

## **The operation was a success, but the patient died: Treating numbers may be a health hazard**

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*In modern health care, we are often prevented by the glow of the success of an operation from asking the fundamental question, Did the patient live? A campaign in Sydney, for example, successfully achieved a significant increase in the number of Pap smears being carried out. However, a closer look revealed that there had been no commensurate increase in detected abnormalities: the community did not better survive. How can medicine be made more responsive to the question of outcome? Some ideas for health outcome initiatives are presented.*

When I was a medical student, I had a professor in biochemistry who told us that it was the principle at the nearby teaching hospital that no patient was allowed to die unless in electrolyte and acid-base balance. At that stage in my career, as it does now, this seemed bizarre, a bit like the elaborate cosmetic rituals which some people extend to their recently deceased relatives before burial.

The first chapter of CHRISTIAN BARNARD's new autobiographic book *Second Life* describes his feelings when his first cardiac transplant patient, Washansky, in 1967 died of lung infection. The operation had been a success, but the patient had died. We can understand how BARNARD felt - but nevertheless the patient died. I have chosen the title of this paper to provoke your interest in the relationship between what we do as clinicians and its effect on the health status of our patients.

Of course none of us ignores this question, but our activities sometimes dominate our horizons and we lose sight of where we are heading. Busily providing a clinical service, or undertaking a certain diagnostic procedure, the question as to whether it contributes to the improvement of our patients' health gets lost.

D.A. HENDERSON from *Johns Hopkins University* in Baltimore gives an interesting example of how, if we do not look at what we are achieving in terms of improvements in health, we can make some terrible mistakes. He described recently how the global immunisation program, which was put in place over a decade ago, operated for 12 years before any evaluation of its efficacy was made. While we may have taken for granted that immunisation would confer tremendous

benefits and does no harm, and may well do some good, we need evaluation to make quite sure the outcomes are what we hoped for.

HENDERSON describes how in Latin America not long ago, an investigation was made into the success of trivalent immunisation against polio. Rather to everyone's astonishment, what was found was that there was a remarkably high incidence rate for *Type III polio* among children. Further investigation revealed that the level of Type III immunity was much less than predicted and that the vaccine which worked well in temperate climates was only assuring about 40% immunity in its current dosage. By increasing the dose, immunity levels of 80% were achieved and cases of Type III polio decreased. The message here is obvious: It is valuable to look at the outcome as well as the process to make sure that not only is the operation a success, but also that the patient is alive.

The principle applies just as powerfully in the high technology world of the teaching hospital. Recently I was speaking to a clinician in the hospital where I work about older patients whom he treats for cardiac failure. His answer (and he is a very good clinician) went something like this:

Well, I see patients come in here with heart failure and we treat them with the latest drugs and they go out and then often they come back and maybe come back a third time and then they just disappear. I don't really know what happens to them: maybe they get better, maybe they die. All I know is that they don't come back.

The doctor who made this comment is an excellent, experienced clinician. There are many others who would not recognise there was a problem, and would not ask the question about what became of the people they treated. Instead they would see their duty purely in terms of getting a pair of ventricles beating strongly again and clearing the hospital bed.

And the system of health care in Australia is such, not unlike that in most other Western countries, that it asks no questions of the clinicians as to how much

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<b>Performance indicators</b>
- average length of stay
- throughput
- cost per bed per day
- productivity savings through improved structural efficiency
- greater technical efficiency

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*Tab. 1: The hospital system in NSW-Performance indicators*

they improve the health status of their patients. Instead, the health-care financiers in my country (principally the state and federal government) stand or fall on the success with which they manage financial budgets and waiting lists and other measures of activity (see *Tab. 1*). They are not voted in or out of office according to their achievements in improving health status.

How have we come to this position in modern medicine where the activity of the system has come to dominate thinking and auditing? This is a question that only a sociologist could answer, and I do not propose to pursue it much further here. It is true that assessing the impact of what we do on the lives of our patients may sometimes not be an easy task, especially when the improvements are beyond the easy reach of conventional quantitative measures of improved life expectancy, improved quality of life and improved patient satisfaction. But we often do less than we might reasonably expect in terms of measuring outcomes. Most of our quality assurance procedures focus on the process of what we do rather than on what comes out of our efforts.

The difficulty that this leads us into is that, while we concern ourselves with the process or even half-way signposts to success, from time to time it can mislead us into concluding that our efforts are efficacious when in fact they are not. In other words, we can be misled by the success of the operation, and prevented by the glow of that success from asking the fundamental question, Did the patient live?

