PRODUCTIVITY COMMISSION

DRAFT RESEARCH REPORT

STANDARD SETTING
AND
LABORATORY ACCREDITATION
JULY 2006

COMMENTS ON THE REPORT

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General Practitioners

Owner Operators of Cat. M.

Pathology Laboratory Apollo Bay

for the last 30 years.

Apollo Bay **August 2006**

Moore Street Clinic

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1. TERMS OF REFERENCE

1.1 The history of the Pathology Industry and its relationship with Government is not adequately discussed. Four companies now receive 80% of total Government outlays.

1.2 The cost impact is nowhere estimated or evaluated.

1.3 The value of "Standard Setting" is largely assumed and needs more discussion.

1.4 There can be no standard in rapidly developing technology as attempts to do so are quickly overtaken by events. NATAs regulated Stage Coach Industry would be obscured by the steam from the passing trains.

1.5 Standards are inevitably concerned with the past. Computers built to the standards of 1961 would not sell today. Competition automatically changes standards. The threatened regulate, status often depends on the status quo.

1.6 There is no discussion on the circumstances surrounding any standard. On the Central African plateau in a village you can distinguish between malaria and trypanosomiasis (sleeping sickness) by putting a drop of blood on a glass slide. In trypanosomiasis rouleaux are formed easily visible to the naked eye. This test would not be approved by NATA in a laboratory in Sydney. The threshold of referral from one lab to another forms no part of a NATA Standard. This is a large omission. In the care of the sick the prevailing circumstances decide the standards of investigation and treatment.

1.7 There is no discussion on the effect and manipulation of standards for social, employment, financial, or political purposes. Yet these represent the main cost impact of standards.

1.8 Standards frequently prevent the provision of services. A test that doesn't meet a standard does not mean it is of no use.

1.9 The miniscule direct cost to the government of NATA is not the point of the enquiry. The Terms of Reference specify the cost impact on business and the wide community. They are nowhere addressed or calculated and yet are clearly very large.

1.10 Uniform standards, often given as the justification for standards, are only relevant under uniform circumstances. Frequently in medicine this uniformity does not exist making standards irrelevant, counterproductive, or actually harmful. A necessary test will not be done or a necessary piece of equipment will not be purchased because the cost of uniformity is too great.

1.11 Original solutions are always discouraged by existing standards especially if the existing standards have legal or financial implications.

1.12 In a broad sense we may say that manufacturing has been driven offshore to avoid Australian "standards". We may also say that small Pathology Laboratories cannot be operated because of Australian (NATA) standards. Yet the Government is in favour of manufacturing and legislates in favour of small laboratories.

1.13 The capacity for standards to stop things being done is considerable, if largely unseen.

1.14 Consumer satisfaction, not benefits to providers, should be the only justification for a standard. Standards and regulation create monetary values and imperatives not all of which are in the public interest.

1.15 The "advantage" of <u>not</u> having a service is that there is no consumer dissatisfaction. Consumer inconvenience, because there is no service, can be defused on the grounds of standards. Thirty years ago the Post Office would not put three extensions on one line because it was against the industry standard. Now every child has their own phone.

2. PATHOLOGY STANDARD SETTING AND LABORATORY ACCREDITATION

Many of the general observations made in respect of the terms of reference can be demonstrated from the experience of owning and running our own laboratory as part of our general practice for the last 30 years.

2.1 Background

Initially, 30 years ago, there was no laboratory in the town and therefore no standards. The nearest Pathologist was 120 kms away, as is still the case. Major road trauma, obstetrical deliveries (25 a year), serious ongoing illness of all kinds was managed in the small 14 bed hospital with no laboratory assistance – there was no courier service. Two doctors in partnership then arrived financing and equipping a laboratory as part of their general practice. For 20 years they remained the only two doctors in the town. Biochemistry, haematology, bacteriology and a small blood transfusion service was maintained. The doctors did most of the work themselves. The methods were very time consuming and labour intensive, a part time technician was employed. The practice became a teaching unit of the University of Melbourne Medical School.

