A member of the Australian Cancer Society
Director: Dr Nigel Gray A.M. MB. BS. Hon. LL.D. FRACP, FRACMA

Anti-Cancer Council of Victoria

28 July 1989

49-1319

Dr. H. Mitchell
Victorian Cytology (Gynaecological) Service
PO Box 253B
Melbourne Vic 3001

Dear Heather,

Here's a response to your letter of July 20. I'm not phoning as I'm doing this in the evening.

Apropos Ron Hastings letter, I would certainly suggest you conduct negotiations in writing.

I don't see anything wrong with giving him a clear assurance that nobody associated with the Registry has any intention of bypassing the usual channels of communication and following up women who require such follow-up. At this point in time I'm a bit uncertain about what the final system for contacting women, who may have been missed by their GP, will turn out to be.

Apropos reminder letters - let's leave this to the future. I agree we don't need to draw the AMA's attention to it. It would be better to make our own mind up before we talk to anyone else.

Yours sincerely,

Nigel

Nigel Gray
Director

VICTORIAN CYTOLOGY (GYNAECOLOGICAL) SERVICE
236-254 St. Kilda Road, Melbourne, 3004

P.O. BOX 253B
MELBOURNE
VICTORIA 3001
AUSTRALIA
Telephone: (03) 614-6822

Director: GABRIELE MEDLEY
M.B., B.S., F.R.C.P.A., F.I.A.C.

24 JUL 1989

20 July, 1989

Dr N Gray
Anti-Cancer Council of Victoria
1 Rathdowne St
CARLTON 3053

Dear Nigel,

I enclose a copy of a letter from Ron Hastings which you may care to phone me about once you have read it.

The issue Alan Rassaby is referring to at the top of page 2 is the follow-up of women with abnormal smears. I am perfectly comfortable with the Registry following the usual channels of communication in seeking follow-up information about women where further investigations (such as colposcopy or biopsy) have been recommended - first to the pathology laboratory, second to the GP, and finally to the women only in exceptional circumstances. Under the latter circumstances, one is really seeking confirmation that the woman was given the abnormal report rather than details of the histology.

As regards the sequence for women with abnormal reports where the recommendation is for early repeat cytology, I suspect most GPs won't particularly want to bear the cost of postage of the letters to women. As the reminders will be issued on Registry letterhead, there is little to gain from the GP being directly involved in posting the letter. Perhaps sending a list to GPs of the women who have had early reminder letters sent after a previously abnormal result would be helpful to the GP and acceptable to the AMA.

Alan does not appear to have given any undertaking about the sequence of contact for reminder letters to women whose tests were normal - but we don't need to draw the AMA's attention to this. My immediate reaction is that we will achieve little by antagonising the AMA.

At some stage I guess I should write back to Ron Hastings - even if only to say that I have referred his letter on to the Management Committee of the Registry. I dislike "private" negotiations about this type of issue where the AMA is involved.

With kind regards,
Yours sincerely,

Heather

Heather Mitchell

AUSTRALIAN MEDICAL ASSOCIATION
(VICTORIAN BRANCH)

293 Royal Parade, Parkville, Victoria, 3052
Telephone: 347 8722 Telegrams: MELMED, Melbourne Telex: 32906 Facsimile: 347 9871

Please address all correspondence to: The Executive Director

July 14, 1989

A.bl/811:B.aq/8-2

Dr. Heather Mitchell,
Acting Director,
Victorian Cytology (Gynaecological) Service,
236-254 St. Kilda Road,
MELBOURNE, 3004.

Dear ~~Dr. Mitchell~~ Heather,

It has taken me a long time to get round to it, but I did say I would drop you a note when I had clarified my recollections on the understanding we reached during negotiations with the Minister's advisers about some aspects of the Cancer (Central Registry) legislation.

The main point I wanted to make was that the Minister's people clearly understood our need for assurances about all reminder notices going through the relevant medical practitioner wherever possible. I am enclosing a copy of the letter of March 15 from Alan Rassaby, and you will see that the last paragraph in particular makes this intention clear.

If this point has not been translated into legislation we shall have difficulty with it. In any case I would be glad of your thoughts.

Yours sincerely,

Ken

R. R. HASTINGS
Executive Director

Noted by
OB 23/3

11055

55

# Health Department Victoria

Reference No.

Address all mail to
P.O. Box 4057 G.P.O.
Melbourne, Victoria.
Australia 3001

[illegible]IVED
[illegible]89

15th March, 1989

Mr Ron Hastings
Executive Director
Australian Medical Association
Victorian Branch
293 Royal Parade
PARKVILLE VIC. 3052

Dear Mr Hastings,

Thank you for participating in a recent meeting with officers of the Health Department Victoria and the Anti-Cancer Council of Victoria on the Cancer (Central Registers) Bill.

The Minister is delighted that we have now found common ground.

