Just Another Smear Campaign

by

Dr. Gabriele Medley

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The Chairman of the meeting was Mr. David Brownbill.

Traditionally throughout the ages the medical and legal professions shared a generally similar role in the community. It was essentially a reactive role. We were recruited into people's lives when something was very wrong. Our task was to make things better if possible, preferably not to make things worse. However there was recognition and general acceptance that this may not be possible, that a successful outcome could not be guaranteed.

In the second half of this century there has been a gradual evolution of the role of our professions from this reactive one to a proactive role. In the legal arena this has meant a redefinition from bad luck, *c'est la vie*, Acts of God and so on to attributable fault. In the medical arena it has meant an intrusion into the lives of apparently healthy people by the concepts of disease prevention and everlasting life. In both cases, at least in the developed or Western world, there has been the surreptitious insinuation of the presumed right that we are delivered into the world with an absolute guarantee of good health, good fortune and freedom from disaster. It is popularly not recognised that in the process we have become enmeshed in a complex web of environmental, scientific, intellectual, electronic and mechanical activity which has of itself created a whole new set of hazards that mitigate against this guarantee. In short we have been led to an expectation that cannot possibly be met by performance.

I would like to address two issues. The first of these is the concept of screening for disease. Screening programs are a luxury enjoyed by affluent communities. In Australia they are funded by public money, taxpayers money. There is therefore the expectation that they are cost effective, that is, the cost of having a program is less than the cost of not having it. This imposes certain limitations on such a program. Both the cost and the benefit must be measurable. An increase in cost must yield an appropriate gain in efficacy. This is what we as taxpayers demand of Public Health policy.

The aim of a screening program is to identify those people with a high probability of having the lesion in question, and those people with a high probability of being free of disease. Screening predicts a likelihood of disease which results in triaging into a process of diagnostic testing.

A screening test differs from conventional diagnostic testing in the following ways:

a. It is applied to asymptomatic persons with no sign of disease on examination.

b. Only a single test is used, and in at least the two major programs operating in Australia (i.e. breast and cervical cancer screening) the test is likely to be entirely human dependent

c. The frequency of abnormality is very low, thus in the absence of evidence to the contrary the assumption is that the result will be normal.

In order to fund a screening program, it needs to be shown to fulfil certain criteria.

1. That the disease must be common enough to pose a major community problem.

2. That the biology of the disease is suitable, that is the disease should optimally be characterised by precursor lesions, or less desirably, detectable stigmata of preclinical disease, of which a significant percentage could be expected to evolve into life threatening disease if not detected and treated.

3. That the selected test must be simple and minimally invasive with a high level of community acceptance

4. That detection and treatment of such lesions will prevent morbidity and mortality from the disease

A screening program is made up of a series of steps, sometimes termed the screening cascade.

1. Recruitment of the at risk population.

2. Obtaining an appropriate test sample, for example, a Pap smear in the case of screening for cervical cancer, or a mammogram in the case of screening for breast cancer.

3. Interpreting the sample.

4. Communicating the result of the test.

5. Appropriately managing those individuals who have a non-normal result.

6. Monitoring the program outcomes and feeding the results of such monitoring into policy and planning processes in order to maintain continuous quality improvement of each step in the cascade.

The main problems of screening tests are:

1. The unsatisfactory test:

This means that for some reason the test cannot be interpreted with confidence. This is not a black and white situation. In the example of the Pap smear or the mammogram, in which there is a subjective element in the interpretation of a test sample (which may for a variety of reasons be of quite variable quality), the experience and confidence

of the interpreter is also a variable. If one considers the Pap smear, the rate varies by a factor of ten when examined across all laboratories; in Britain, where the Public Health policy is a three to five year screening interval, the rate of unsatisfactory smears may be up to 10%. This means that one in every ten women who have the test has to have it repeated, with associated anxiety, cost and inconvenience. In Australia where the Public Health policy is for a two year screening interval, the rate is usually below 5%. However this is approximately ten times higher than was considered to be reasonable ten years ago, an important factor when retrospective review of such tests is undertaken.

2. The false positive test:

This means that a test is interpreted as significantly abnormal, resulting in triaging into a process of diagnostic testing which subsequently fails to identify evidence of significant disease. It should be noted that this does not always mean that disease is not present, but at the time of diagnostic testing, a lesion cannot be confirmed. The rate of false positive tests depends on the specificity of the test system. Again, where the interpretation has the subjectivity of a Pap smear, the specificity will vary with the interpreter. A very cautious or nervous interpreter is at risk of having a low specificity, under the impression that it is better to be safe than sorry. The outcome of such a policy is that many will be subjected to the anxiety and discomfort of unnecessary invasive and in rare instances detrimental investigation. Of course there will always be some false positive tests in which a decision is appropriately made that the inability to exclude the possibility of disease mandates investigation which may subsequently identify a benign cause for the findings.