2.2 Impact of Technology and size on Management Methods

Automation developed initially in the bigger laboratories. This altered the standard of work and the expectations both financial and technical of the large providers. The small laboratory was effected by these trends; the two doctors had to "go offshore" to purchase automated equipment, initially British and American added to later by French and German instruments. The capital costs escalated, not of necessity, because the work could still be done the old economical way, but because the larger laboratories changed the character of their outcomes and concerns. The increasing work loads that their equipment enabled them to do led the large labs to seek reassurance in organizational procedures, what could loosely be called "checks" on performance. Their increasing isolation from patient care and patient contact, plus the employment of larger numbers of non medical personnel, exacerbated the trend to bureaucratic procedures.

2.3 Pathologists as Managers and Entrepreneurs

The Pathologists stopped "marketing" their skills but instead the equipment, capital and organizations that had been created. This was a crucial development.

There was no logical reason why this should have impinged on doctors doing their own laboratory work on their own patients. For these doctors the laboratory was simply one of many methods they used to secure good patient care. The outcome was patient satisfaction and recovery. The relative accuracy and consistency of the tests done was continually monitored by commonsense and the clinical outcomes. There are no absolutes in laboratory findings. There was no profit to be made. Our outgoings have always exceeded our income as would be the case with all similar small laboratories.

2.4 Pathology as a Restrictive Monopoly

The pathology industry, as it became, was criticized for the costs generated. The Health Insurance Commission endeavouring to control costs and the pathology companies, (as they had become), attempting to control competition, went to standards, inspectors and approvals. In Victoria the Royal College of General Practitioners inspected doctor operated labs. The fee was modest, $750. Licences were brought into use not only for labs but for the Collecting Centres used by large laboratories. A fee was negotiated simply for patients attending Collection Centres. All of these activities by the bigger laboratories produced what is known as an "income stream" that came to be traded for money.

2.5 Advent of Small Automated Analysers

As in the computer industry the equipment improved and became much smaller. The Pathology Industry very much depends on the computer industry. The arrival of the "personal lab" like the laptop computer was imminent. The Pathology Industry buttressed its monopoly position by imposing what it termed uniform standards. NATA took over the accreditation and inspection of Category M Labs from the Royal College of General Practitioners. The costs and bureaucracy ballooned enormously. A small lab doing tests on around 6 patients a day had a total of 17 people from NATA through its premises – only one of the NATA contingent being a general practitioner. NATA charged $160/hour simply as a reading fee.

2.6 Provision of Services Prevented by Cost of Regulation

Regulatory charges for 2003 – 2004 came to $17,716 which was 38% of the total laboratory income, or put in another way, 4.6 months of the annual gross laboratory income. See Appendix for a breakdown of these costs. The H.I.C. itself was concerned and reinstated the Royal College of General Practitioners as an accreditating authority. The R.C.G.P. found the cost of doing the accreditation too much and refused to do it. This is the ultimate bureaucratic end point where the costs of the accreditors are so high they cannot afford to be accreditors. [Appendix]

2.7 Cost Impact on Wider Community

The prevention of things being done produces much greater costs. Because a white cell count cannot be done (cost $14.65) a patient is sent to a base hospital by helicopter ($8,000). This happens all the time.

2.8 Public Expenditure Role of NATA

The activities of NATA effectively prevent the dissemination of laboratory technology, (e.g. blood clotting test see below). The H.I.C have effectively made NATA standards "referenced standards" as it is only by courtesy of NATA that funding is provided. There

are virtually no legislative checks and balances on an organization which, in practice, is responsible for the disbursement of $1.5 billion government funding a year. An important "tool" which should be available to every medical practitioner, automated pathology equipment, is being discouraged and prevented by the present arrangements. The virtually monopolistic situation enjoyed by large Pathology Providers in large hospitals is also encouraged by the existing arrangements. They also serve to channel Federal Funds into State run hospitals.

NATA will say it has nothing to do with these arrangements – this is disingenuous. It is clear that NATA discourages, I would say prevents, new entrants. The cost of equipping even a small doctor owned and operated laboratory is substantial, couple this with the cost of regulation and the financial barriers to undeniably improved patient care become insurmountable. The pathology industry, which is cut off from patient care, can never conceive anyone doing anything other than for profit. Cat M. Laboratories make no money.