My understanding of decisions taken at the meeting is as follows -

- there should be no statutory obligation to seek the informed consent of every women before test results are sent to the Register. Nevertheless, materials explaining the nature and purpose of the Register should be released to all medical practitioners on proclamation of the Act and should make it clear that they should make every effort to ensure that patients are fully informed about all aspects of the Register, including their right to object to test results being forwarded to the Register;
- proposed s.62(4) and s.62(7)(d) should be removed from the Bill by House amendment;
- I am to suggest to the Minister that she make a statement during the course of the debate on the Bill encapsulating her views about the application of the informed consent doctrine;

555 Collins Street, Melbourne. Telephone (03) 616 7777

- the AMA should be closely consulted on the preparation of the written materials to be sent to practitioners. The materials should also contain protocols indicating the exceptional circumstances in which the Register should communicate direct with those women who have abnormal smears and those circumstances in which the normal protocol should apply (i.e. communication first with the pathologist and, if no reply is forthcoming, with the practitioner and subsequently the women).

As a result of our meeting, I think that we now have a better scheme. I hope that I may look forward to your continued support for this Bill during its passage and implementation and I thank you for your input to date.

Yours sincerely,

ALAN RASSABY
Manager, Policy and Legislation Review

c.c.: O. Stagoll, HDV
N. Gray, Anti-Cancer Council of Victoria
L Hunter, HDV

id274/125-126/vmd

VICTORIAN CYTOLOGY (GYNAECOLOGICAL) SERVICE
236-254 St. Kilda Road, Melbourne, 3004

Director: GABRIELE MEDLEY
M.B.,B.S.,F.R.C.P.A.,F.I.A.C.

P.O. BOX 253B
MELBOURNE
VICTORIA 3001
AUSTRALIA
Telephone: (03) 614-6822

for Pol
Agenda meeting
Nigel

This a legal opinion on a couple of points Heather & Gabrielle were worried about in the Registry. Heather says Hamish Russell has interpreted this to mean that when a woman's smear comes in, they cannot link it to previous VC(G)S results. I am not so sure. Would you put your mind to this important point before our Monday meeting?

Robin

23 June, 1989

Dr H Russell
General Manager
Health Secretariat
Health Department Victoria
555 Collins St
MELBOURNE VIC 3000

Dear Dr Russell,

[illegible]

Re: Victorian Cervical Cytology Registry established under Section 62 of the Cancer (Central Registers) Bill

We understand this Bill is to be proclaimed on 1 July 1989. Although registry staff met with Mr Howard Race yesterday to discuss the Bill, several important issues require further clarification; Mr Race suggested it was appropriate that we contact you. Advice on the following points is urgently needed as further developmental work on the registry cannot proceed until these issues are resolved.

1) SUBSECTIONS 1, 2, 3 & 4

These sections refer to the forwarding of reports to an organization that maintains a prescribed register. If a woman objects to her report being forwarded, can this be interpreted that personal identifying information, as distinct from the report (that is, the result of the test), may be forwarded to the organization maintaining a prescribed register?

If this were so, the register would be able to monitor the non-participation rate. This would be desirable as additional educational programs about the register could be undertaken to address non-participation, if it was shown to be a sizeable problem.

2) SUBSECTION 3

Pathology laboratories are concerned that "honest mistakes" will occur and the registry will be notified of results of some non-participating women. Not surprisingly, they find the prospect of a $1000 penalty on each such occasion rather daunting. If prosecutions were seen to eventuate from the inevitable "honest mistakes", participation in the registry by laboratories would be likely to be minimal.

Consider the following possible scenario. A data-entry person at a laboratory fails to enter an objection onto the laboratory computer. The person who transfers the information from the laboratory to the register forwards details of all reports which are not identified on the laboratory computer as having an objection raised, including some where an objection has not been identified on the laboratory computer.

Under these circumstances, can subsection 3 be interpreted that no infringement has occurred as the latter person, being the person who forwards the report, does not know of the objection? Does incorporation of the laboratory affect the position?

To minimise the possiblity of such honest mistakes occurring, the registry plans to assist participating laboratories by making available relevant guidelines. Where the registry was informed of such a mistake, it would obviously deal with the situation by reference to subsection 7.

We understand from our discussions with Mr Race that the probability of a prosecution under subsection 3 is not considered to be high.

Must be able to demonstrate the process.

Knowing of the objection

Unwittingly doing it – would be a defence.

## 3) SUBSECTIONS 5 (a) & (b)

In seeking to fulfil these functions, it will be necessary for the register to have available the results of histopathology tests which are taken as a consequence of a positive result on the screening test. In the absence of this information, it will not be possible for the register to know the appropriate time to send the reminder letter or to adequately follow up women with positive results. The nature of the histopathology findings is required as the timing and frequency of subsequent reminders will vary depending on whether the biopsy reveals benign or pre-malignant findings.

While the wording of the legislation is broad, the intent is clear. It was to ensure that women with abnormal results receive notification of them (this does not always happen currently), that the prediction of abnormality on the screening test can be confirmed (see the speech of Hon M Tehan to the Legislative Council 18 April 1989 paragraphs 6 & 7), and that such women receive reminder letters at appropriate intervals as some of them will remain at high risk for a subsequent abnormality.

Thus in developing the educational material for seeking women's participation in the register the registry is making it clear that if the Pap test is abnormal, the results of any other relevant confirmatory tests will be sought to fulfil the registry's functions with respect to Subsections 5 (a) and (b).

