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## **Can Personal Health Record Booklets Improve Cancer Screening Behaviors?**

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## **Abstract**

**Background:** Despite the widespread use of written health education materials as interventions, relatively few studies had adequately evaluated the effectiveness of such materials at changing health behaviors among the general population.

**Design:** Randomized, controlled trial.

**Setting / Participants:** Ten matched pairs of small, rural towns in New South Wales, Australia, with total populations of approximately 25,000 in each group.

**Intervention:** The Personal Health Record Booklets (PHRBs) included the latest, evidence-based recommendations for reducing risk of cancer and cardiovascular disease and were developed using leading behavior change theories, to maximize their likely impact. They included an explanatory letter, a gender-specific Better Health Booklet and a gender-specific Better Health Diary. They were personally mailed to everyone aged 20 to 60 years (around 12,600 people) in the 10 intervention towns following a media campaign. Family practitioners in the intervention towns were recruited to support and encourage people to use the PHRBs.

**Main Outcome Measures:** Health Insurance Commission data for Pap tests, mammograms and skin operations were obtained for 5 years pre-intervention and 1 year post-intervention.

**Results:** No significant increases in the rates of these procedures were detected in either short or long term follow-ups.

**Conclusions:** While PHRBs may represent an inexpensive, easy to produce and time-efficient method of communicating information to the general population, it appears unlikely that any significant behavioral change will result unless such materials are targeted towards high-risk groups or represent the first intervention for a particular risk factor.

**Keywords:** Neoplasms – Prevention & Control; Cardiovascular Diseases – Prevention & Control; Randomised, Controlled Trials; Intervention Studies.

## INTRODUCTION

Cancer was the leading cause of death in Australia in 1999<sup>1</sup>. Despite knowing the risk factors for many cancers and the availability of screening tests, many Australian adults are still failing to engage in behaviors which result in the prevention or early detection of cancer<sup>2-4</sup>.

Personal Health Record Booklets (PHRBs) represent a potentially cost-effective way to improve preventive and screening behavior rates. From a behavioral change standpoint<sup>5-7</sup>, they provide predisposing and enabling factors in the form of knowledge about desired behaviors and space for recording times and dates of behaviors. As a permanent set of concrete guidelines with the facility for recording behaviors, they may provide an effective method of communicating information about the impact and likelihood of disease and reduce individuals' likelihood of forgetting to comply with recommended behaviors, thereby overcoming many known barriers to preventive practices<sup>2,8-11</sup>.

A review of research on written health education materials published between 1985 and 2000 was undertaken to determine how to maximise the PHRBs' effectiveness. The review revealed 62 studies assessing the effectiveness of such materials<sup>12-73</sup>. However, the validity of many results was questionable, with many studies suffering major methodological limitations: 13 (21%) had no pre-test measures of target behaviors<sup>20,21,34,39,41,43,51,54,61-65</sup>; 20 (32%) used no or inappropriate control groups<sup>13,20,21,37,38,42-44,46,59,61,62,64,66-72</sup>; eight (13%) used non-random sampling or allocating techniques<sup>21,36,46-48,57,58,60</sup>; 19 (31%) used inadequate sample sizes or failed to state them<sup>14,21,22,25,31,35-39,40,47,49-51,54,58,60,72</sup>; and 21 (34%) used only subjective measures<sup>12,15,16,21,30,39,40,42,47-49,53,56,57,58,60,63,64,70,71,73</sup>. Therefore, despite widespread use of written health education materials, relatively few studies existed which had adequately evaluated their effectiveness at changing behavior.

Fourteen methodologically sound studies assessed written health education materials' effectiveness at changing various health behaviors among general populations and high-risk samples<sup>17-19,23,24,26-29,32,33,45,52,55</sup>. They showed mixed results, with nine (60%) finding no significant improvements<sup>17-19,23,24,26,28,29,33</sup>. Generally, studies reporting significant changes used more detailed, comprehensive materials: four out of seven studies employing detailed materials<sup>27,32,45,55</sup> but only one of seven employing briefer materials<sup>52</sup> reported significant behavior changes.

