A randomized controlled trial of a smoking cessation intervention during pregnancy (RWH 1994-6)

Robin Bell Mary Panjari
Jill Astbury Sue Bishop
Greg Rice Jim Doery

Department of Perinatal Medicine, Royal Women's Hospital
Key Centre for Women's Health, University of Melbourne
Department of Biochemistry, Monash Medical Centre

Where are we now (Victoria)?

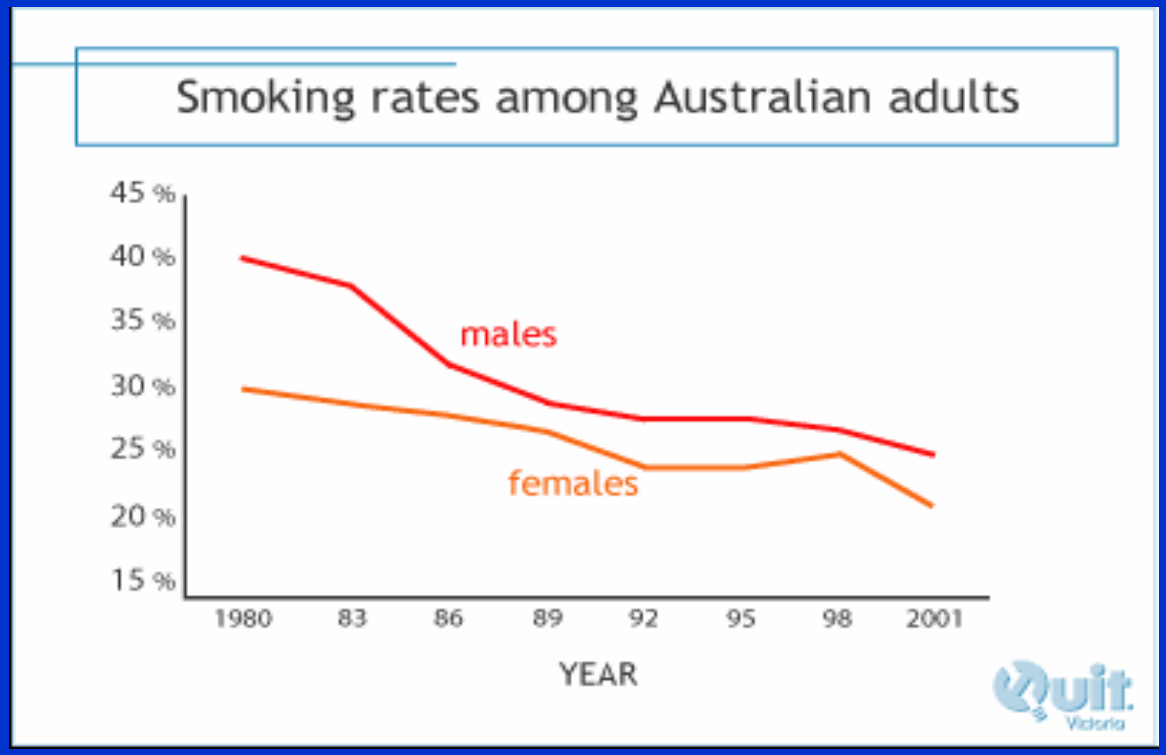
- One of the 10 Victorian Maternity Care performance indicators (number 7) is: the rate of women offered appropriate interventions in relation to smoking
- The average rate of women assessed and offered appropriate advice in relation to smoking behaviour at their first antenatal appointment among reporting hospitals remains high at 96.3 per cent, a slight increase from the 2005-06 rate
- The rate of women who were identified as smokers or recent quitters and were again given appropriate advice in relation to smoking prior to 20 weeks has increased markedly to 82.6 percent

  (DHS website http://www.health.vic.gov.au/maternitycare/progs.htm Dec 2007)

Where are we now (RWH)?

- Smoking room for in-patients is gone
- Smoking is assessed at the booking visit with the question: have you smoked in the last 12 months?
- If the answer to that question is yes then the woman is asked more detailed questions and is followed up again before 20 weeks and again at 30 and 38 weeks
- The woman is asked whether her partner smokes (there is literature directed at fathers who smoke)
- The pregnancy-specific QUIT literature is provided
- There is staff training about smoking in pregnancy (available state-wide) with an emphasis on motivational interviewing (Cate Nagle)

Where are we now?



