

The business man and the laboratory: standards guarantee profits

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I wish to thank the Malaysian Society of Pathologists for the invitation to attend this meeting, and the opportunity it has given me, as newly elected President of the Royal College of Pathologists of Australasia to meet with you and to share at first hand, what problems we are facing in Australia and New Zealand and to learn from you what is happening with Pathology in Malaysia.

I am not a business man. When I was appointed an Associate Professor I was told by a colleague, that meant I could associate with Professors. Perhaps I could say that I am an associate of business people involved with the management committee of our laboratory.

Though I am not yet aware of the problem first hand in Malaysia, one can presume that here, as elsewhere in the world, there are changes and pressures of change, based primarily on financial and economic considerations. Such change, like any change that is direct from outside our control, and which appears to be more related to cost containment than direct patient benefit, can be an uncomfortable and unsettling process.

ETHICS AND THE MARKET OF PATHOLOGY

I would first like to address the question of the business man and the laboratory. 21 years ago Dr Earle Hackett, as a former president of my College, in a lecture on the future of pathology, stated "now at this time you are going to tell me that Pathology is the practice of a profession and not a business, and I will reply that a profession is an advice giving occupation which operates simply through face to face confidential exchanges between a trained professional and a client and does not involve elaborate equipment, numerous subordinates, large capital investments and all the trappings of technology and communication links of a modern medical laboratory".

To look at the market of pathology, it is similar in Australia and New Zealand in that the money for pathology testing comes in the main from the government or ultimately from the taxpayer with little from insurance or the individual directly.

This means that there are government imposed rules or legislation as medical standards, that one must have, before one can enter as a player on the market.

All reputable businesses in a business environment, operate generally bound by a group of rules or ethics – without which there is the risk of anarchy.

Of course in medicine for 2400 years, the medical profession has subscribed to a code of ethics – the Hippocratic Oath, and while that code has changed in detail over the years the general theme is to ensure that the patient's best interests are protected.

However, some critics accuse the profession, that ethics are simply a form of individual protection and blatant self interest whereby those already in practice put up barriers to make it more difficult for new comers to get started or barriers to maintain prices and keep out competition. Some also take it further and accuse the profession of trying to keep the population in ignorance and dependency by prohibiting advertising and other methods of informing the public.

There are good reasons for ethical rules to protect the patient against dishonesty or fee splitting, as for example the case of a GP who refers patients to a laboratory for a large number of tests and is paid a fee per referral or a percentage as a reward. This is unacceptable. However, consider the scenario where being a major orderer of laboratory tests, the laboratory may pay for this doctor and his partner to attend a medical conference overseas, staying in luxury surroundings, attending many of the highlights and attractions to be found in that city, and not attending much of the conference which the doctor is not interested in. In fact, in such a scenario, everyone is happy, the patient who may feel he has been thoroughly investigated, the laboratory who have maximised their profits and the GP and his partner who have had an overseas holiday/conference.

But it is unethical because a doctor should only recommend those diagnostic tests which seem necessary to assist in the care of the patient, as the more the tests done, the more likely there are false negatives and positives and further unnecessary investigations, and also that

limited resources have been used that could have benefited other patients.

This example shows that doctors can gain significantly from unethical behaviour or conversely that medical ethics are intended to primarily protect the interests of the patient. However in New Zealand with the Commerce Commission and in Australia with the Trades Practice Act, in particular the Competitor Policy Reform Act 1995, there has been recent reviews of medical ethics, because it is accepted that unrestricted competition may not always produce the best possible economic and social income.

There have been complaints that many of the current professional regulations go beyond what is needed for client protection, and are a way to provide or continue monopolistic services. Therefore anti competitive rules will be targeted by those bodies, whereas professional rules that protected clients from unacceptable practice will be accepted.

For this reason in New Zealand Dr Brian Linehan, the Chairman of the NZMA and, incidentally a senior pathologist, has had the ethical rules of the NZMA scrutinised by the Commerce Commission. Similarly for these reasons the ethical rules of the College of Pathologists are currently under review.

The difficulty with business coming into pathology is not the arrival of business men or companies who generally work to ethical rules, but the fringe group present in most business endeavours who skirt or push the fringes to defend the right of what they are doing under the guise of it being an ordinary commercial activity.

Therefore one can rightly ask, what is different about a medical laboratory testing from an ordinary commercial service.

The difference, I believe is the considerable information asymmetry between the doctor and the patient. The latter can certainly assess some peripheral aspects of that service such as whether they had to wait, whether the procedure undertaken, such as venesection, was done in a proper manner by a competent and therefore presumably adequately trained nurse. As for the more fundamental question of whether they needed those tests, or whether other tests which were necessary for a correct diagnosis were not asked for, they have no way of judging.

However with more openness, more information available in the Press, the Web etc, and better communication, this information asymmetry which leads to market failures is becoming more balanced.

Thus therefore, as Medical Practitioners,

pathologists have general ethical values, which try and ensure the patient is protected.

However, ethical rules are not enough. As a provider of funds, the government expects that those funds they provide for a pathology service are spent appropriately for the welfare of the patients and therefore other specific legislation has been produced.

