FOR DEBATE

Cervical screening: time to change the policy

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ABSTRACT

- In 1991, the "organised approach to preventing cancer of the cervix" recommended Pap smears every two years for women aged 18–70 years who have ever been sexually active.
- The two-year interval was a compromise step towards the scientifically supported three-year interval, as many influential groups were strongly attached to annual screening. When other components of the organised approach were in place, the policy was to be reviewed.
- Since the safeguards in the "organised approach" have been proven effective, it is appropriate to change the policy to recommend a three-year interval. Increasing the interval would allow more resources to be allocated to enrolling women currently underscreened and to evaluating and improving the program.
- The age of commencing smears could also be reconsidered to reflect the balance of potential benefits and harm in young women, for whom cancer is very rare but follow-up investigation common.
- If consensus is not reached within the profession, an evidence-based decision may need to be made at the political level.

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IN 1991, Australia adopted a comprehensive "organised approach to preventing cancer of the cervix".[1] The policy introduced the concept of considering cervical screening as a whole program rather than simply a test. The components of the program are shown in Box 1. Currently, the national cervical screening policy is to perform cervical smears on women every two years, starting between the ages of 18 and 20, or within one to two years of starting sexual intercourse, whichever is later.

A series of other activities were established to ensure that every stage of the screening pathway is managed effectively throughout Australia. The Commonwealth Department of Health funded cervical smear registries that could track smear-taking, provide reminders for women and produce quality-control information at each stage of the pathway. Guidelines for reporting smears and for managing women with abnormal smears were established. A variety of national and local publicity campaigns and educational activities have encouraged women to attend and urged doctors to refocus on higher-risk populations — particularly older women, women who have never had a smear previously, and women from underserviced groups.

Australian national policy

Reaching consensus on a national policy was not easy. In 1985 the National Health and Medical Research Council adopted a three-yearly cervical screening policy,[2] but this was largely ignored. Estimates given by the International Agency for Research on Cancer in 1986 suggested that three-yearly screening would prevent about 90.8% of squamous cervical cancer, two-yearly screening 92.5%, and annual screening 93.5%.[3] Thus, in doing two to three times as many smears, with all the burden this entails, the gain in cancers prevented by annual smears is marginal. A consensus development meeting held in 1988 under the auspices of the Australian Cancer Society agreed that the scientific evidence supported three-yearly screening. A major evaluation program on the current state of screening then culminated in a report to the Australian Health Ministers' Advisory Council (AHMAC).[4] The report showed that 55%–65% of women under 50 years had a smear within two years, and these rates were higher among young urban women, but low among older and rural women, including Indigenous and migrant women. More than half the cost of the program went into follow-up services rather than smear-taking and reporting. The AHMAC report suggested that a longer interval between smears, better quality of smears, and greater effort to reach underserved groups would improve the effectiveness of the screening program without increasing costs. However, many gynaecologists, pathologists and a few women's groups were unwilling to accept the recommendation of a three-year interval because of concerns about lack of sensitivity, the quality of smears and their interpretation, and assertions that without reminder services and follow-up such a long interval would be unsafe.

The outcome was that in 1990 a two-year interval was adopted, not by consensus, but by political intervention. It was intended to be temporary, until the full program of quality assurance was in place and fail-safe reminder services were available through State screening cytology registers — a process expected to take about three years. However, establishment of the registers took longer than expected. Indeed, the final one (in Queensland) only came online in 1999.[5] In 1994, an early evaluation of the program recommended that the policy not be changed at that time, but suggested review within five years.[6]

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1: Components of the "organised approach to cervical screening"[1]

- Recruitment of all at-risk women
- Available and acceptable quality smear-taking
- High-quality reporting of Pap smears
- Notification of results to both smear-takers and women
- Appropriate management of women with abnormal smears
- Reminder services for women with normal smears
- Monitoring systems for
  - Quality assurance
  - Feedback on performance for each participating smear-taker and laboratory
  - Monitoring of overall effect of the program

All the planned activities of the national program are now in place, including regular evaluation. Pathology quality assurance is now substantially improved and a uniform reporting system is used. The proportion of women being screened is steadily rising.[5] Most doctors and women now seem to accept the two-year interval, although some laboratories continued to recommend annual smears for many patients until accreditation regulations required them to recommend two-yearly follow-up for all negative smears.[7] Thus, a substantial number of women are still having annual smears.[7,8]