% of women reporting smoking at first antenatal visit RWH 2007 15.2% (23% 1994)

(Lynn Rigg, Manager, Clinical Practice Improvement Unit RWH April 2008

A randomized controlled trial of a smoking cessation intervention during pregnancy

- Smoking was considered the single most important preventable cause of unfavorable reproductive outcome in first world countries
- In 1995 smoking during pregnancy was estimated to cause:
  - 23% of all LBW, 51% of LBW amongst smokers

  (Quantification of drug caused morbidity and mortality in Australia 1995 National Drug Strategy)
- Preliminary findings established that:
  - 30% of the women attending the RWH ANC were smoking prior to pregnancy
  - 23% of pre-pregnancy smokers reported having quit by the first antenatal visit
  - Of those still smoking at the first antenatal visit, only 7% quit prior to delivery

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- There was evidence at that time that smoking interventions during pregnancy were effective
  (Oxford database of Perinatal Trials 1993: smoking status, mean birth weight, close to showing reduced risk of pre-term delivery)
- Not clear what aspects of a program made it effective (intense, multi-faceted)
- Were programs transposable from one setting to another?
- Needed objective assessment of smoking status (urinary cotinine, UC)

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- Funded by an NHMRC project grant
- Recruitment occurred between 1994-6

- Survey of antenatal clinic staff:
  - Rated smoking as a serious risk to mother and unborn baby
  - Rated quitting as difficult
  - Rated the effect of counseling as moderate
  - Felt their knowledge and skills to deal with smoking were inadequate
  - Rated the time availability to deal with the issue as poor
  - Criticized hospital policy in relation to smoking
    (at that stage there was a designated smoking area for inpatients)

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- We designed an intervention that was as intense as we could afford to deliver, used existing resources (Quit materials) and had the potential to be implemented
- Multi-dimensional
- Delivered outside of the standard antenatal visit

  (more time, standard delivery, variation in staff acceptance)
- Power calculation:

  1200 smokers to detect a difference in mean birth weight (BW) of 90g

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- Booking visit-recruitment and randomization
- Control group received routine care (including the Quit literature)
- Intervention group: 4 counseling sessions
  - Booking visit 25 min including Quit video + literature
  - Follow-up visits at 16-20, 24 and 28 weeks
  - Sessions were personalized, informal and non-judgmental (+/- partner)
  - Strong verbal message to quit
  - Based on facilitating behavioural change: identification of smoking cues, goal setting, the 4 Ds…

Complexity of recruitment

- How to ask whether someone is a smoker
- Started asking women in groups whether they were currently smoking
- Ended up asking women individually:
  Have you had one puff of any cigarette (including someone else's) in the last week?