PROFESSIONAL INPUT IN HEALTH REFORMS

I will preface my further remarks to the New Zealand scene. Though similar in their aims, New Zealand and Australian government policies in pathology, in control of expenditure and value for money, have differed markedly. Pathologists in New Zealand have generally been excluded from discussion about the health reforms. The reforms have been in the hands of economists and had a business focus, and the pejorative term of "provider capture" has been used endlessly over the past 6 years to exclude professional medical input into decision making. In Australia they have at least been consulted and through the College, and through some joint Federal, College and Private Pathology (AAPP) committees, they have had opportunities to put their viewpoint in a constructive dialogue in health policy development, at the Federal level though I should say that has not necessarily been extended to certain states in Australia who are responsible for hospitals as opposed to Medicare funding.

Hopefully in New Zealand with the recognised failure of the first and second impetus to achieve the savings that were thought to be present from inefficiencies in the health system and the inability of managers to achieve productivity gains and care without the cooperation of the medical profession, there is starting to be an acceptance that a lot of the turmoil caused by professional exclusion and cutting of funds, has been counterproductive. There is also more honesty. Now there is talk of appropriate rationing of health care as to a % of GNP and the idea that there was money present, but it was not available being locked up in the system, is seen for the illusion that it was.

LICENSING

I would now like to discuss the question of licensing to enter pathology as a pathologist in New Zealand. Licensing is to ensure that a person has a minimum level of skill, training and experience, and is founded in medicine and

law, where choosing an incompetent practitioner can result in injury and cost to the client. Other professions generally have certification to indicate a certain level of competence, but that does not prevent others not so certified from practising.

The Medical Practitioners Act 1995

This new act focuses very clearly on ways of registration and ways of ensuring all registered doctors are fit and competent to practice from the time their names are put on the register and throughout their professional life.

The principle purpose of this act is to protect the health and safety of members of the public by prescribing mechanisms to ensure that medical practitioners are competent to practice medicine. It attains this purpose by:

- (a) imposing various restrictions on who can practice medicine.
- (b) registering practitioners and issuing of annual practice certificates
- (c) providing for the review of the competence of medical practitioners to practice medicine
- (d) providing for the disciplining of medical practitioners
- (e) providing certain protection for practitioners who take part in approved quality assurance schemes.

Important to pathology and pathologists from this document are:

- (1) *Doctors, including pathologists and GP's, are vocationally registered*, otherwise they can only practice probationally under supervision or temporary registration as for a visitor to New Zealand, e.g. visiting surgeon demonstrating new techniques. In pathology, it has been important that the standard to be measured as a pathologist is Fellowship RCPA. By the year 2001 there is further requirement for mandatory recertification activities, at present being met by participation in the College CPDP (Continual Professional Development Programme) and in the College Quality Assurance Programmes.
- (2) *The laboratory must be accredited by Telarc* (Testing Laboratory Registration Council) – or International Accreditation New Zealand as its new name to receive government funds.

This registration of medical laboratories commenced in 1978, when Dr Brian Linehan as President of the New Zealand Society of

Pathology and Professor Peter Herdson, New Zealand Councillor RCPA, decided that standards of laboratory practice should be set up by the profession, before it was setup by someone else.

Telarc arose in the 1960's from the realisation that if New Zealand manufactured goods were to compete on world markets they must be thoroughly tested and undergo quality control processes.

The medical arm of Telarc – Medrac was set up by an act of parliament as a user pays statutory body with the promotion and recognition of laboratories to reach International Standards of quality management and Technical performance as its main aim.

The quality managed criteria currently embody the requirements of ISO 25 and ISO 9002 in New Zealand. In Australia, the standards are those set up by the National Pathology Australian Accreditation Council (NPAAC), a statutory body.

In New Zealand, progress of registration was slow, until the last two years, when it became mandatory. This has been the reason some smaller laboratories in private and public have sought mergers or joint ventures with larger laboratories both hospital or community based so that Telarc standards could be met.

It is apparent with this compulsory licensing that the playing field has become more even, as without it, some laboratories would continue to function with inadequate methods, and machinery and inexperienced or unsupervised staff. These laboratories because they are not having the same overheads, qualified staff etc as those registered, would have a profit margin unavailable to the others, i.e. uniform standards are needed for all providers of laboratory services.

The funder has also accepted a draft "National Quality and Service Standard" set up by the College and Telarc for all laboratories who wish to claim from the schedule prices for tests provided by the government.

These requirements require vocationally registered pathologists, Telarc registration, and staffing under the control of pathologists, scientists and qualified technical assistants to undergo appropriate ongoing training and development, appropriate External and Internal Quality Control measures etc.

These standards have been accepted by the New Zealand Committee of the College, but not signed off yet, as we are concerned that near patient testing should have standards written

also before they are funded, and the recognition that **though** often accurate and convenient, they tend to be considerably more expensive per test than the same test done in a large laboratory.

Once one has the appropriate license or licenses, one can **start** to play in the game.

This in New Zealand has, in the community, as well as in some of the smaller laboratories involved businessmen being involved with pathologists.

Certainly in our private community sector, competition is desired by the official side and by GP's because the choice leads to competitive pricing in contract pricing.

