Ethics and law

Information provision in cervical screening in Australia

Jane H Williams
BA, MDevStud
PhD Candidate[1]

Stacy M Carter
BAppSci, MPH(Hons), PhD
Associate Professor[1]

Lucie Rychetnik
BSc(Hons), MPH, PhD
Associate Professor[2]

1 Centre for Values, Ethics and the Law in Medicine, University of Sydney, Sydney, NSW.
2 School of Medicine, University of Notre Dame, Sydney, NSW.

jane.h.williams@sydney.edu.au

doi: 10.5694/mja13.10999

Ethically sound clinical practice includes ensuring patient consent for investigations and treatments, including screening. Consent involves a competent individual receiving material information and advice about a procedure or treatment, and making a decision based on that information and her or his preferences and values. Thus, all valid consent is by definition informed consent,[1,2] and communication of material information is an essential prerequisite. What is considered material in the case of cervical screening will vary from woman to woman and will depend on her actual and perceived risk. Arguably, more information should be provided for procedures such as screening that are offered to people who are well.[3]

While recognising the benefits of the Australian cervical screening program, we argue that current arrangements may not provide the material information required for consent.

Summary

- The National Cervical Screening Program and associated state and territory organisations are responsible for promoting cervical screening. Communication via multiple media channels encourages women to be screened. However, some communications are not clear about the risk of cervical cancer and the protective capacity and reliability of the Pap test. The potential harms of screening are rarely presented.
- Women usually receive Pap tests from general practitioners, who often screen opportunistically during appointments. Screening targets and incentive payments encourage high screening rates.
- Consent is an important ethical principle in the delivery of all health care. Provision of material information is one of the elements of valid consent.
- The combination of arguably ambiguous communications, screening participation targets and opportunistic testing under time pressure seems likely to undermine opportunities for women to be informed.
- Of particular concern are women who are less likely to benefit, those who are more likely to experience harm, and some groups of disadvantaged women.
- Improved communications could include providing patients with information on the absolute risk of cervical cancer, and the morbidity and mortality benefits and harms of screening. Screening programs internationally have begun providing such information.
- Areas for further research include the appropriate roles of the programs, screeners and individuals in providing and seeking information. Such work would identify the optimum method for informing women in the screening process.

Cervical screening and cervical cancer in Australia: an overview

Of existing cancer prevention and early detection programs, cervical screening is the least controversial. It has a long history, it appears to be very effective, and Australia has among the lowest incidence of cervical cancer in the world.[4,5] In Australia, women aged 18–70 years are encouraged to screen every 2 years, an intensive program by international standards. The National Cervical Screening Program (NCSP) and each state or territory screening program are expected to inform women of the service and promote it; to be screened requires a clinical intervention, usually involving a general practitioner. In April 2014, the Medical Services Advisory Committee made recommendations for substantial changes to the NCSP, reflecting updated evidence. Subject to agreement from the Australian Government, changes are likely to be brought in from 2016, making now an excellent time to address any relevant ethical tensions.[6]

The absolute risk of a cervical cancer diagnosis is low. In Australia, the incidence among the screening target population is nine per 100 000 women per year, down from 17.4 per 100 000 per year in 1991, when the organised program began. This decline is attributed to the success of the program.[7] The most recently reported Australian mortality rate is two per 100 000 women per year.

A United Kingdom estimate is that 1000 women must be screened once every 5 years for 35 years to avoid one cervical cancer death.[8] Of Australian women in the target population with a cervix, 57% were screened in 2010–2011, with 83% participation over 5 years.[7] Cervical cancer disproportionately affects women of lower socioeconomic status, yet this group is less likely to participate in screening.[7] It is not known how many unscreened women make an informed decision not to screen, or how much non-attendance is due to other factors.