However, these studies still had some limitations. First, only five involved the distribution of written health education materials to the general population<sup>18,28,29,32,33</sup>, of which only one reported a significant behavior change<sup>32</sup>. This study used a detailed information booklet with space for recipients to record their behaviors, whereas the others used briefer pamphlets.

Second, only two reviewed studies provided Australian data<sup>18,28</sup>. Both involved brief interventions aimed at single risk factors and were ineffective at changing the desired behaviors.

Third, no reviewed studies assessed the cost of producing and distributing the materials or their ultimate cost-effectiveness. Given the limited health budget available, cost-effectiveness has become an essential element of intervention evaluation. If the current intervention were found to be a cost-effective method of increasing desired behaviors, the potential would exist to significantly reduce cancer risk factors at a relatively low cost, potentially leading to long-term reductions in health care costs.

Therefore, the potential for the increased effectiveness of detailed written health education materials addressing multiple risk factors and the lack of Australian data regarding the cost-effectiveness of such materials aimed at the general population led to the conclusion that a randomized, controlled trial could provide valuable data in this area. This study evaluated the effectiveness of PHRBs, combined with mass media strategies, at increasing age- and gender-specific cancer preventive and screening behaviors among the general populations of ten intervention towns in comparison to ten matched control towns.

## **METHODS**

### **Study design**

A randomized, controlled trial was undertaken involving 10 matched pairs of rural towns in New South Wales, Australia. Towns were selected as the unit of randomization for several reasons: to test the effectiveness of a community-wide strategy; to allow the use of objective Health Insurance Commission data; and to decrease the likelihood of contamination between intervention and control groups.

### **Town selection**

Towns were eligible if they had: non-metropolitan postcodes; total populations between 1000 and 5000; at least one family practitioner; were more than 20km from another town; and were not currently or imminently involved in similar projects. Using 1986 census data<sup>74</sup>, 41 eligible towns were matched on demographic variables (population density and proportions of residents of Aboriginal or Torres Strait Islander origin, born overseas, in the labor force and unemployed), total population, number of family practitioners and predominant industries. The two towns most closely matched on these variables were then paired. Where a town was similar to an already paired town, the next most similar town was selected to

complete the pair. This process continued until ten pairs were formed. One town in each matched pair was then randomly assigned to the intervention group, with the remaining towns comprising the control group.

## **Intervention**

### **Personal Health Record Booklets**

In April 1993, each adult aged 20 to 60 years inclusive, listed on the electoral registers of intervention towns was personally mailed a PHRB comprising:

- i. **an introductory letter** explaining the need to engage in preventive and screening behaviors related to cancer.
- ii. **"Better Health Booklet"** providing information about the prevalence of cancer and cardiovascular disease, recommendations about preventive, screening and early detection behaviors to reduce the risk of these illnesses and details about where to get further information. Male and female versions were produced with the female version containing information about breast and cervical cancer and each having gender-specific information regarding safe alcohol intakes.
- iii. **"Better Health Diary"** a wallet-sized diary with spaces for recording important health information (eg blood group) and screening events. Male and female versions were produced with the male version omitting the sections on breast and cervical screening.

### **Development of booklets**

#### **i. recommended behaviors**

These were selected based on the burden of illness associated with the corresponding disease, evidence of the efficacy of early detection and the effectiveness of existing screening or preventive behaviors.

**ii. source of recommendations**

The specific recommendations included in the PHRBs (bi-annual Pap tests, annual clinical breast examinations and regular breast and skin self-examinations) were determined using a wide range of evidence-based preventive literature. Where available, Australian guidelines, such as the Australian Cancer Society's guidelines for cancer prevention<sup>75-77</sup>, were used. Where there was no explicit statement of the frequency with which a preventive behavior should be performed, the United States' Preventive Services Task Forces' guidelines<sup>78</sup> were used. Leading behavior change theories and principles (eg: Health Belief and PRECEDE-PROCEED Models<sup>5,7</sup>) were utilized in designing the materials in order to maximize behavior change.