The registry staff would appreciate comments on the above.

No legal reason why the above is a problem.

Histopath. is a "cancer test" 5(a) (ii) (a)

## 4) ACCESS OF REGISTRY TO PRE-EXISTING VC(G)S DATABASE

In developing the concept of a register of Pap smear results for Victorian women, the invaluable nature of the record-linked files of the VC(G)S was recognised.

Currently the VC(G)S file holds the results of 5 million Pap tests taken over a 25 year period. 500,000 of these test results are abnormal and identify a subgroup of women at high risk of cancer. It has been standard practice within VC(G)S to interpret current tests in the light of previous results. It is accepted that this is one reason for the high standard of cervical cytology reporting that has been documented within Victoria. It was because this value was increasingly being eroded by the fragmentation of records into many laboratories that the idea of a registry was developed.

The VC(G)S has planned to make available to the register the previous screening history of each woman who agrees to be on the register prospectively. In our community and professional consultation and in our briefing of politicians, this proposed policy was discussed explicitly. The Board of Management of the VC(G)S has unanimously agreed to the policy. Obviously the VC(G)S cannot now approach each of the women who are on its current file with the right to object, as we lack postal addresses for many women on our file.

We believe the proposed policy is consistent with the intent of those who have lobbied for the register and with the speech by the Hon L Kokocinski to the Legislative Council on 18 April 1989 ("...the registry will allow cytopathologists to have access to a woman's previous Pap smear results when reading a current test. In this way a woman will not have to go chasing around the place for the result of Pap smears going back ten years".)

We would value an opinion of the legality of our proposed policy in this regard.

We would greatly appreciate the opportunity to discuss these points with the lawyers of the Health Department, as we can proceed no further with the registry until we receive clarification on them. I will telephone you on Monday 26 June to arrange a mutually convenient time.

"NO MATCH"
sticker

- legislation is prospective
- ask @ time by Dr.
  covering prev. tests

Yours sincerely,

Gabriele Medley.

(Dr) Gabriele Medley
Director

if prev. record could be
readily identified

- nothing means "yes"
- Something " "no"

positive election
or not making a negative

VICTORIAN
GOVERNMENT
SOLICITOR

Your Ref:
My Ref:
Extension:

Legal Adviser
Health Department Victoria

TO: Dr Hamish Russell, Health Secretariat

DATE: 6 July 1989

SUBJECT: Cancer (Central Registers) Bill

---

I refer to your memorandum dated 26th June 1989 requesting my advice on the issues raised in letter of 23rd June 1989 from Dr G Medley, Director, Victorian Cytology (Gynaecological) Service.

My advice to you is of a preliminary nature only, as some matters will require clarification from Dr Medley.

The new section 62 of the Cancer Act 1958 ("the Act") is set out in section 7 of the Cancer (Central Registers) Bill.

REPORTS.

What constitutes a "report or the test" has not been defined in the Act or prescribed by regulation.

It would seem to me that to enable a report to serve the purpose of a prescribed register, in this case, the Cervical Register, the report must include at least the following:-

1. The name of the person who has undergone the cancer test.
2. The address of that person.
3. The nature of the cancer test.
4. The result of that test.
5. The date the test was conducted.

I consider that if a person objects under section 62(3) of the Act to a report being forwarded to the Cervical Register, the objection relates to the forwarding of any part of the report. Legislative amendment would be required to give effect to the proposal that personal identifying information may be forwarded to the Register notwithstanding an objection by the person who has undergone the cancer test.

I do note however that Dr Medley in paragraph 2 of her letter equates "the result of the test" with a "report". I am happy to discuss this matter with Dr Medley further.

....2

## FORWARDING OF REPORTS.

Section 62(3) of the Act will provide a $1000 penalty for knowingly forwarding a report to a prescribed register when the person who has undergone the cancer test has objected to the forwarding of the report.

To be liable under the section I consider that the person forwarding the report must have a knowledge of the wrongfulness of his/her act. That is, the person must be aware of the objection and send the report regardless.

Section 38 of the Interpretation of Legislation Act 1984 defines "person" to include a "body politic or corporate as well as an individual".

Accordingly, section 62(3) of the Act would also apply to incorporated laboratories. The facts relating to each incident would have to be examined, but I do anticipate that prosecutions would be unlikely in respect of "honest mistakes" by individuals or companies.

## HISTOPATHOLOGY TESTS.

The purpose of the legislation is to establish registries of results from cancer tests.

"Cancer Test" will be defined in section 59 of the Act as -

> "an examination or a test that is undertaken to determine whether a person is suffering from cancer and that is -
>
> (a) a pathological examintion of a specimen from the person; or
>
> (b) any other examination or test whatever prescribed as a cancer test."

If it can be determined that a histopathology test is a cancer test as defined in paragraph (a) the legislation automatically provides for the test to be forwarded to the Cervical Rgistry. If it cannot be defined in this way, and as a matter of policy, it is desirable or necessary to obtain those results, histopathology tests should be prescribed as "cancer tests" pursuant to paragraph (b).