I want to use an example to illustrate this simple point. It comes from Australia where in 1988 a concerted public campaign was mounted in my state to encourage older women to have a Pap smear. Let me call the intervention *Operation Pap Smear* - or *The Operation* for short.

There was concern felt by gynaecologists and women who were health workers in Sydney worried about women's health that especially many older women had not availed themselves of Pap smears, available either free through Family Planning Clinics, or through their general practitioner. In Australia where we have universal health insurance, having a Pap smear done at their GP's office doesn't cost the patient much, but there are many reasons why perhaps 20 - 40% of women, depending on their socioeconomic and educational standards, may not have had a Pap smear done.

I work in *western Sydney* which is an area with 1,5 million people for the most part living suburban lives. It spreads west rather like *Los Angeles* and covers a wide coastal plain. Western Sydney is less affluent than eastern Sydney. It is the dormitory area for much of central Sydney. In the western Sydney area, which is also highly multiracial I might add, perhaps 40% of women who should have

had a Pap smear do not appear to have had one. There are difficulties in the way in which records are kept about who has Pap smears in Australia and so drawing this conclusion is not entirely secure. There are many reasons why women do not seek to have a Pap smear done. But there would be few medical people who would argue with the idea that a publicity campaign designed to improve the uptake of Pap smears among older women would not make good sense. So in February to May 1988 there was an extensive advertising campaign to encourage women to have a Pap smear.

What did it achieve? The first thing it achieved was a significant increase in the number of Pap smears being carried out. This was documented by my colleagues

lab	Pre campaign		Post campaign		odds ratio	95 % CI
	No of Pap smears 2/85 - 5/88	% abnormal	No of Pap smears 2/88 - 5/88	% abnormal		
1	29 000	0.85	5 200	0.56	0.66	0.44-0.98
2	19 400	8.20*	4 200	6.92	0.84	0.74-0.96
1 + 2					0.82	0.73-0.9

\*includes minor atypia

*Tab. 2: Effect of health education campaign on the percentage of Pap smears reported as abnormal by two laboratories*

LES IRWIG *and others* and reported in a letter to the *Medical Journal of Australia* (see *Tab. 2*). If you had been satisfied with intermediate markers of success you might have felt this was extremely gratifying news. But IRWIG *and his colleagues* went one step further. They sought evidence from two major laboratories that read Pap smears that there had been a commensurate increase in detected abnormalities. There had not. Indeed, they conclude that there appears to have been a decrease in the rate of detected abnormalities that almost equals the increase in screening activity.

What explanation lies behind this observation I do not know, but it gives little comfort to those who funded the advertising campaign, if it indeed was the agent responsible for the increase in screening activity (which they were happy enough to claim until IRWIG's findings came out). The same number of cases were being detected before as after. A further analysis of the severity of the detected abnormalities showed that these had not changed either. All that activity therefore cannot have had any real health gain.

*The operation was a success*, but the patient, in this case the community, was not dead, but was none the better for it. The costs associated with this increase of screening activity and the advertising came out of someone's pocket and was not available for something else as a result. So someone lost out as a result: perhaps someone even missed out on some lifesaving procedure. A patient - someone, somewhere - may have died even though *Operation Pap Smear* was judged to be a success.

Let us think about this example a little further and relate it to some of the things that are covered in other parts of this book. Had the results that IRWIG *and his colleagues* found been different, there may still have been questions to ask about the value of *Operation Pap Smear*. The most important of those is the one, To what extent does finding abnormalities by means of a Pap smear improve the health of the recipients? It may sound odd to ask this question, given that the conventional view is so firmly of the opinion that the benefits of Pap screening outweigh the negative side, but it is a reasonable question to ask, if only in that it sends us to the medical literature in search of evidence. Others are dealing with this aspect of screening more fully in other contributions in this book. The point I want to make here is that unless there is solid evidence that detecting abnormalities on Pap smears improves the quality and quantity of life enjoyed by those who have the lesions detected, then it cannot be said that anything has been gained.

Let us think of another scenario. In this one there are more abnormalities detected as a result of *Operation Pap Smear*, but they are at the minor end of the spectrum. Women with such abnormalities detected will enter the medical system and be turned from ordinary people into patients - they will have colposcopy and laser treatment and observation and so forth. This disturbance to their lives will be considered worthwhile if there are real health gains that follow. How sure are we about that? Their survival may appear to be longer, but that may be simply because they have had their lesions detected earlier than they would have been without *Operation Pap Smear* (see Fig. 1).