**iii. pilot-testing**

The entire PHRB package was pilot-tested by a convenience sample of 30 laypersons who gave feedback on: whether they would keep and read such materials if mailed to them; factors that would make them more likely to open, read and keep them; which parts they may use later; their opinion on the size, length, number of pictures, amount of information, ease of understanding, sections that were the most and least useful, the perceived message of the package; and their demographic characteristics. Feedback from this process, which is discussed in more detail elsewhere<sup>79</sup>, was used to refine the PHRB package for final distribution. The PHRB was assessed, using Rightwriter<sup>80</sup>, as requiring a reading age equivalent to year seven (12 years of age). This was considered acceptable as 86% of New South Wales' adults met this requirement<sup>81</sup>.

**iv. endorsement by professional bodies**

The NSW Cancer Council and the Royal Australian College of General Practitioners endorsed the final PHRB and agreed for their logos and written endorsements to appear on the materials.



### **Health Care Professional Involvement**

Health care professionals in the intervention towns were sent pre-final drafts of the PHRB, an introductory letter and consent form. All 18 family practitioners consented to support and promote the PHRBs by: allowing their name and practice details to be included in the media campaign as an alternate source for obtaining PHRBs; checking if their patients had received PHRBs; offering copies to patients not receiving one; and actively encouraging their patients to read and use the PHRB. One family practitioner felt unable to check whether his patients had received their PHRBs but consented to support the study in the other ways.

### **Media campaign**

Local media campaigns were conducted in each intervention town 10 days pre-distribution of the PHRBs to raise awareness and maximise the likelihood they would be read and retained. The campaign involved distributing promotional leaflets to every household and large posters to all health, public and social venues. Media releases were published in local newspaper editions immediately pre-distribution. Approximately six weeks post-distribution, a second promotional campaign, consisting of another household leaflet drop and media release, reminded people about the importance of preventive strategies, urged them to use the diaries and provided information on obtaining additional PHRBs. Radio and television campaigns were not possible due to the geographical proximity of many intervention and control towns.

### **Measures**

#### **Process Measures**

##### ***Recall and Use of PHRBs***

A random sample of 136 people from the intervention towns were selected for telephone interviews six weeks post-distribution. Participants were asked if they recalled receiving the

PHRB, if they had kept it, how much of it they had read and whether they had engaged in any recommended behaviors or written anything in the diary.

### ***Family Practitioners' Attitudes towards and support of PHRBs***

In July 1993, the 18 family practitioners in the intervention towns were mailed surveys about their attitudes towards and support of the PHRBs and their patients' use of them.

### **Outcome Measures**

The effectiveness of the PHRBs was assessed in terms of short- and long-term changes in the total number of selected procedures and the number among high-risk groups. Short-term changes were assessed in the first full quarter (June – August 1993) post-distribution of the PHRBs. Long-term changes were assessed in the 12 months post-distribution.

### **Procedure Outcomes**

Health Insurance Commission (HIC) data were used to assess health behavior change as they cover all health procedures conducted under the Australian Medicare Program (approximately 90% of all health procedures)<sup>82,83</sup>, including figures on major behaviors of interest (Pap and mammographic testing; and skin operations, as an indicator of skin examinations). Furthermore, they provide objective measures which are less prone to inaccuracy than self-reported health data, which have been consistently shown to overestimate compliance with recommended preventive and screening<sup>84,85</sup>.

### **High-risk groups**

For Pap testing, the high-risk groups were women not having had a Pap test in the previous two years and women over 49 years. For skin operations, the high-risk group was individuals

over 49 years. These groups were considered at higher risk because they are less well screened or more likely to develop the disease<sup>78,86</sup>. No high-risk groups were explored for mammographic testing as the numbers were too small to allow sub-group analyses.

### **Statistical analyses**

Contingency tables were used to determine the expected number of each health behavior, based on HIC data for the 19 quarters prior to the intervention. Statistical differences in the rates of short- and long-term changes between intervention and control towns were determined by calculating z-statistics for each town pair. One-tailed Wilcoxon signed-ranks tests<sup>87</sup> were conducted to assess whether there were any short- or long-term increases in the total number of procedures and the number of procedures among high-risk groups.

To reduce the possibility of Type I errors occurring, a Bonferroni adjustment of the critical p-value was made<sup>87</sup>. Therefore p-values of 0.0125, or less, were required for results to be considered significant.

## **RESULTS**

### **Subjects**

Towns in the control and intervention groups were similar on matched variables including, demographics, total population, number of family practitioners and predominant industries (see Table 1). In each group, approximately half the subjects were female, 95% were Australian-born and most had not finished high school. Each group had 18 family practitioners in total and agriculture was the predominant industry in both.