Cervical screening delivers benefits but can also cause harm

There are known risks associated with cancer screening. The benefits outweigh the risk of harm for many people. However, any cancer screening program will harm some people. A possible harm is the detection and treatment of inconsequential disease.[9] Cervical screening detects lesions (dysplasia) on the cervix, which may progress to cervical cancer. Lesions are caused by human papillomavirus (HPV) infection but will not be present in all cases. Most infections and lesions are transient, particularly in younger women. Current screening methods are unable to distinguish between transient and persistent (more dangerous) dysplasia. As a result, screening may lead to treatment for lesions that would have regressed spontaneously. Physical harms of treating cervical lesions can include subsequent cervical incompetence and adverse perinatal outcomes.[10,11] Psychological harms caused by abnormal screening results and associated treatments are well documented.[12] This is not a criticism of Australia's NCSP; the problem is inherent in any cervical screening program, arising from the natural history of the HPV infection. In response, the International Agency for Research on Cancer now recommends against screening women aged under 25 years.[4]

Public communications tend to overstate benefit and understate limitations and harms

Cervical screening programs exist to minimise the burden of cervical cancer in populations. This often translates into an objective of maximising participation. To achieve high uptake in the target population, screening promotion materials are widely used. However, they deliver messages that do not provide complete information about the limitations of screening, especially for younger women who may be at higher risk of harm because of much higher rates of transient HPV infection.[4]

A range of public promotion materials is available from each state or territory program and the NCSP. A summary of how key information was treated in program promotions in 2013 is provided in the Appendix (online at mja.com.au).[7,10,11,13,14]

All programs quantified the benefit of cervical screening using a figure resembling an estimate of relative risk reduction. Studies show that relative risk is not well understood by the general public. If the aim of communication is to assist a woman to understand the likelihood of her individual benefit, relative risk should be avoided in favour of frequency, absolute risk and the numbers needed to screen to avoid one death.[13] A recent ethical assessment of persuasion in the context of health interventions endorsed provision of data, but warned against using misleading statistics, specifically those relating to relative risk.[15]

To be fully informed, women need to understand all the relevant benefits and harms of screening. Yet neither these nor the limitations of the test are addressed in most program materials. For the purposes of a clinical interaction, program communications do not encourage women to seek more or tailored information to assist decision making.

GPs work under conditions not conducive to informing about screening

GPs carry out around 80% of cervical screening in Australia.[16] They are required to provide ethically sound care, which includes patient consent for interventions. However, current conditions do not encourage GPs to ensure that women are sufficiently informed about Pap testing.

The role of a clinician includes offering recommendations based on evidence and experience. The highly sensitive and personal nature of cervical screening means that persuasion to overcome an individual's bias against a procedure, if it is likely to benefit her, is ethically justifiable.[15] However, such persuasion should occur in the context of providing as much information as the woman requires. GPs are expected to maximise the number of eligible women under their care who participate in screening. They have screening targets to meet, and incentive payments are made if they meet them. For some busy GPs, this may be a disincentive to initiate discussions about screening if there is a chance that fuller information may lead women to choose not to be screened.[17,18] (The situation would be quite different, for example, if there were a Medicare item number for discussing cervical screening options rather than an incentive payment for screening.) Informing women is made more difficult by the complexity of screening epidemiology, in which GPs rarely have training.[19,20]

The combination of potentially misleading and persuasive public communications, the complexity of the evidence, screening targets, and the challenge of fitting opportunistic screening into busy family practice appointments seems likely to undermine adequate provision of information. The extent of public material available (far greater than for many conditions that GPs manage) may reduce GPs' perception of the need to inform women at the time of testing. The imperative to screen means that even an adequately informed woman may be labelled noncompliant if she delays or refuses screening, and that her GP may be judged negatively against performance criteria.

Incomplete information is more likely to affect some groups of women than others

Women aged under 25 years are least likely to benefit from screening, due to the very low incidence of cervical cancer in this age group. They are also most likely to experience harm from overtreatment, because of high rates of HPV and higher likelihood of future pregnancies.[4] An increasing proportion of younger women will be vaccinated against HPV, altering both the benefit–risk relationship and their information needs.