Recent research has shown that the absence of endocervical cells on a smear does not necessarily mean a greater chance of developing cancer and therefore does not require an early repeat smear.[9]

Other national policies

Most countries with national policies recommend a three-year interval between Pap smears (see Box 2). The United States and Germany are now the only countries in which certain government or professional bodies recommend annual smears,[10,14] although the US Preventive Services Task Force and the American Academy of Family Physicians both recommend "at least three-yearly" smears.[12,13] Canada also has varying recommendations. Finland is notable for its five-year interval, which, since its introduction in 1963, has led to a 90% reduction in squamous cervical cancer incidence.[19] Finland's experience shows that, for an effective program, ensuring full population coverage is more important than frequent smears. The United Kingdom, with a 3–5-year interval, launched an organised approach in 1988 with incentives for general practitioners. This has led to a dramatic drop in invasive cancer incidence compared with the previous "unorganised" approach.[20,21] Thus, Australia's current two-year interval is at the "more frequent" end of the policy range relative to other Western countries with effective programs.

Age for commencing screening

The recommended age for starting screening is also variable (Box 2). The American Cancer Society and the American College of Obstetricians and Gynecologists recommend screening all women from age 18, even if they have not commenced sexual activity — a recommendation that must surely be ignored by most doctors. UK guidelines recommend screening from age 20, while the European group

2: Cervical screening polices of various Western countries

Country/organisation	Interval between smears (years)	Starting age (years)	For sexually active women only?	Number of initial annual repeats	Stopping age (years)	Lifetime number of smears
United States:						
American Cancer Society[10,11]						
American College of Obstetricians and Gynecologists[12]	1*	18	No†	3	NS§	50+
American Medical Association[12]						
US Task Force[13]						
American Academy of Family Physicians[12]	At least every 3 years	18	Yes‡	2–3	NS§	19+
American Academy of Preventive Medicine[12]						
Germany[14]	1	>20	NS§	NA¶	NS§	50+
Canada:	2	All ages	Yes	3	70	26
Ontario,[15] British Columbia[16]	3	18	Yes	2	70	19+
Task Force on Preventive Health Care[17]						
Australia[1]	2	18	Yes	0	70	27
New Zealand[18]	3	20	Yes	1	70	17
Belgium, Denmark, France, Italy, Sweden[14]	3	20–30	NS§	0	60–65	13–14
United Kingdom[14]	3 or 5	30	NS§	0	64	10–16
Ireland[14]	5	25	NS§	0	60	8
Finland,[19] The Netherlands[14]	5	30	NS§	0	60	7

*May be up to 3 years by negotiation between a woman and her doctor, after three normal annual smears. †Smears recommended for all women, whether sexually active or not. ‡Smears only recommended for women who have been sexually active. §Not explicitly stated in the references found. ¶Not applicable because of annual smears policy.

recommends "screening should start at the latest before the age of 30 years and definitely not before 20 years".[22]

Starting too early may cause considerable morbidity as a result of the procedures used to investigate false positive results. Over half of a sample of US college women contracted papillomavirus infections in the first few years after commencing sexual activity, but most of these infections resolved spontaneously within a year.[23] One in every 13 smears in women under the age of 25 leads to colposcopy,[24,25] which may result in biopsy and treatment. High-grade cytological abnormalities are diagnosed in about 1.4% of women screened under the age of 25, although the risk of invasive disease at this age is extremely low[5] and the majority of these abnormalities will regress without treatment.[26] While doctors are pleased to find and treat an abnormality, such intervention is only helpful to the small fraction of women whose changes would progress to cancer. Minor abnormalities that come and go are unimportant and can cause unnecessary alarm. While treatment of some papillomavirus infections is useful for symptom control, this does nothing to prevent the incorporation of high-risk wart virus into the genome of cervical cells, or the subsequent development of cancer. It would be better to commence screening after this period of initial viral reactions, as our current understanding is that the malignant process usually takes more than 10 years to develop[24] after infection with specific papillomavirus types.[26,27] The proportion of abnormal smears decreases with age, but abnormalities among older women have a much greater chance of leading to true malignancy.[24]