## ACCESS BY REGISTRY TO PRE-EXISTING DATA BASE.

Whilst I have considered this issue briefly there would appear to be no statutory provision either authorising or prohibiting such access.

....3

Before considerring this matter further I would appreciate advice from Dr Medley regarding the terms upon which the original data base was collected. For instance, is a person likely to be aware of their listing on the data base and what consent, if any, was obtained regarding the use of the results.

I should add that in perusing the legislation I have experienced difficulty ~~sufficientl~~y in interpreting section 62. Sub-section 62(4) is open to the interpretation that a report can be forwarded under section 62(1) or (2) if paragraphs (a) and (b) of section 62(4) are satisfied. There would be no difficulty in interpretation if the words "before a report is forwarded to an organization under sub-sections (1) or (2)" were not used. Sub-section (4) would simply mean that the steps referred to therein must be taken by a person who makes an examination or takes a specimen. The prohibition imposed by sub-section (3) on persons referred to in sub-sections (1) and (2) would be unambiguous. However the inclusion of these words is inconsistent with the prohibition imposed by sub-section (3) and in my vie w exposes those who are asked to apply the legislation to the risk of prosecution under sub-section (3).

K J O'BRIEN
LEGAL ADVISER

per: P Beeh

Discuss c RM – [illegible]

[illegible]

[illegible]

A member of the Australian Cancer Society
Director: Dr Nigel Gray A.M. MB, BS, Hon. LL.D, FRACP, FRACMA

Anti-Cancer Council of Victoria

2 May 1989

CVX-C-09/1

FOR INFORMATION

Dr Nigel Gray
Director
Anti-Cancer Council of Victoria

Dear Nigel

I write to say that the legislation to facilitate the working of the cervix cytology registry has now passed through the Upper House with appropriate amendments. It is likely that it will be a formality for it to go through the Lower House before being finally passed in the Upper House in the next few weeks.

This means that there will be legislation in place to enable you to take part in the registry as we discussed. The legislation has been amended to ensure that the medical practitioners taking smears do notify women about the registry .It also ensures that they are given some written acknowledgement if they do decide to opt out. The medical practitioner who takes such smears is obliged to clearly mark your request slip saying that this particular result should not be forwarded to the registry. We shall be working on creative ways of ensuring that this system works and that everyone is clear about which results go in, and which don't.

You will recall that we thought it best to pilot the program by sending results to and from the registry via fax machines in the first instance. To do this we need to arrange for your daily worksheets for Pap smears to be translated in your computer to a request for information from the registry about particular women whose Pap smears you have in the laboratory that day. We can either pay for your own programmer to write the program, if it can be done at a reasonable cost, or else provide the programming for you. Dr Peter Rose is the person dealing with the computer programming at the registry end, as you heard the other evening. He has a clear understanding of what is needed.

I write now as we would envisage that the registry should be starting to work by June. In the first instance, the registry will be of major benefit to you in supplying the women's past history when you have a current smear in the laboratory. The next advantage, which will occur with time, is the registry's ability to follow up on abnormal smears which are reported. In this case a system will be developed for working with you and your referring medical practitioners without interference in your professional relationship.

As we discussed the other evening, it is not envisaged that we will be sending reminder notices to women with normal smears for several years. This will give us plenty of time to work through establishing the registry, and making sure that the system work before the registry starts having direct contact with women in the community.

At this stage, I need to know whether you want to write the program necessary to have your computer put the results in a printed form for fax transmission (and for the registry to reimburse you for that cost), or whether you would like some help from us to do this. I also would like to know the average number of smears that are performed in your laboratory per month so that we can look at the long-term possibility of supplying a dedicated personal computer with modern linkage for handling all the results. The fax transmission may well be suitable for those laboratories only performing a relatively small number of smears.

I look forward to hearing from you with these preliminary details at your earliest convenience. The next step will be for me to come out to your laboratory and have a look at how the system might work in your own environment.

Kind regards

Dr Robin Marks
Director of Programs

A member of the Australian Cancer Society
Director: Dr Nigel Gray A.M. MB. BS. Hon. LL.D. FRACP. FRACMA

**Anti-Cancer Council of Victoria**

1 May 1989 41-785

Ms Onella Stagoll
Manager
Women's Health Policy & Programs Unit
Health Department - Victoria
555 Collins Street
Melbourne 3000

Dear Onella,

**Re: Membership of the Victorian Cervical Cytology Registry
Interim Management Committee**

In response to a request by Mr M.N. Cauchi, Chairman of the State Committee, Royal Australian College of Pathologists, the Interim Management Committee has agreed it would benefit from the appointment of a private pathologist to its membership.

Given that the close cooperation of private pathologists will be crucial to the Registry's success, the absence of such a pathologist in the Committee's original membership was considered an oversight that should be corrected as soon as possible.

All members have been selected on the basis of their individual expertise and experience, rather than specific organisational representation. The Interim Committee would therefore like to put forward two nominations: Dr Ralph Zito, Pathologist, Sacred Heart Hospital and Dr. Richard Reed, Chairman, Melbourne Pathology, St. George's Hospital.

To effect this appointment, would you please forward these names to the Minister of Health, The Honourable Caroline Hogg, for her consideration.

