Estimation of a lower bound for the cumulative incidence of failure of female tubal sterilisation in NSW: a population-based study.

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PREFACE

I. Note on the Author's Contribution

The author was responsible for all aspects of the study reported in this thesis and for all aspects of the thesis itself, with the exception of address standardisation computer programmes which the author co-wrote with Ms Kim Lim in the late 1990s at then Epidemiology and Health Surveillance Branch in the New South Wales Department of Health. All other computer programming, data processing and analysis was undertaken solely by the author, as was the conception and design of the study and the writing of this work.

This thesis was supervised by Professor Bob Cumming of the School of Public Health, University of Sydney, who provided invaluable advice and many suggestions for the improvement of the study and this document.

Two published, peer-reviewed papers are also submitted as addenda to this thesis. Although they are not directly related to the primary topic of the thesis, they relate to record linkage methodological and privacy issues which arose in the course of work for this thesis. Both were written during the course of the author's candidacy for the degree for which this thesis is submitted. The author's contribution to these papers in indicated in the section titled "Authors' Contributions" on the penultimate page of each paper.

II. Institutional Human Ethics Committee Approvals and Consent

At the time that the author performed the record linkage for this study in 2001 and 2002, approval by an institutional human ethics committee for linkage of an

administrative data set such the one used for this study to itself (internal linkage), for the purposes of research and health services quality assurance, was not required, as specified by the then current Privacy Code of Practice for NSW Health, which was a statutory code of practice pursuant to the *Privacy and Personal Information Protection Act 1998* (NSW). Written permission to make use of administrative data within the confines of the NSW Department of Health for the purposes of this study was obtained in 2001 from Dr Andrew Wilson, who was then the NSW Chief Health Officer and Deputy Director-General, Population Health, of the NSW Department of Health.

This study did not involve any direct or indirect contact or communication with any human or animal subjects – the work involved only the manipulation of data which had already been collected for related purposes. All reasonable steps were successfully taken to ensure the preservation of privacy during the manipulation of these data. Further details are provided in Section 3.2.13 of this work.

III. Acknowledgements

I would like to acknowledge the work of Ms Kim Lim, who has been my valued friend and colleague in the NSW Department of Health for many years and with whom I jointly developed the techniques and general approaches to probabilistic record linkage used in this study.

I would also like to thank Dr Louisa Jorm, Director of Epidemiology and Health Surveillance Branch (later known as the Centre for Epidemiology and Research) for her unstinting encouragement and support.

I am also grateful to my family for their forbearance while this work has been undertaken.

Finally I thank Professor Bob Cumming for his sage advice and patience while supervising this thesis.

ABSTRACT

Female tubal sterilisation, often referred to as "tubal ligation" but more often performed these days using laparoscopically-applied metal clips, remains a popular form of contraception in women who have completed their families. A review of the literature on the incidence of failure of tubal sterilisation found many reports of case-series and small clinic-based studies, but only a few larger studies with good epidemiological designs, most recently the US CREST study conducted during the 1980s and early 1990s. The CREST study reported a conditional (life-table) cumulative incidence of failure of 0.55, 0.84, 1.18 and 1.85
per 100 women at 1, 2, 4 and 10 years of follow-up respectively. The study described here estimated a lower bound for the incidence of tubal sterilisation failure in NSW by probabilistically linking routinely-collected hospital admission records for women undergoing sterilisation surgery to hospital admission records for the same women which were indicative of subsequent conception or which represented censoring events such as hysterectomy or death in hospital. Data for the period July 1992 to June 2000 were used. Kaplan-Meier and proportional-hazards survival analyses were performed on the resulting linked data set. The conditional cumulative incidence per 100 women at 1, 2 4 and 8 years of follow-up was estimated to be 0.74 (95% CI 0.68-0.81), 1.05 (0.97-1.13), 1.33 (1.23-1.42) and 1.51 (1.39-1.62) respectively. Forty percent of failures ended in abortion and 14% presented as ectopic pregnancies. Age, private health insurance status and sterilisation in a smaller hospital were all found to be associated with lower rates of failure. Strong evidence of time-limited excess numbers of failures in women undergoing surgery in particular hospitals was also found. The study demonstrates the feasibility of using linked, routinely-collected health data to evaluate relatively rare, long-term outcomes such as sterilisation failure on a population-wide basis.