logistic parameters for the linear predictor (4) correspond to $\lambda = (2.6, -0.11, 1.6, -2.1)^T$. Also, the null hypothesis is $\psi = 0$ and the sample size that yields the desired power is required to detect the alternative

TABLE 3
Logistic regression estimates for the changepoint model

Effect	Estimate	Standard error	t-statistic
Intercept	2.6	0.3	8.4
Cohort effect b	-0.11	0.007	-16
Period effect t	1.6	2	0.77
Period effect squared, t^2	-2.1	1.4	-1.5
Epoch e	0.049	1.5	0.033
Epoch \times period effect, $e \times t$	6.9	68	0.1
Epoch \times period effect squared, $e \times t^2$	12	22	0.52

$\psi' = (0.049, 6.9, 12)^T$. As illustrated in Fig. 1, this alternative corresponds to a steady increase in the prevalence of infection from approximately 15% between 1960–66 to approximately 40% in 1969, depending on which birth cohort is under consideration.

Using equations (4)–(9) we find that $\Delta = 0.0048$ and $\Xi = 0.99$. Using these values the non-centrality parameter (7) and the power function $1 - \mathcal{D}_{q+1, \gamma_n}(\chi_{q+1, 1-\alpha}^2)$ can be computed for any sample size n .

Fig. 3 shows the resulting power curve and shows that, for size $\alpha = 0.05$ tests, to achieve 0.80 probability of detecting the type of deviation as estimated among subjects in the 1958–69 study would require 23 subjects per birth cohort per year over the 10-year period 1960–69.

5. Discussion

The purpose of this paper is to provide statistical methods for specifying sample sizes tailored for detecting important deviations from existing secular trends in an active public health surveillance system. In particular these sample size specifications are derived from statistical models which are designed to investigate how age, period and cohort effects modify secular trends. Brown *et al.* (1975) described alternative models for testing the constancy of regression relationships over time.

In important related literature, Frisén (1992) described methods for evaluating statistical surveillance systems as they are used continuously over time. Within this context, the rate at which a surveillance system yields a false positive indication of a deviation from acceptable secular trends is called the ‘false alarm’ rate. Because statistical tests in these systems are regularly and repeatedly over time, the overall false alarm rate of the system necessarily

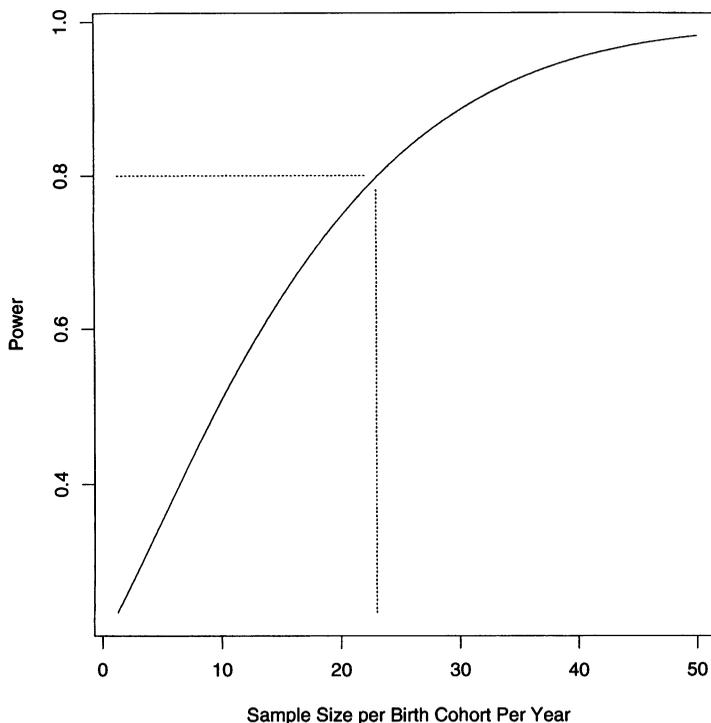


Fig. 3. Power curve for the changepoint model (sample size for 80% power, 23)

exceeds the false alarm rate that would be expected from a single application of the statistical test to assess whether a deviation has occurred.

The decision to declare a significant deviation from existing secular trends is *never* based on purely statistical considerations. However, it seems reasonable to design a surveillance system so that the false alarm rate over a time frame of specified duration is controlled and known with precision. In this regard, the false alarm rate for a single assessment during the time frame can be adjusted downwards using any of a variety of conventional statistical methods so that the specified overall false alarm rate for the larger time frame is attained. The effect of this adjustment is to require larger sample sizes each year to maintain statistical power over the time frame.

The methods described in this paper are based on the assumption that inference regarding a potential deviation in the secular trend is desired over the most recent T years, where T is specified. Also, it is assumed that the objective of the statistical design is to detect a potential deviation that begins immediately after year \mathcal{T} ($1 \leq \mathcal{T} \leq T - 1$) where \mathcal{T} is specified. As we specify \mathcal{T} increasingly closer to $T - 1$ the implication is that we wish to specify a sampling design that is sensitive to more recent changes in the secular trends. In this case, we would naturally expect that the sample size requirements would increase.

As a final note, Self *et al.* (1992) have provided comprehensive simulation studies that indicate that deviance tests based on the sample size derived from using the approximation to the non-centrality parameter (7) of the χ^2 -distribution yield tests with nominal power.

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