Thank you for your help in this matter.

Yours sincerely

Nigel Gray.

Nigel Gray
Chairperson
Interim Management Committee
Victorian Cervical Registry

KEOGH HOUSE, 1 RATHDOWNE STREET, CARLTON SOUTH, AUSTRALIA 3053 ☎ (03) 662 3300
Facsimile: (03) 663 3412 Telex: ACCV AA 34158

A member of the Australian Cancer Society
Director: Dr Nigel Gray A.M. MB BS, Hon. LL.D. FRACP, FRACMA
Anti-Cancer Council of Victoria

4 April 1989

49-918

Mr M.N. Cauchi
Head, Section Haematology/Immunology
Pathology Department
Royal Women's Hospital
132 Grattan Street
Carlton Vic 3053

Dear Maurice,

Robin Marks told me of your discussion about the Interim Management Committee of the pap smear register. It may be helpful if I put the whole issue down on paper as I am not really in control of what happens. The situation is as follows:

1. A decision was made within the Health Department to set up an Interim Management Committee for the register. I understand this was because Canberra had allocated funding for the register and they needed an Interim Management Committee to develop the concept prior to the establishment of a permanent management committee following the passage of the Bill through parliament.

2. I wasn't privy to any of these discussions. I received an invitation to chair the committee just before leaving to go overseas for the whole of February. I chaired a meeting prior to departure and another one immediately after my return. I expect there will be one or two more meetings and that then the committee will disband and give way to the subcommittee of the VC(G)S which will manage the register in the long term.

3. We were allowed to invite outsiders to join the committee through the Minister for Health. At the last committee meeting (10-3-89) it was agreed that it had been a mistake not to invite one of the private cooperating pathologists to join the committee. It was with this in mind that I rang you to let you know that the committee agreed with the contention of the college that a pathologist should have been on it, and that they believed that it was desirable to complement Gabriele Medley's presence with the attendance of a cooperating private pathologist. The two names which came forward were Ralph Zeto and Richard Reed. They were sent off to the minister, as suggestions, straight after the last meeting and I have not yet heard which of them is to be invited. It will be a ministerial decision.

4. No-one on the committee is nominated to the committee by any organisation. All of us are there in our own right. The composition of the committee is:

Myself
Dr. Gabriele Medley
Dr. Robin Marks
Prof. Roger Pepperell
Ms Onella Stagoll
Ms Christine Evely
Ms Heather Jarman
Dr. Heather Mitchell
Mr Ed Wilson
Ms Gillian Ednie

In summary I don't have any power to change things. Further, the committee will only meeting a couple of more times before giving way to the VC(G)S subcommittee which will manage the register.

Under these circumstances, no matter how much I would like to help, there's nothing I can do about changing things.

I hope this clarifies the situation. I can assure you that the Interim Management Committee will be attempting not to make any irrevocable decisions. It is operating in limbo, to some extent, for the simple reason that the legislation is not yet passed by parliament and is quite likely to be amended.

I hope this explanation is helpful.

Best wishes.

Yours sincerely,

Nigel

Nigel Gray
Director

A member of the Australian Cancer Society
Director: Dr Nigel Gray A.M. MB. BS. Hon. LL.D. FRACP. FRACMA

Anti-Cancer Council of Victoria

31 March 1989

49-909

Ms O. Stagoll
Women's Health Policy Unit
Health Department Victoria
555 Collins Street
Melbourne 3000

Dear Onella,

I went to see to David White together with Gabriele Medley and Roger Pepperell in late January. The objective was to stimulate his department to sort out the bureaucratic confusion over the VC(G)S budget. This sorting out process has been substantially delayed by the development of the report of the Review Committee but David undertook to review the problem within a month (which time I was to be overseas) and made an appointment with Gabriele in late February.

You weren't at the meeting with David White - I'm not sure why - but it would be a pity to see this initiative founder.

Another issue which comes to my mind as a result of some Easter thinking about the VC(G)S resolves itself into a question: Has the VC(G)S Board been fully informed about the pap register. I know about it and Roger knows about it but the present Board probably hasn't considered it in any depth. Perhaps it isn't necessary if they're going to be replaced in the near future, because the new Board might be the group which needs to make the relevant decisions to set up the Pap Registry Management Committee as a subcommittee.

We may need to chat about this.

Cheers.

Yours sincerely,

Nigel

Nigel Gray
Director

c.c. R. Marks
G.Medley

KEOGH HOUSE, 1 RATHDOWNE STREET, CARLTON SOUTH, AUSTRALIA 3053 ☎ (03) 662 3300
Facsimile: (03) 663 3412 Telex: ACCV AA 34158

Pop Registry

AUSTRALIAN MEDICAL ASSOCIATION
(VICTORIAN BRANCH)

293 Royal Parade, Parkville, Victoria, 3052
Telephone: 347 8722 Telegrams: MELMED, Melbourne Telex: 32906 Facsimile: 347 9871

Please address all correspondence to: The Executive Director

March 17, 1989.
A.bl/811.

Mr. Alan Rassaby,
Manager, Policy and Legislation Review,
Health Department Victoria,
P.O. Box 4057, G.P.O.,
MELBOURNE. VIC. 3001.