3. The false negative test:

This means that a test is interpreted as normal, and within a defined time (such as in the two years which constitute the recommended screening interval) either clinical or investigational evidence of significant disease is manifested. This may be due to the true absence of abnormality in the test sample; to the failure to detect or correctly interpret the test sample; or to the development of disease within the specified time frame, that is, inherently rapidly progressive disease. The rate of false negative tests depends on the sensitivity of the test system. Once again this is not an absolute or constant when the test is inherently subjective. In the case of the Pap smear, it has been repeatedly demonstrated that the retrospectoscope is a much more sensitive instrument than the microscope. The knowledge of a lesion

which is usually available to the reviewer of a suspect smear will of itself raise the ability to recognise cells that were too few in number or lacked the necessary definition of malignant criteria to be detected during a conventional screening process.

It must be noted that a false negative screening test does not, of necessity, result in a bad outcome since most of the diseases for which programs are in place undergo relatively slow progression, and prevention or early detection can still be achieved if the recommended screening interval for repeat tests is observed.

Thus in summary:

- Screening can only establish the probability that disease is present in an individual and the probability that it is not.
- Screening must balance sensitivity versus specificity.
- Screening in any program must balance safety versus cost.
- Screening cannot give a guarantee.

The second issue I would like to discuss is the impact of litigation on screening services. Although you may expect me to indulge in a litany of disaster, I believe that an increased accountability has developed in our profession over the past decade which some will say is a natural evolution of the concept of quality assurance, but others will claim is as a result of the actual or perceived litigious climate under which we now operate.

I therefore would like to consider both a positive and negative impact of the threat that now envelopes us on the individual steps of the screening cascade. I intend to use as my example the Australian program of screening to prevent cervical squamous cell cancer, using conventional Pap smears. This is a program with proven efficacy and the scenario I am using represents the era of post-1994, following the extensive media publicity surrounding the recent case of Rhonda O'Shea, with which most of you will be familiar.

To obtain a comprehensive view we must understand the effect on women who must be recruited into the program, on those who take Pap smears (usually medical practitioners), on the staff of the laboratory reporting the smear, on the management of the abnormal smear, and finally on those who make policy and allocate resources to the program.

1. The recruitment process

Those women who are well screened become anxious that they also may be the recipients of a false negative report. As a result they present for early repeat smears, and in some cases they are driven

to visit multiple practitioners in order to reassure themselves with three monthly or six monthly tests. Apart from the psychological harm caused, this behaviour seriously overloads a system dependent on highly trained and scarce specialised staff, risking compromise of quality with little or no benefit on the burden of disease.

Those women who are unscreened grasp the adverse and often exaggerated and highly sensationalised publicity to reinforce their reluctance to have the test. They remain unscreened and form a continuing pool of invasive or potentially invasive disease.

On the other hand the upside of the process is that a few responsible journalists use the opportunity to present a balanced view in which the real limitations of the program are identified side by side with the real benefits, and women are encouraged to participate and to have realistic expectations of what can be delivered. Perhaps also at least some women have become proactive in relation to taking responsibility for presenting for tests, and ensuring that they receive a report, rather than relying on others to initiate both these steps.

2. The practitioners who take smears

Some opt out of the process and simply send women elsewhere. Others communicate their anxiety by encouraging early and frequent repeat smears. The fear of not taking a satisfactory smear leads to unnecessarily vigorous smear taking resulting in thick, difficult to interpret samples. Exaggerated and opportunistic claims about the reduction in false negative smears offered by new technologies and adjunct tests lead to overuse of such tests often at high cost, and once again encourage an unrealistic expectation that there is now a guarantee of accuracy. An overcautious response to reports of intrinsically benign changes results in recommendation for further investigation and a consequent perception of a surge of false positive tests. Once again it's better to be safe than sorry.

On the other hand it must be conceded that there has been an increasing awareness by educational bodies that are responsible for training health care professionals that increased efforts are necessary in this matter. As a result educational packages have been developed, addressing the need to recruit women, the need for care in sampling, the need to put in place fail-safe methods of ensuring that women receive the results of their tests, and the desirability of Registers to have in place recall initiatives as a safety net for women who are overdue for screening.