2.9 Doctors the "Real" Consumers of Laboratory Outcomes

The fundamental misconception that runs through the Draft Report is that patients are the "consumers" of laboratory outcomes. This is not correct; doctors – non pathology doctors are the consumers. Apart from the small doctor owned Cat M. labs the Pathology Industry cannot charge unless the work is referred to it by a doctor. This is nowhere made clear in the Report. The work done, the result of the test is sent to the referring doctor who uses it as part of an exceedingly complex "data base" for the treatment and care of a patient. In this way every laboratory result is subjected to an external evaluation. The test may be only marginally significant, it may be accurate but too late, or approximate and timely. It may arrive too late to be of any use. The doctor will know the characteristics of the lab he uses. The methods they use may produce persistently high or persistently low readings. The Pathology concern may not be open at weekends or public holidays – patient care is influenced by the conditions of employment of laboratory scientists and technicians, it may be "too expensive" to call them out. Hospital equipment standing idle cannot be used by a doctor because of job demarcation arrangements aided and abetted by T.G.A. and NATA regulations.

2.10 Obsolescence Funded by Current Arrangements

The Draft Report which seems to have a large input from NATA produces, if I may say so, an Alice in Wonderland view of reality. No doctor organization is listed in the consultation process yet doctors are the consumers. No calculation of the real cost to patients is in any way attempted. No mention is made or assessed of the importance of changing technologies. Medicare buttressed by NATA is funding obsolescence.

Take one example; the blood clotting test known as the I.N.R. done regularly on the large number of patients on anticoagulation therapy. In Germany the small highly accurate instrument to do this, on blood from a finger prick, is given free to every patient by the Government. Here the same test is restricted to Approved Pathology laboratories.

Patient Episode collection fee around $16.00, reimbursement for the test $11.40. Consultation to get the lab referral to do the test is $39.40. Further consultation to get the result $39.40. Opportunity cost to patient going to and waiting in a collection centre, pain of venopuncture to get blood for the "economical" methods in use in large laboratories etc. For a doctor to be able to do this test on a finger prick in 30 seconds at the one consultation requires the doctor to be a NATA approved pathology provider (if Medicare is to reimburse the cost). We are informed that at some collecting centres this test makes up 60% of the work load.

The Productivity Commission is not supposed to be a mutual admiration society. Much of the Report sounds like Jesuits talking to Jesuits. I don't think, in respect of the pathology aspects of NATA, that this is what the Government had in mind.

2.11 Changes to the NATA – Pathology Industry – Medicare Nexus.
This needs to be changed.

The mindset of restricting pathology testing needs to be changed. There needs to be a lot more pathology done not less. In any event this is going to occur.

All doctors should be encouraged to use the convenient, reliable, rapidly emerging modern technology. Blood counts, electrolytes, renal function tests, blood clotting tests are all reliably automated and can easily be done by any doctor. These make up around 40% of the pathology payments made by Medicare.

The payment system needs to be altered with a capped sum paid to each doctor who registers himself as having the required instruments. The capped sum paid monthly would reimburse him for any pathology work. If for any reason the doctor preferred to refer the work to the Pathology Industry then the charge raised on Medicare by the Pathology Industry would be deducted from the doctor's monthly capped sum. There is of course always going to be a need for complex or infrequently done tests that can only be performed by the Pathology Industry. Pathologists will never be out of work.

2.12 Involvement in Doctor Operated Laboratories not required

The doctor doing his own work on his own patients (The Cat. M Lab situation) should not require accreditation in any way. Doctors are accredited and trusted to look after patients, that is their role. If they are incompetent or produce unreliable "results" a wide range of legislative and regulatory remedies are available already. Why should a simple procedure like a blood count be subject to costly and absurdly complex regulation by NATA, when orthopaedics, cardiology, paediatrics, even neuro surgery have no such regulatory components. Doctors in all locations and even more so in isolated locations engage in all of these demanding, highly skilled, responsible activities. They would face censure if they did not. The one activity regulated to the hilt by NATA is pathology – the reason is simply money – not patient care. Change the money rules and NATA could assume its proper role as a technical expert panel giving advice when required to the industry. NATA has no role in patient care it is far too complicated a matter for them.

2.13 Monetary value created by Licenses and Restrictions.

In an ongoing "limitless" market like Pathology restrictions and licences create value which can then be traded. The primary purpose of NATA seen in that light is to increase the monetary value of the Pathology Industry and therefore its cost to Government. Patient care is already regulated and the regulators are called doctors, there should be no interference with that role.