Dear Mr. Rassaby,

Thank you for your letter of 15th March, 1989, further to our discussion about the Cancer (Central Registers) Bill.

I am happy to record my agreement with the understandings reached at our meeting, to which you refer in your letter. We look forward to a statement by the Minister, during the course of debate on the Bill, in which she identifies her general views about the application of the informed consent doctrine. As you know, we would hope that her view coincides with ours to the extent that we have attempted to impress upon Professor Louis Waller the undesirability of any formularised compulsory protocol for giving information to patients and/or recording the patient's acknowledgement and consequent giving of consent.

I have fully discussed the position with the Branch President (Dr. Bill McCubbery) and am happy to now say that we support the Bill and will continue to co-operate in the pursuit of the objectives to which the Bill is directed. Of course, the practical implementation of the whole scheme depends upon the continued full involvement of the AMA in the necessary secondary activities and in the work of the various committees, working parties etc., some of which are already proceeding.

Yours sincerely,

R.R. Hastings

R.R. Hastings
EXECUTIVE DIRECTOR.

Health Department Victoria

Address all mail to
P.O. Box 4057 G.P.O.
Melbourne, Victoria.
Australia 3001

Reference No.

15th March, 1989

Mr Ron Hastings
Executive Director
Australian Medical Association
Victorian Branch
293 Royal Parade
PARKVILLE VIC. 3052

Dear Mr Hastings,

Thank you for participating in a recent meeting with officers of the Health Department Victoria and the Anti-Cancer Council of Victoria on the Cancer (Central Registers) Bill.

The Minister is delighted that we have now found common ground.

My understanding of decisions taken at the meeting is as follows -

. there should be no statutory obligation to seek the informed consent of every women before test results are sent to the Register. Nevertheless, materials explaining the nature and purpose of the Register should be released to all medical practitioners on proclamation of the Act and should make it clear that they should make every effort to ensure that patients are fully informed about all aspects of the Register, including their right to object to test results being forwarded to the Register;

. proposed s.62(4) and s.62(7)(d) should be removed from the Bill by House amendment;

. I am to suggest to the Minister that she make a statement during the course of the debate on the Bill encapsulating her views about the application of the informed consent doctrine;

555 Collins Street, Melbourne. Telephone (03) 616 7777

- the AMA should be closely consulted on the preparation of the written materials to be sent to practitioners. The materials should also contain protocols indicating the exceptional circumstances in which the Register should communicate direct with those women who have abnormal smears and those circumstances in which the normal protocol should apply (i.e. communication first with the pathologist and, if no reply is forthcoming, with the practitioner and subsequently the women).

As a result of our meeting, I think that we now have a better scheme. I hope that I may look forward to your continued support for this Bill during its passage and implementation and I thank you for your input to date.

Yours sincerely,

ALAN RASSABY
Manager, Policy and Legislation Review

c.c.: O. Stagoll, HDV
N. Gray, Anti-Cancer Council of Victoria
L Hunter, HDV

id274/125-126/vmd

20 MAR 1989

Health Department Victoria

Address all mail to
P.O. Box 4057 G.P.O.
Melbourne, Victoria.
Australia 3001

Reference No.

15th March, 1989

Mr Ron Hastings
Executive Director
Australian Medical Association
Victorian Branch
293 Royal Parade
PARKVILLE VIC. 3052

Dear Mr Hastings,

Thank you for participating in a recent meeting with officers of the Health Department Victoria and the Anti-Cancer Council of Victoria on the Cancer (Central Registers) Bill.

The Minister is delighted that we have now found common ground.

My understanding of decisions taken at the meeting is as follows -

- there should be no statutory obligation to seek the informed consent of every women before test results are sent to the Register. Nevertheless, materials explaining the nature and purpose of the Register should be released to all medical practitioners on proclamation of the Act and should make it clear that they should make every effort to ensure that patients are fully informed about all aspects of the Register, including their right to object to test results being forwarded to the Register;
- proposed s.62(4) and s.62(7)(d) should be removed from the Bill by House amendment;
- I am to suggest to the Minister that she make a statement during the course of the debate on the Bill encapsulating her views about the application of the informed consent doctrine;

TO RM ✓
DA ✓
DH ✓

555 Collins Street, Melbourne. Telephone (03) 616 7777

- the AMA should be closely consulted on the preparation of the written materials to be sent to practitioners. The materials should also contain protocols indicating the exceptional circumstances in which the Register should communicate direct with those women who have abnormal smears and those circumstances in which the normal protocol should apply (i.e. communication first with the pathologist and, if no reply is forthcoming, with the practitioner and subsequently the women).

As a result of our meeting, I think that we now have a better scheme. I hope that I may look forward to your continued support for this Bill during its passage and implementation and I thank you for your input to date.

Yours sincerely,

ALAN RASSABY
Manager, Policy and Legislation Review

c.c.: O. Stagoll, HDV
N. Gray, Anti-Cancer Council of Victoria
L Hunter, HDV

id274/125-126/vmd

Health Department Victoria

Address all mail to
P.O. Box 4057 G.P.O.
Melbourne, Victoria.
Australia 3001

Reference No.