Socioeconomically disadvantaged women tend to have lower health literacy (http://www.abs.gov.au/ausstats/abs@.nsf/mf/4233.0), higher rates of cervical cancer and lower screening rates.[7] Additionally, Aboriginal and Torres Strait Islander women bear a disproportionately high burden, with a cervical cancer mortality rate five times higher than the non-Indigenous rate.[7] These groups' particular needs are different because they may be more likely to benefit from screening but may currently screen less than groups with lower incidence. A more tailored approach may help ensure that these groups receive the information they need to consent.

Addressing the ethical tension between population uptake and individual consent

Cervical screening is effective in preventing a proportion of cervical cancers and is of benefit to some women. However, this does not diminish the ethical requirement to communicate sufficient information to support valid consent to medical interventions. We have argued that current circumstances appear likely to undermine this requirement.

Alternatives to a persuasion-style public education campaign have been suggested. Such changes would require a shift in national policy to remove the requirement to increase screening participation in each 2-year cycle. Australia could follow the existing international precedent for encouraging informed decision making about screening.[21] Canadian guidelines propose to include rates of discussion of cervical screening as a program indicator, along with rates of testing.[22] In the UK, the National Health Service explicitly communicates the benefits and limitations of the Pap test: "It is your choice whether to have a cervical screening test or not. This leaflet aims to help you decide".[23] Proposals for screening, such as "consider an offer", provide a framework for policymakers and practitioners to use in letting individuals decide whether they want to make their own decision about screening or whether to hand that decision on to a well informed health care provider.[24] There have been calls for screening information to be provided by a neutral body rather than a screening organisation.[25]

Australians have already advocated for decision making based on more explicit material information and individual values.[9] Such an approach may encourage women to have a conversation about the test with their health care providers, and encourage screeners to seek out sufficient knowledge so they can adequately respond. An emphasis on providing information appropriate to heterogeneous groups and individuals could help ensure that women of limited literacy are informed along with other women with diverse concerns.

Thinking about the ethics of cancer screening means thinking about many dimensions of screening programs. We have only considered the ethical significance of informing. It is in the nature of cervical screening — which is both a population-based program and a personal clinical service — that there may be tensions between the obligations of program managers to meet population objectives and the obligations of clinicians to provide ethically sound care for their patients. It would be difficult to argue that a patient should waive their interests in being informed about a procedure — or a clinician their duty to inform — because this would serve population-based goals. On the population side, there are generally held commitments to honesty in public communication and to ensuring legitimacy of state actions that are relevant to our consideration of how we should communicate about screening. This is not an easy balance to strike, but there would be value in public communications that encourage women to consider screening and to discuss this with their clinicians; and in financial incentives and resources to support GPs discussing screening in detail with their patients, rather than the current incentives focused on participation rates.

The current renewal of the NCSP provides an excellent opportunity to consider such options.

Acknowledgements: We thank Alex Barratt for useful discussions and helpful feedback on an earlier draft of this manuscript. This work was funded by National Health and Medical Research Council (NHMRC) project grant 1023197. Stacy Carter is supported by NHMRC Career Development Fellowship 1032963.

Competing interests: No relevant disclosures.

Provenance: Not commissioned; externally peer reviewed.

1 Beauchamp TL, Childress J. Principles of biomedical ethics. 4th ed. New York: Oxford University Press, 1994.

2 National Health and Medical Research Council. General guidelines for medical practitioners on providing information to patients. Canberra: NHMRC, 2004. https://www.nhmrc.gov.au/guidelines/publications/e57 (accessed Jul 2014).

3 Skene L, Smallwood R. Informed consent: lessons from Australia. *BMJ* 2002; 324: 39-41.

4 International Agency for Research on Cancer. IARC handbooks of cancer prevention. Vol. 10: cervix cancer screening. Lyon: IARC Press, 2005.