Objections to policy change

Objections to longer intervals and higher commencement age include the low sensitivity of smears, errors in detection, the possibility of a rapid-onset variant of cancer in young women, clinical presentation of some cancers *after* screening, and the apparent increase in adenocarcinoma.[28]

While one 1995 meta-analysis suggested that a single smear may have a sensitivity as low as 30%–50%,[29] a more recent study has estimated sensitivities in the range 51%–88%.[30] Moreover, the power of the screening program comes from repeated opportunities to screen during the long pre-invasive phase. Even when carefully sought, little evidence can be found for accelerated disease among young women.[26,31] Besides, screening programs only work effectively for chronic, slowly developing diseases — screening for rapidly invasive cases is futile. Any screening program will miss some squamous cell cancers, as a pathology report reflects cell morphology at an arbitrary point in a spectrum of changes and depends greatly on judgement, whether it be by humans or by machines. The theoretical maximum preventive ability is slightly over 90%.[3,30]

Adenocarcinoma of the cervix usually represents only a small proportion of cervical cancers, but Pap smears cannot reliably detect it, so they have little effect on its incidence. As the incidence of invasive squamous cancer decreases, the apparent proportion of adenocarcinomas will increase, as it has done in Finland.[19]

Effect on women of having Pap smears

Having a cervical smear is an uncomfortable procedure, and some women find it embarrassing and demeaning.[32,33] One would therefore expect that women would prefer a less frequent screening interval and fewer smears in their lifetime. In the absence of screening, perhaps at worst only one in 50 Australian women would get cervical cancer over their lifetime, so the 98% who would not get this cancer will never benefit from screening. On the other hand, there are definite risks associated with having a "positive" smear result — over a lifetime, annual smears appear likely to expose 75% of women to having colposcopy.[25] These women are referred for further investigation, and often for biopsy and ablative therapy. While gynaecologists regard these as "minor procedures", women find them unpleasant, and the healing process may take several weeks.[34] There is also a small risk of complications, including cervical stenosis. Some women misunderstand the implications of a positive smear, and may think they have cancer,[35,36] while some develop definite psychological distress.[35-37]

New technologies for taking and reading smears promise greater sensitivity, but their reduced specificity leads to more false positives.[29,30]

As the frequency of smears increases, the benefits (in terms of detection and prevention of cancers) increase only marginally, while costs and potential harm rise substantially.[30] Therefore, reducing the amount of unnecessary treatment by reducing the frequency of smears and starting them at a later age is worthwhile, provided this does not substantially increase the chance of untreatable invasive cancer.

Making change

After 10 years, the time has come to change to a three-year interval, and to start screening at age 25, or several years after sexual activity commences.

Such a change may prove difficult to implement. It will require rethinking the reminder interval for the smear registries, and a certain amount of reprogramming. It would reduce cost,[5] although some claim that economic arguments are not relevant when women's lives are at stake. Even accepting that premiss, greater value per dollar and less chance of harm would be obtained by rediverting energy and funding to currently underserved and high-risk groups of women. Mechanisms to reward practitioners for population screening coverage might require amendment to focus their activity better. Perhaps some of the savings made by increasing the interval between smears could go towards increasing the Medicare rebate for women who have smears at the recommended interval.

Doctors and pathology laboratories who have always been opposed to the two-year interval will have even more difficulty accepting the three-year interval, but this reluctance is largely based on emotion rather than science. Fearing legal censure and citing the *O'Shea* case,[38] some laboratories have been recommending that doctors screen more frequently than two-yearly.[8] However, the court case

in question was about failure to refer for postcoital bleeding and inadequate laboratory standards and is irrelevant for those who follow the screening guidelines. Mandatory performance standards for laboratories, which from 1999 have required that a reminder notice be issued at two-yearly intervals after normal smears, should change the recommended interval to three years.

One might even ask whether it is ethical to recommend more frequent smears without giving full information and obtaining proper consent. Young, educated urban women, who are currently the group most likely to have smears at less than two-yearly intervals, should be informed through publicity campaigns that this is unnecessary and may be harmful. While a woman may request more frequent smears, there is no obligation on the rest of the population to encourage and subsidise this through Medicare.

Clearly, a policy change cannot be made instantaneously, and will require consideration and consultation, but, once again, achieving consensus is unlikely. It may require another political decision!

Competing interests

None declared.

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