[illegible] Prof Regarding

15th March, 1989

Mr Ron Hastings
Executive Director
Australian Medical Association
 Victorian Branch
293 Royal Parade
PARKVILLE VIC. 3052

Dear Mr Hastings,

Thank you for participating in a recent meeting with officers of the Health Department Victoria and the Anti-Cancer Council of Victoria on the Cancer (Central Registers) Bill.

The Minister is delighted that we have now found common ground.

My understanding of decisions taken at the meeting is as follows -

- there should be no statutory obligation to seek the informed consent of every women before test results are sent to the Register. Nevertheless, materials explaining the nature and purpose of the Register should be released to all medical practitioners on proclamation of the Act and should make it clear that they should make every effort to ensure that patients are fully informed about all aspects of the Register, including their right to object to test results being forwarded to the Register;
- proposed s.62(4) and s.62(7)(d) should be removed from the Bill by House amendment;
- I am to suggest to the Minister that she make a statement during the course of the debate on the Bill encapsulating her views about the application of the informed consent doctrine;

- the AMA should be closely consulted on the preparation of the written materials to be sent to practitioners. The materials should also contain protocols indicating the exceptional circumstances in which the Register should communicate direct with those women who have abnormal smears and those circumstances in which the normal protocol should apply (i.e. communication first with the pathologist and, if no reply is forthcoming, with the practitioner and subsequently the women).

As a result of our meeting, I think that we now have a better scheme. I hope that I may look forward to your continued support for this Bill during its passage and implementation and I thank you for your input to date.

Yours sincerely,

ALAN RASSABY
Manager, Policy and Legislation Review

c.c.: O. Stagoll, HDV
N. Gray, Anti-Cancer Council of Victoria
L Hunter, HDV

id274/125-126/vmd

The Royal College of Pathologists of Australasia

STATE COMMITTEE
VICTORIA

Rang him 14.3.89.

1. Ralph Zito or Richard Reed OK
2. He suggested Dempster [illegible] [illegible] and no mention of [illegible]
3. [illegible] ahead [illegible] off.
4. He's happy. Would like to be kept informed,

8 March 1989

Dr Nigel Gray
Anti-Cancer Council of Victoria
1 Rathdowne Street
CARLTON VIC 3053

Dear Dr Gray

<u>RE: Victorian Cervical Cytology Registry</u>.

I understand that an Interim Management Committee of the Victorian Cervical Cytology Registry has been set up. I am disappointed that a nominee from the Royal College of Pathologist of Australasia has not been formally sought, to take part in this Committee.

Yours sincerely

DR M N CAUCHI
CHAIRMAN
STATE COMMITTEE
RCPA

MC:vp

[illegible]

RECEIVED
13 FEB 1989

AUSTRALIAN MEDICAL ASSOCIATION
(VICTORIAN BRANCH)

293 Royal Parade, Parkville, Victoria, 3052
Telephone: 347 8722 Telegrams: MELMED, Melbourne Telex: 32906 Facsimile: 347 9871

Please address all correspondence to: The Executive Director

[illegible] Release -

February 9, 1988.
A.bl/811

Dr. Robin Marks,
Director of Programmes & Management,
Anti-Cancer Council of Victoria,
1 Rathdowne Street,
CARLTON SOUTH. VIC. 3053.

Dear Robin,

As discussed, this letter briefly summarises the areas of concern we have with the Cancer (Central Registers) Bill, and follows our more detailed discussion with you and Ms. Dorothy Reading on Tuesday last.

1. The patients in question are private citizens, not suspected of suffering from any contagious disease or other condition which has the potential for affecting the rights of other citizens. We therefore insist that disclosure of clinical information arising from private medical attention should not be transmitted to a third party unless the patient has given fully informed consent.

2. The ability of other parties to access the centrally held data, if a patient has agreed to information being centrally held, should be rigidly identified in the Act and not left for control through subordinate legislation or administrative ordinance.

3. Any follow-up of patients, whether because of positive results from a previous test or because of the simple effluxion of time since a previous test, must be via the usual medical attendant.

4. Medical practitioners should be very heavily present on steering committees and the formal committee of management, and in all cases they should be nominated by the AMA and in at least one case, should be formally representative of the AMA.

../2

Our discussions with the then Minister (David White) on 3rd February, 1989, covered all of the above points and, as you may be advised by the Health Department officers who were present at that discussion, the Minister was sympathetic on all points and in some cases gave a positive commitment. It was his request that we discuss with you the possibility of agreed ways of resolving any difference of view. I do not believe there is a fundamental disagreement between our view and yours and, as discussed, we look forward to urgent discussion with Mr. Alan Rassaby so that any necessary changes may be introduced without delaying passage of the legislation during the autumn session of Parliament.

Kind regards.

Yours sincerely,

R.R. Hastings
EXECUTIVE DIRECTOR.