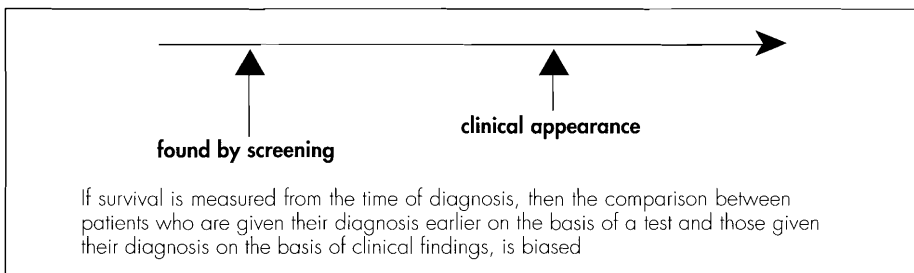


Fig. 1: Screening and lead-time bias

Thus, as we can see from this relatively simple example, an operation may be judged a success, but people may die or have their quality of life compromised as a result. We can summarise the points thus:

1. Before promoting more of a preventive or therapeutic intervention among people who may not otherwise have used it, we need to assure ourselves of the evidence of benefit and consider its cost.
2. It is possible to produce an increase in activity (in this case women seeking a Pap smear) without doing anything to improve health outcomes.
3. Screening, which converts ordinary persons into patients if they are positive, carries a cost and this must be considered.

The question of success has still other aspects to it that we would do well to consider. Other contributions in this book will consider the risks and benefits of other preventive procedures. But let us look at several questions that one would need to answer to satisfy oneself about a screening test such as the Pap smear test.

As has been pointed out recently by BLACK and WELCH, the ability of a screening test to find disease is directly proportional to the frequency of that condition in the community. That is obvious. What is less obvious is that if the condition that one is screening for is mild, and not serious, then it is likely to be more common (because of itself it doesn't kill people) and unrecognised (because mild conditions don't present for diagnosis). But as BLACK and WELCH point out, this means that the milder and less disease-like the condition is, the more likely you are to find it on screening, but that such conditions have a variable natural history and may not carry any serious prognosis. This is referred to as *disease state bias*.

Now all that I have said so far is hardly surprising. Taking care to determine the likely consequences of our medical actions, be they therapeutic or preventive, is hardly the stuff of a social revolution. However, it is not as common as one might expect in the health care system. In New South Wales, where I work, the focus of the attention of the system is on activity. I have referred already to its concern with bed days and throughput. With some recent initiatives calling the attention of the system to *health outcomes* many people are realising just how far the system has drifted from its primary objects. Such drift is not easily arrested and poses a very significant challenge to managers in the system.

I obviously do not know how you, as a reader of this book, are convinced about the necessity for appraising critically what we do in terms of what it achieves. I assume that you would not be reading this if these ideas had no appeal to you. So let me guess that you are already on my side. The question that you and

I both face, then, and one that I hope we will not resile from in this conference is, How do we make the system more responsive to this approach? There is not much use in spending our time here congratulating ourselves on how clever our insights are, how superior we are to all those foolish people out there who are concerned only with process and not with assessing outcome. That will get us nowhere. If we believe that by concentrating on the success of the operation patients die, then we have an ethical obligation to change the system that perpetuates that approach. How can we proceed? This is a complex question and you would need me to be a professional manager, which I'm not, to answer it. But I have some ideas, born of my own experience as a medical educator and as someone working within a health bureaucracy to some extent.

First, we need to be willing to educate others in the language that we use to assess health outcomes. In this book you will meet terms like sensitivity, specificity, positive and negative predictive value and so forth which are essential if we are to progress the ideas of measuring real health gains and outcomes from procedures. But these are difficult ideas and need to be communicated. We must each become apostles of the new language and enlighten colleagues, students, friends and administrators with our enthusiasm for this new way of thinking. We need to enlist people to our cause.

Second, we need to argue for resources to establish demonstration projects that will enable people to gain practical insights into what is needed to measure the outcomes of our actions. In NSW we have fifteen such projects under way at present. None are big deals but each will change the culture slightly in the direction of greater interest in outcomes.

Third, we need to take into account other initiatives such as total quality management and quality assurance and turn these to our advantage, building into these efforts, which often concentrate on process, questions about outcome. In these ways it seems to me we can proceed down a new pathway that is more likely to benefit our patients than the one that concerns itself only with the processes that end at the hospital door. True, important questions can be asked within this environment and many randomised controlled trials have been done in that setting. But as the hospital walls begin to tumble as day-only surgery and other procedures gain in momentum, this artificiality becomes less and less tolerable. It is time for us to ask and keep on asking, What is this achieving? Is it the best use of the scarce resources we have to improve the health of individuals and the community? It is time for us to ask, when people say to us that the operation was a success, But did the patient survive? Was the quality of his life enhanced?

*The operation was a success, but the patient died*

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*Further reading*

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