Complexity of recruitment

9193 new patients

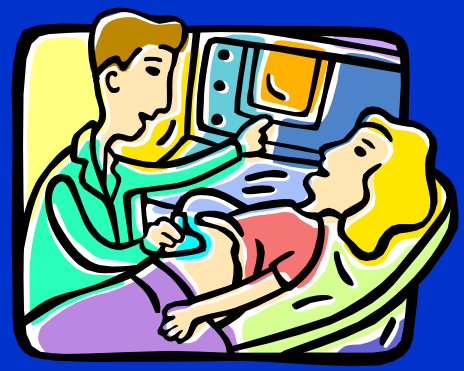
2567 pre-pregnancy smokers

6626 non-smokers

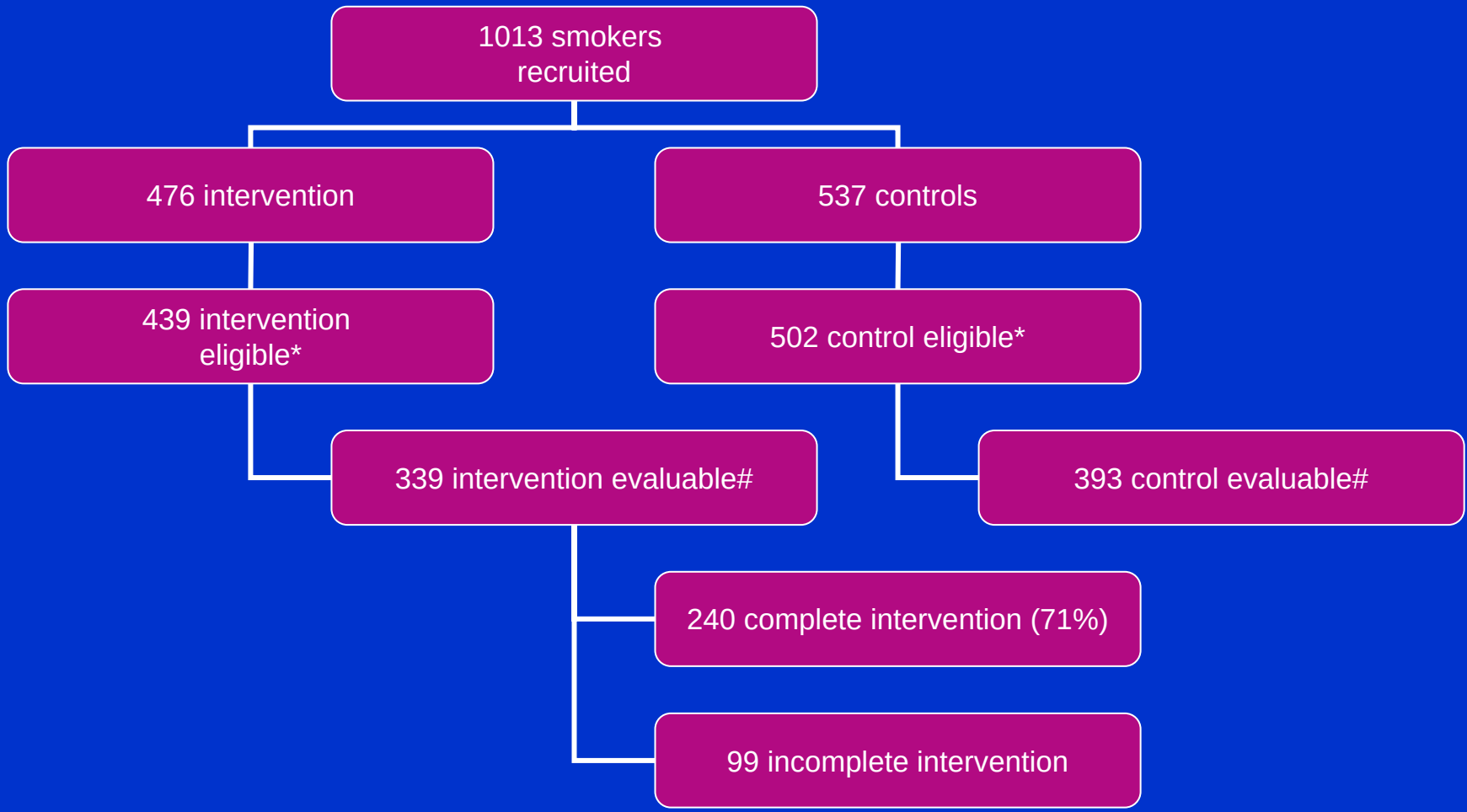
1942 smokers

625 quitters at booking visit

1013 recruited (<1200)



Complexity of the course of the trial



*Ineligible= >20 weeks, twins, transferred to CDU… (8%)

not evaluable (23%) =miscarriage/TOP, transferred to another hospital, withdrew from study, lost to follow-up..

Complexities of the analysis

- Between group comparisons: baseline
  - Groups very similar to each other
    26 years old 12 weeks gestation at recruitment 50% nulliparous
  - Self-declared smoking at baseline comparable
    average of 11 cigs/day for an average of 10 years
  - Urinary cotinines at baseline comparable (910 ng/ml)

- Between and within group comparisons: late pregnancy
  - No change in self-reported smoking in control group (11 cigs/day) but the intervention group reported smoking less (8.7cigs/day)
  - Urinary cotinines were not significantly different (720ng/ml I 769ng/ml C)
  - Both groups showed highly significant reductions in urinary cotinine and the reductions were comparable (~140 ng/ml)
  - Quitters (self-declared cessation + maximum UC level)
    11.9% intervention 9.8% controls (p=0.41)

Clinical outcomes

- Crude difference in mean BW between groups 84g (p=0.04) (3250g I, 3166g C)
- Pre-term birth:
  - intervention 5.3% controls 8.7% (p=0.07)
- 6 weeks post-partum:
  - % not smoking (self-reported): intervention 16% controls 12% (p=0.13)
  - Similar proportions of both groups breast feeding (47%)

Complexities of interpretation

- We did not include booking visit spontaneous quitters
  - Despite this we had a relatively high quit rate amongst controls
  - This “raised the bar” against which to assess the impact of the intervention
- Why the high quit rate amongst controls?
  - Only motivated women agreed to participate?
  - Being in the study acted as an intervention?
- Why was our intervention not more effective?
  - Bar too high to start with?
  - Intervention not sufficiently intense/effective?
  - Too much “noise” in UC measurements?
  - Study underpowered?

Complexities of interpretation

- Difference in mean BW 84g
- Difference in risk of pre-term birth 2.4%

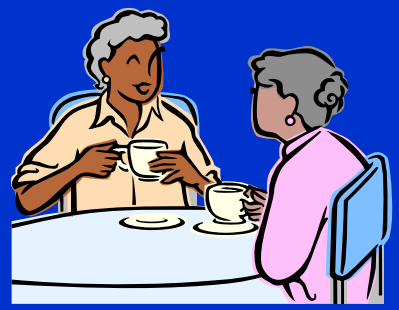
- No difference in UC levels

- Was the cotinine data too crude to measure the impact of the intervention?

  or

- Was the benefit of the intervention not simply mediated by change in smoking?

  (social support) (unlikely)



Complexities of interpretation

Qualitative feedback:

- interviewed women about the intervention
- data not coded
- Some women denied ever seeing the Quit video

Financial analysis (not health economics):

- Defeated by “virtual admissions”
- Change in the hospital financial record system mid-way through the study

Longer term follow-up

- At 6 months we could only contact ~50% of the participants (mobile)

Complexities of reporting

- Report (ANZJOG 1999) was naïve
- Standards in terms of randomisation and allocation concealment were consistent with best practice but we did not report the trial to a standard consistent with its execution
- First version of the CONSORT statement was published in 1996 and revised in 2001

What did we contribute?

- Understanding of the spontaneous quitter
- Data for the meta-analysis
- Contribution to the formulation of KPI and the wording of the questions about smoking
- ?Contribution to the change in “culture” at RWH in relation to smoking in pregnancy
- Funding of an intervention delivered outside the standard antenatal consultation fell down the crack between who would provide the service (obstetrics) and who would benefit (neonatology)

Front cover of the training manual on smoking in pregnancy used state-wide