[INSERT TABLE 1 APPROXIMATELY HERE]

**Process measures survey****Recall and Use of PHRBs**

Thirty-six (26%) of the 136 recipients could not be contacted due to disconnected telephones (n=17); having moved (n=13); unavailability during the study period (n=5); and death (n=1). Ninety-eight (98%) of the 100 eligible individuals consented to participate. Of these, 75% recalled receiving the PHRBs, with 52% of these having kept both the booklet and diary and 4% having kept the diary only. One third had read at least half the booklet, however, only 12% had completed any of the diary. Overall, 31% of participants freely recalled at least one aspect of the initial media campaign.

**Family Practitioners' Attitudes towards and support of PHRBs**

Twelve (67%) of the 18 family practitioners completed the survey. Of these, 72% had at least flicked through the booklet. Of these, none disagreed with its recommendations and most (58%) thought it would help patients improve their health. However, all encouraged their patients to use the PHRB only if the patient initiated its discussion.

**Outcomes: Short-term changes**

The overall number of Pap tests, mammograms and skin operations was lower than expected in most intervention and control towns in the quarter immediately following the intervention (see Table 2). There were no significant differences in the overall numbers of Pap tests, mammograms and skin operations between intervention and control towns (see Table 2).

Similarly, there were no significant increases in Pap test and skin operation rates among high-risk groups in the intervention group in the post-intervention quarter (see Table 2). The number of Pap tests among high-risk groups was lower than expected in most intervention

and control towns (see Table 2). The observed number of skin operations exceeded the expected number in five intervention towns and four control towns (see Table 2).

[INSERT TABLE 2 APPROXIMATELY HERE]

### **Outcomes: Long term changes**

In the year following the intervention, the number of Pap tests performed exceeded the number expected in five intervention towns and three control towns (see Table 3). More mammograms than expected were observed in seven intervention and four control towns. The number of skin operations performed was greater than expected in less than half of the intervention and control towns (see Table 3). There were no significant increases in the intervention group in the overall number of Pap tests, mammograms and skin operations performed in the post-intervention year (see Table 3).

Pap tests among high-risk groups exceeded the number expected in more intervention than control towns but the number of skin operations performed was greater than expected in more control than intervention towns (see Table 3). There were no significant increases in Pap tests or skin operations among high-risk groups in intervention towns in the post-intervention year (see Table 3).

[INSERT TABLE 3 APPROXIMATELY HERE]

### **Cost-effectiveness of PHRB**

Although of limited interest due to the lack of significant effects, the PHRBs were an inexpensive intervention, costing only AU\$1.47 per person to produce and deliver, in 1995 dollars.

## DISCUSSION

Several limitations of the study should be considered. First, this study assessed the PHRBs' effect on only three behaviors for which objective data were available. Although the other behaviours included in the PHRB (ie: smoking, nutrition and alcohol intake) may have shown significant differences between intervention and control towns, this is considered unlikely given the consistency of the non-significant results of the monitored behaviors.

Second, although Health Insurance Commission data offered the most appropriate measure of change, they are not perfect, excluding up to 10% of medical procedures<sup>82,83</sup>. However, it is unlikely that such procedures would vary systematically or significantly between intervention and control towns.

Third, screening mammograms were not freely available in these rural towns at the time of the study, possibly affecting rates of mammograms in these towns. However, it is unlikely this would have affected women in intervention and control towns significantly differently.

Fourth, the HIC data on Pap tests group both diagnostic and screening Pap tests together, preventing assessment of only the latter. However, as the former have represented only 11% of all Pap tests conducted since differential coding was introduced, this is considered unlikely to have affected the results.

Fifth, the relatively short one year follow-up period could have underestimated the PHRBs' effect. However, this is considered unlikely as rates of each measured behavior showed substantial room for improvement and the intervention's impact was likely to be at its greatest immediately post-distribution.

Lastly, this study was conducted in rural towns fitting specific criteria to allow matching of town pairs. Therefore this study's findings can be generalised to only similar rural towns.