BUSINESS PERSPECTIVES

Though standards are important to ensure value for money, nothing guarantees profits. If that were so, the pathology business would become risk free, and more people would enter it and profits would evaporate with increased competition.

Ultimately to make a profit in competitive business one needs to take risks in search of returns and we take risks to hopefully generate better returns than our competitors.

Growth may be maintained by:

- (1) new markets i.e. expansion,
- (2) altered test ordering – by this I don't mean inducements, but publicity by various groups may increase certain test ordering e.g. cholesterol fractions, cervical and breast screening programmes, melanoma campaigns, and
- (3) increase market share – by marketing ones' strength

Market share can also be influenced by takeovers, mergers and joint ventures. This allows rationalisation and economies of scale, operating leverages or spreading the fixed costs, with reduction of buildings, collection centres, cars, automated equipment, leading to increased volumes on a reduced cost structure.

These have become frequent in New Zealand with all such changes occurring with community laboratories and the smaller hospital laboratories.

With modern communications it is a fact of life that the majority of pathology testing can be processed off site at a distance with local stat facilities for emergencies. Similarly some expensive tests in terms of complexity, reagent costs, short shelf life of reagents and expertise may well justify rationalisation off site.

Tendering is a well recognised business tool,

which does require certain rules and conditions as laid down in the tender document and presupposes a level playing field for all those involved with no chance of cost shifting.

It is a potential problem where tendering involves a set of standards or ethics between tenderers. Non medical health providers may not feel bound by the same rules, and the quality of the service provided requires monitoring to ensure the service is not being compromised to meet financial cost cutting objectives and/or profit maximisation, and that low tenders are not being entered to drive out competitors and establish a long term monopoly.

With tendering, because of test numbers, discounting of automated tests may be possible. Above a certain threshold where fixed costs in equipment, staff and reagents involved in machine usage, once met, the test can then be discounted.

It goes without saying that from a business point of view that marginal discounting can only be applied above certain volumes. To discount the base rate will be financially ruinous.

A business perspective of pathology is that it is an information service, not a testing operation, and one must maintain this focus. What they are looking at is the result, not an internal focus on how that result is achieved.

With regulation of laboratories, quality assurance and increasing automation, the quality of numerical testing is not an area for competition in New Zealand.

Thus ***the crucial role of the specialist pathologist is not really protecting a machine, but to ensure that value is added to the results*** by meaningful comments to help confirm or give a differential diagnosis, i.e. back to a professional one-to-one consultation.

Turn around times are constantly a measure of efficiency. Preanalytical, analytical and postanalytical, analysis is needed.

Efficiency in the absence of perspective, can be a higher form of ignorance. We need to be effective, which is doing the right thing.

With these changes, to improve business, with competition, you need further investment.

INVESTMENTS

Human resources are a major investment (44%) of our laboratory expenditure. Besides the legal obligations under the terms of the Privacy Act and Employment Contract Act, Human Rights Act, there is training, work conditions, personal goals. There is in business in New Zealand now

a need to have human resource personnel.

Financial management, is essential in monitoring departments, controlling costs, appropriate tender prices and forecasting and budget preparation.

Information systems is one of the major investments, not only to control data, machine testing, but also delivery of information back to the customer. We have had laboratories giving or should I say more correctly providing computers to practices where they can **download** results directly.

There is a thin line here, where incentives and inducements start and efficiencies in the delivery of post analytical results end. Suffice to say, that though illegal in Australia, this has been sanctioned by the non action of the official side in New Zealand who wish to see more GP practices utilising computers.

It is argued that the provision of a computer, does not act as an inducement to order further tests, but does ensure laboratory loyalty and improved turnaround times.

Marketing of the laboratory to its customers has become very important. The perception of the laboratory and its staff, its ability to react to complaints and see where difficulties may occur, are of prime importance. It is important that the marketing division doesn't get too far away from management, and it is well informed about the laboratory's ethical practice and management guidelines that its pathologists have agreed to.

With competition, it is of interest that in 1992, our laboratory leased a small computer system which was run out of the laboratory, and we did not have a marketing section. Within the last five years we have invested large sums in an in-house computer system, and have several full time personnel in marketing and client contact, part of our risk **taking** development.

CONCLUDING REMARKS

Therefore, in summary, I believe there needs to be consensus through consultation and regulation, as to an appropriate level of standards which the laboratories must practice under.

These standards will vary from country to country, and will be refined and not be static.

I believe that standards cannot guarantee profits and returns on investment, but are necessary for good business practice, assurance of value for money spent and for the welfare of the patients i.e. quality care. In fact profits may fall, but ethical standards do ensure that unethical business practices do not profit unfairly over

those looking to achieve good standards of practice.

I would like to briefly discuss the P word. Much is made of the difference between public and private. Each must be efficient and with appropriate standards. There must be recognition of a different work load mix, often more difficult or esoteric tests in the public sector, the importance of autopsy and audit review, the increased costs of which must be allowed for there to be fair **competition**.

However, the major problems from this approach is the reluctance to provide proper funding for teaching and research, both in Australia and New Zealand, but that is another story.