5 International Agency for Research on Cancer. GLOBOCAN 2012: estimated cancer incidence, mortality and prevalence worldwide in 2012. http://globocan.iarc.fr/Pages/fact_sheets_cancer.aspx (accessed Jul 2014).

6 Australian Government Department of Health National Cervical Screening Program. National Cervical Screening Program Renewal. http://www.cancerscreening.gov.au/internet/screening/publishing.nsf/Content/ncsp-renewal (accessed Aug 2014).

7 Australian Institute of Health and Welfare. Cervical screening in Australia 2010-2011. Canberra: AIHW, 2013. (AIHW Cat. No. CAN 72; Cancer Series 76.) http://www.aihw.gov.au/publication-detail/?id=60129543402 (accessed Jul 2014).

8 Raffle AE, Alden B, Quinn M, et al. Outcomes of screening to prevent cancer: analysis of cumulative incidence of cervical abnormality and modelling of cases and deaths prevented. *BMJ* 2003; 326: 901.

9 Barratt A, Mannes P, Irwig L, et al. Cancer screening. *J Epidemiol Community Health* 2002; 56: 899-902.

10 Kyrgiou M, Arbyn M, Martin-Hirsch P, Paraskevaidis E. Increased risk of preterm birth after treatment for CIN. *BMJ* 2012; 345: e5847.

11 Arbyn M, Kyrgiou M, Simoens C, et al. Perinatal mortality and other severe adverse pregnancy outcomes associated with treatment of cervical intraepithelial neoplasia: meta-analysis. *BMJ* 2008; 337: a1284.

12 McCaffery KJ, Irwig L, Turner R, et al. Psychosocial outcomes of three triage methods for the management of borderline abnormal cervical smears: an open randomised trial. *BMJ* 2010; 340: b4491.

13 Akl EA, Oxman AD, Herrin J, et al. Framing of health information messages. *Cochrane Database Syst Rev* 2011; (12): CD006777.

14 Sasieni P, Castanon A, Cuzick J. Effectiveness of cervical screening with age: population based case-control study of prospectively recorded data. *BMJ* 2009; 339: b2968.

15 Shaw D, Elger B. Evidence-based persuasion: an ethical imperative. *JAMA* 2013; 309: 1689-1690.

16 Australian Government Department of Health National Cervical Screening Program. Information for health professionals. Canberra: DoH, 2013. http://www.cancerscreening.gov.au/internet/screening/publishing.nsf/Content/professionals (accessed Nov 2013).

17 Powell N. Cervical screening. *Lancet* 2000; 355: 411.

18 Raffle AE. Information about screening – is it to achieve high uptake or to ensure informed choice? *Health Expect* 2001; 4: 92-98.

19 Moyer VA. What we don't know can hurt our patients: physician innumeracy and overuse of screening tests. *Ann Intern Med* 2012; 156: 392-393.

20 Wegwarth O, Schwartz LM, Woloshin S, et al. Do physicians understand cancer screening statistics? A national survey of primary care physicians in the United States. *Ann Intern Med* 2012; 156: 340-349.

21 Stefanek ME. Uninformed compliance or informed choice? A needed shift in our approach to cancer screening. *J Natl Cancer Inst* 2011; 103: 1821-1826.

22 Canadian Task Force on Preventative Health Care, Dickinson J, Tsakonas E, et al. Recommendations on screening for cervical cancer. *CMAJ* 2013; 185: 35-45.

23 Informed Choice about Cancer Screening. NHS cervical screening: helping you decide. London: National Health Service, 2013. http://www.informedchoiceaboutcancerscreening.org/wp-content/uploads/2013/11/FINAL-cervical-screening-helping-you-decide.pdf (accessed Jul 2014).

24 Entwistle VA, Carter SM, Trevena L, et al. Communicating about screening. *BMJ* 2008; 337: a1591.

25 Jørgensen K, Brodersen J, Hartling OJ, et al. Informed choice requires information about both benefits and harms. *J Med Ethics* 2009; 35: 268-269. ☐