Despite these limitations, the study has a number of strengths. First, any confounding due to contamination between intervention and control groups was reduced by randomising whole towns. Had individuals been randomised, family, friends and neighbours could have been assigned to different groups, increasing the likelihood of confounding. Additionally, family practitioners would have treated people in both groups and using the PHRBs with intervention group patients may have had flow on effects to control group patients.

Second, the study had strong outcome measures, based on objective rather than self-reported health information, which has consistently been shown to be less than accurate<sup>84,85</sup>. Third, based on the review discussed earlier, this study represents the largest, methodologically-sound trial of written health education materials' effect on preventive and screening health behaviors at the general population level. Finally, the intervention's cost was kept at a level that would have enabled implementation of this intervention on a national level, had it proved effective.

Overall, the results indicated that the PHRBs had no significant effect on the recommended preventive and screening behaviors. However, it is worth noting the consistently lower than expected numbers of each procedure across intervention and control towns and among the high-risk groups. As contingency tables are based on the premise that numbers, in this case procedures, increase at the same rate over time, there is no recognition of any plateau in the numbers. If rates of procedures had plateaued, the contingency tables' presumption of a continued increase would explain the overall lower than expected rates observed.

It is important to consider why the PHRBs were ineffective. First, it is unlikely that not receiving the PHRBs can fully explain it as only 5% were returned to sender.

Second, less support than expected received from intervention town family practitioners. Although all signed consent forms agreeing to support the project in a number of ways, their process surveys showed they were providing less support than they had agreed to. Crucially, doctors did not discuss the PHRB with patients unless they initiated the discussion.

Third, this intervention aimed to change health behaviors among the general population. The review discussed earlier showed that interventions aimed at specific populations were more effective at changing behavior. However, given the high number of health recommendations included in the PHRB, it was more appropriate to distribute it to the general population, hoping that the whole-community effect would compensate.

In conclusion then, the authors believe this trial employed all the latest evidence to optimize the PHRBs' success, including: systematically reviewing the relevant literature; formulating recommendations in accordance with national and international guidelines; designing the PHRBs in accordance with leading behaviour change theories; and gaining official endorsements from leading national health bodies. Therefore, the consistently disappointing results should be of concern to other health professionals using such simple strategies. Although written health education materials may represent inexpensive, easy to produce and time-efficient methods of communicating information to the general population, it appears unlikely that any significant behavioral change will result unless the materials are targeted towards high-risk groups, represent the first intervention for a particular risk factor or form part of larger, multi-faceted interventions.



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**Table 1: Overall demographic characteristics of Intervention and Control groups**

Variable	Control Group	Intervention Group
Total population	23,408	24,581
Smallest town population	1,178	1,095
Largest town population	4,618	4,796
% of females <sup>a</sup>	48.8	48.9
% of Aboriginals & Torres Strait Islanders <sup>a</sup>	3.9	5.4
% born in Australia <sup>a</sup>	94.9	95.7
% left school aged $\leq$ 16 years <sup>bc</sup>	70.5	70.6
% with personal income $\leq$ \$22,000 <sup>b</sup>	86.6	86.1
% in the labour force <sup>b</sup>	60.0	61.8
% unemployed <sup>d</sup>	10.4	11.2
% employed in:		
- Agriculture <sup>d</sup>	41.6	41.6
- Community Services <sup>d</sup>	13.3	13.7
- Wholesale/Retail <sup>d</sup>	12.3	12.7
- Other industry <sup>d</sup>	32.3	31.6
Number of Family Practitioners	18	18
Number of Community Health Centres	8	8

<sup>a</sup> The total population represented the denominator for these variables.

<sup>b</sup> The total population aged 15 years or over represented the denominator for these variables.

<sup>c</sup> In Australia, high school education is completed at age 18 years.

<sup>d</sup> The total labour force represented the denominator for these variables.