Enclosures: Appendices A, B and C

26th August 2006 Dr James Lawless Dr Margaret Lawless

OUTGOINGS PAID TO NATA FOR CAT. M. LABORATORY

NATA

Invoice Date		
14.4.03	Application for Accreditation of Medical Testing	$907.50
23.6.03	Travel relating to Advisory Visit	74.99
23.6.03	On-site time, writing and confirmation of report (Melissa) (2.50hrs at $155/hr)	426.25
14.10.03	Initial Assessment on 15.8.03 (11.50hrs at $160/hr)	2,034.78
23.2.04	Pro Rata Membership Fee	1,089.75
23.2.04	Field Technical Unit Haem/Bio Field Technical Unit Microbiology	675.07 675.07
23.2.04	Writing Confirmation of Report on Initial Assessment (15.8.03) (1.40hr at $160/hr)	246.40
23.2.04	Expenses and costs (Travel & Accommodation 15.8.03)	811.07
24.6.04	Follow-up Initial Assessment on 17.3.04 (7.50hrs at $160/hr)	1,320.00
24.6.04	Accommodation and Travel Costs for 17.3.04	335.06
1.7.04	Annual Membership	1,270.50
1.7.04	Field Technical Unit Haem/Bio Field Technical Unit Microbiology	792.00 792.00
20.12.04	Writing and Confirmation of Report and follow up 17.3.04 (24.80hrs at $160/hr)	4,364.80
TOTAL	(20 months)	15,815.24

Per month $790
Per year $9,480

OUTGOINGS PAID TO HEALTH INSURANCE COMMISSION AND QUALITY ASSURANCE PROGRAMS FOR CAT. M. LABORATORY

HEALTH INSURANCE COMMISSION ANNUAL CHARGES	
APPROVED PATHOLOGY AUTHORITY (DRS J & M)	$1,500.00
APPROVED PATHOLOGY PRACTITIONER (DR. J.)	500.00
APPROVED PATHOLOGY PRACTITIONER (DR. M.)	500.00
ACCREDITED PATHOLOGY LABORATORY	750.00
Total	3,250.00
QUALITY ASSURANCE PROGRAMS (MANDATORY)	4,626.00
TOTAL ANNUAL CHARGES. GOVT & QUALITY ASSURANCE	7,876.00
ADD N.A.T.A	9,480.00
TOTAL ANNUAL CHARGES	17,716.00
TOTAL ANNUAL LAB INCOME 2003-2004	46,458.00

Regulatory Fees amount to 38% of Total Income
Which is 4.6 months total income for the privilege of doing required Pathology 24hrs a day 7 days a week on patients living 120kms away from the nearest Pathologist.

3.3 APPENDIX C

THE ROYAL AUSTRALIAN COLLEGE OF GENERAL PRACTITIONERS

December 21, 2005

Drs J & M Lawless
1 Moore Street
Apollo Bay VIC 3233

Dear Drs Lawless

Re: RACGP: Accreditation of Category M Pathology Laboratories

In March 2005 Medicare Australia (formerly The Health Insurance Commission) ratified the RACGP as a suitable body to accredit Category M Pathology Laboratories in Victoria in accordance with the Accredited Pathology Laboratories Approval Principles 2002.

A formal application was submitted to Medicare Australia in June 2003, however due to a number of lengthy delays, the deed of arrangements was not signed by all parties until this year. Category M laboratories previously accredited by the College had no choice but to accept accreditation from NATA (National Accreditation Training Authority).

Whilst the College has approval to accredit Category M laboratories, additional requirements stipulated by Medicare Australia indicate that it is no longer cost effective to do so. Accredited providers are now required to have insurance and there are extra costs of resources, (administration and payment of 3 inspectors) to accredit only 10 Category M Laboratories.

After due consideration, the RACGP Council and Faculty Board of Victoria have decided not to continue with accreditation of Category M laboratories until further notice.

If you have any further queries about the continuation of accreditation by the RACGP please do not hesitate to contact me on 8699 0586 or email morton.rawlin@racgp.org.au

Yours sincerely

Dr Morton Rawlin
Director of Educational Services
RACGP