Introduction

Estimating harm rates for specific patient populations and detecting significant changes in them over time are essential if patient safety in general practice is to be improved. Clinical record review (CRR) is arguably the most suitable method for these purposes, but the optimal values and combinations of its parameters (such as numbers of records and practices) remain unknown. Our aims were to:

1. Determine and quantify CRR parameters;
2. Assess the precision and power of feasible CRR scenarios; and
3. Quantify the minimum requirements for adequate precision and acceptable power.

Method

We explored precision and power of CRR scenarios using Monte Carlo simulation. A range of parameter values were combined in 864 different CRR scenarios, 1000 random data sets were generated for each, and harm rates were estimated and tested for change over time by fitting a generalised linear model with a Poisson response.

Results

CRR scenarios with ≥100 detected harm incidents had harm rate estimates with acceptable precision. Harm reductions of 20% or ≥50% were detected with adequate power by those CRR scenarios with at least 100 and 500 harm incidents respectively. The number of detected harm incidents was dependent on the baseline harm rate multiplied by the length of time reviewed in each record, number of records reviewed per practice, number of practices who reviewed records and the number of times each record was reviewed.

Discussion

We developed a simple formula to calculate the minimum values of CRR parameters required to achieve adequate precision and acceptable power when monitoring harm rates. Our findings have practical implications for health care decision-makers, leaders and researchers aiming to measure and reduce harm at regional or national level.

![Graph showing relationship between parameters of CRR scenarios and their numbers of detected harm incidents.](image)