**Table 2: Post-intervention quarter observed:expected procedure ratios, by town pair, overall and for high-risk groups**

Health Behaviour	Group	Town Pair										T	df	p
		1 <sup>a</sup>	2 <sup>a</sup>	3 <sup>a</sup>	4 <sup>a</sup>	5 <sup>a</sup>	6 <sup>a</sup>	7 <sup>a</sup>	8 <sup>a</sup>	9 <sup>a</sup>	10 <sup>a</sup>			
<b>Overall Town</b>														
Pap tests	I	0.843	0.812	0.772	0.909	0.883	1.629	0.714	0.769	1.047	0.684	11	9	0.958
	C	0.885	1.273	1.012	0.923	0.818	0.833	0.650	0.730	0.758	0.647			
Mammograms	I	0.892	0.423	0.684	1.364	1.118	1.182	1.222	0.563	0.975	1.778	22	9	0.730
	C	1.061	0.833	0.793	1.000	1.300	0.423	0.231	0.706	0.762	1.053			
Skin operations	I	0.861	1.000	0.714	1.280	0.806	1.250	0.500	1.846	1.394	0.440	18	8	0.723
	C	0.970	0.897	1.042	1.000	0.804	0.667	0.486	1.000	0.490	4.571			
<b>High-Risk Groups</b>														
Pap tests (> 49 years)	I	1.200	0.889	0.588	0.857	1.167	3.400	0.800	0.545	1.429	0.643	27	9	0.541
	C	1.000	0.750	0.842	0.333	0.524	0.375	0.421	0.875	0.333	0.400			
Pap tests (unscreened)	I	0.925	1.000	0.864	0.848	1.133	1.737	0.533	0.739	1.391	0.750	19	8	0.682
	C	0.800	1.263	1.071	1.250	0.929	1.000	0.538	0.857	0.588	0.714			
Skin operations (> 49 years)	I	0.892	1.000	0.684	1.500	0.773	1.250	0.625	1.667	1.333	0.615	23.5	8	0.476
	C	0.963	1.118	1.097	1.083	0.875	0.304	0.462	1.111	0.429	0.778			

<sup>a</sup> Value shown =  $\frac{\text{observed number of procedures}}{\text{expected number of procedures}}$

Values > 1 indicate higher than expected and values < 1 indicate lower than expected numbers of procedures

**Table 3: Post-intervention year observed:expected procedure ratios, by town pair, overall and for high-risk groups**

Health Behaviour	Group	Town Pair										T	df	p
		1 <sup>a</sup>	2 <sup>a</sup>	3 <sup>a</sup>	4 <sup>a</sup>	5 <sup>a</sup>	6 <sup>a</sup>	7 <sup>a</sup>	8 <sup>a</sup>	9 <sup>a</sup>	10 <sup>a</sup>			
<b>Overall Town</b>														
Pap tests	I	1.058	0.926	0.736	1.179	0.967	1.055	0.896	1.139	1.081	0.866	27.5	9	0.520
	C	1.019	1.104	0.991	1.220	0.691	0.962	0.973	0.976	0.878	0.844			
Mammograms	I	1.444	0.814	1.089	1.273	1.161	1.029	1.037	1.237	0.816	1.000	30	8	0.203
	C	1.102	0.774	0.992	0.717	1.500	0.744	0.973	0.974	1.097	1.255			
Skin operations	I	0.851	0.906	0.789	1.237	0.842	1.011	0.729	1.015	0.859	0.775	9.5	9	0.970
	C	1.197	0.922	0.799	1.197	0.984	1.109	0.900	0.948	0.860	1.511			
<b>High-Risk Groups</b>														
Pap tests (> 49 years)	I	1.518	0.958	0.724	1.000	1.125	1.400	0.737	1.286	1.317	1.021	38	9	0.154
	C	0.957	1.111	1.119	0.867	0.724	1.476	1.026	0.818	0.861	0.909			
Pap tests (unscreened)	I	1.281	0.967	0.732	1.267	1.192	1.068	0.804	1.273	1.299	0.851	32.5	8	0.130
	C	1.023	1.105	1.239	2.000	0.711	1.375	0.979	1.408	0.895	0.837			
Skin operations (> 49 years)	I	0.863	0.932	0.918	1.246	0.848	0.950	0.719	0.896	0.948	0.811	8	9	0.979
	C	1.236	0.966	0.881	1.133	1.009	0.745	0.943	0.894	0.823	1.708			

<sup>a</sup> Value shown =  $\frac{\text{observed number of procedures}}{\text{expected number of procedures}}$

Values > 1 indicate higher than expected and values < 1 indicate lower than expected numbers of procedures