3. The laboratories that report smears

As a result of media exposure that the process is seriously flawed, with extraordinary emphasis on the failures and a reluctance to report good news, there is a loss of self worth of those professionals whose task is the extremely difficult business of reporting Pap smears. There is a drop out of some, leaving fewer to cope with an abnormally high load. Fear of missing the hard to see cell which will subsequently be found with the retrospectoscope, results in perseveration, over-reporting of non-significant changes, and an increase in false positive reporting. There may be inappropriate enthusiasm for new expensive adjunctive technologies which may offer very small incremental gain in laboratories reporting at the level of world's best practice. It is very difficult for anyone not in the field to understand the inherent problems in a rather subjective assessment process. It is easy to denigrate the technology, forgetting that over the past 50 years it has resulted in an extraordinary reduction in death from cervical cancer in screened communities whilst in underdeveloped unscreened countries this disease is the highest cause of cancer death in women.

There has also been a change in the culture of relationships between the professionals who report tests. The co-operation previously enjoyed between laboratories, including referral for opinion in difficult cases, and sharing of information, is no longer the rule. The concept of the expert witness, with strong division into defendants and plaintiffs camps, has resulted in an atmosphere of suspicion and paranoia which has the potential to prevent previously achievable constructive dialogue.

On the positive side there is now an increasing incentive to employ well-trained staff and to implement continuing educational activities within laboratories. Quality assurance processes are recognised to be an essential, not a luxury optional part of the reporting process. Mandatory participation in external quality assurance programs and implementation of the Performance Standards for Australian Laboratories Reporting Cervical Cytology are integral to laboratory accreditation. There is also a commitment to develop an acceptable process of medicolegal retrospective review of smears that is at least comparable with the routine screening process, unlike the completely artificial and farcical process currently practiced.

4. Management of abnormal smears

Once again fear has resulted in a significant increase in the number of

women who undergo expensive and anxiety inducing investigation for cytological changes which are in no way threatening to life. This results in dilution of resources so that in some instances women who may be under genuine threat could have access to services delayed. There may be a tendency to divert the beneficial and appropriate communication strategies traditional between women who develop cancer and their physicians, due to nervousness about possible self-incrimination, and there is a tendency for women to perceive blame if they have not availed themselves of screening opportunities. The natural anger which may attend the bad outcome of a diagnostic process can be easily diverted into a pathway of seeking legal redress for a perceived negligent event, often on insufficient or no evidence, with delay in the healing process and eventual devastating disappointment.

On the positive side there has been an increasing awareness of the need for meticulous follow up of abnormalities, and an increased willingness by clinicians to participate in laboratories' correlation quality control activities which are an integral part of the continuous quality improvement circuit for those reporting smears.

5. Policy makers and program resourcing bodies

The worst-case scenario would be that the many additions and embellishments of the program, including the payouts from litigation and the escalating costs of medical indemnity, which may gradually be perceived as necessary to its success, will make it completely unaffordable. A successful screening program is inherently "suicidal". The mortality from cervical squamous cell cancer has significantly fallen, and, because of the lag time inherent in such statistics, will continue to fall as a result of the improvements in the program over the past ten years. Thus the importance of the disease as a significant community problem will be perceived to have decreased, and the expense of the program seen as difficult to justify.

The outcome of reduced vigilance will not become immediately apparent, again because of the lag time in mortality statistics, and by the time the Australian statistics start to resemble those of other unscreened populations, it will be too late to retrieve the situation.

The positive side in which we assume that there will be funding for all those initiatives I have detailed above is a little bit optimistic in these cost cutting days. The increasing number of competing health initiatives may well mitigate against the commitment to this program that characterised the early nineties, when comparatively

small investment yielded disproportionate gains due to removal of the relatively simple defects. Now when the residual problems are the hard ones and the incremental improvement is small there is a risk of abandonment.

I have no ready solutions to the problems I have posed. However I would like to see education to encourage realistic expectation of screening programs; setting and monitoring standards of care that can be documented and are accepted by the public, the medical profession and the legal profession; legislation that protects those that maintain these standards, and imposes meaningful sanctions on those that do not; and community structures to ensure that sick people receive appropriate medical and socio-economic support.

In conclusion I would also like to see a bridge across the divide between our professions. Although we are as foreign to each other in some of our behaviour as if we were from different planets, our common avowed goal is to improve the welfare of those we serve, and thus it should not be impossible to find territory that we can jointly occupy in a productive and comfortable, rather than inherently adversarial relationship. I would like to end on a note of optimism that perhaps by being informed we will have taken the first steps towards this goal.