A member of the Australian Cancer Society
Director: Dr Nigel Gray A.M. MB. BS. Hon. LL.D. FRACP. FRACMA
Anti-Cancer Council of Victoria

26 January 1989

49-841

Dr. G. Medley
Victorian Cytology (Gynaecological) Service
P.O. Box 253b
Melbourne Vic 3001

Dear Gabriele,

I noted your comments about the possible difficulties with the Registry of Cervical Smears.

I'm flying blind on this at the moment. I know the background up to the last couple of months but have been asked by the Minister to chair the committee and did not feel I could do anything else but accept. Since it hasn't met I can't comment on your worries but will take them with me to the meeting and make sure nothing is done to interfere with your convenience as best I can. It should be possible!

Cheers.

Yours sincerely,

Nigel

Nigel Gray
Director

VICTORIAN CYTOLOGY (GYNAECOLOGICAL) SERVICE
236-254 St. Kilda Road, Melbourne, 3004

P.O. BOX 253B
MELBOURNE
VICTORIA 3001
AUSTRALIA
Telephone: (03) 614-6822

Director: GABRIELE MEDLEY
M.B., B.S., F.R.C.P.A., F.I.A.C.

17th January, 1989

Dr. Nigel Gray,
Anti-Cancer Council of Victoria,
1 Rathdowne Street,
CARLTON, 3053, Vic.

18 [illegible] 1989

Dear Nigel,

I write to express to you some serious anxieties I hold regarding our long awaited "Registry of Cervical Smears."

There would appear to be two possible, completely different, scenarios for the Registry.

a) That it functions as an independant entity with its own computer, in any site eg. at Anti-Cancer Council. It could have as its nucleus a "down load" of the total V.C.(G.)S. file and would receive all future data either by electronic means or "hard copy" (eg. FAX) depending on the size of the forwarding laboratory.

b) That it functions within the V.C.(G.)S. using the V.C.(G.)S. file and data processing facility as its nucleus but with appropriate hardware and software to deal with both the extra numbers and extra functions associated with the Registry, and utilizing the accumulated expertise of the personnel of the Service with appropriate additional staffing.

This option would, I believe, necessitate that the day to day operation be under the "control" of the V.C.(G.)S. as the daily receipt and output of routine work by the V.C.(G.)S. would remain central and if priorities for tasks needed to be established this would have to be done by V.C.(G.)S. management.

There would, of course, be an "Advisory Board" which would handle philosophical and financial decisions apposite to the Registry but I believe that the staff employed by the Registry would have to be responsible to V.C.(G.)S. management in the performance of their daily tasks.

I have been somewhat disturbed to hear that advertisements are currently being drafted within the Health Department for a "Manager" (Project Director) of the Registry and V.D.U. staff. I believe that some quite fundamental issues need to be sorted out before this occurs.

...2

VCSACK

Nigel, as you know I have a very strong commitment to this Registry, its history really takes its origin in discussions that you and I have had over several years. However I believe that the logistics must be correctly specified right at the benginning if it is to fulfill the "dream" that we have had.

I would be most grateful for your advice.

With kindest regards.

Yours sincerely,

GABRIELE MEDLEY,
DIRECTOR.

VCSACK

VICTORIAN CYTOLOGY (GYNAECOLOGICAL) SERVICE

236-254 St. Kilda Road, Melbourne, 3004

P.O. BOX 253B
MELBOURNE
VICTORIA 3001
AUSTRALIA
Telephone (03) 614-0822

Director GABRIELE MEDLEY
MB.BS FRCPA FIAC

17th January, 1989

Dr. Nigel Gray,
Anti-Cancer Council of Victoria,
1 Rathdowne Street,
CARLTON, 3053, Vic.

Dear Nigel,

I write to express to you some serious anxieties I hold regarding our long awaited "Registry of Cervical Smears."

There would appear to be two possible, completely different, scenarios for the Registry.

a) That it functions as an independant entity with its own computer, in any site eg. at Anti-Cancer Council. It could have as its nucleus a "down load" of the total V.C.(G.)S. file and would receive all future data either by electronic means or "hard copy" (eg. FAX) depending on the size of the forwarding laboratory.

b) That it functions within the V.C.(G.)S. using the V.C.(G.)S. file and data processing facility as its nucleus but with appropriate hardware and software to deal with both the extra numbers and extra functions associated with the Registry, and utilizing the accumulated expertise of the personnel of the Service with appropriate additional staffing.

This option would, I believe, necessitate that the day to day operation be under the "control" of the V.C.(G.)S. as the daily receipt and output of routine work by the V.C.(G.)S. would remain central and if priorities for tasks needed to be established this would have to be done by V.C.(G.)S. management.

There would, of course, be an "Advisory Board" which would handle philosophical and financial decisions apposite to the Registry but I believe that the staff employed by the Registry would have to be responsible to V.C.(G.)S. management in the performance of their daily tasks.

I have been somewhat disturbed to hear that advertisements are currently being drafted within the Health Department for a "Manager" (Project Director) of the Registry and V.D.U. staff. I believe that some quite fundamental issues need to be sorted out before this occurs.

...2

Nigel, as you know I have a very strong commitment to this Registry, its history really takes its origin in discussions that you and I have had over several years. However I believe that the logistics must be correctly specified right at the benginning if it is to fulfill the "dream" that we have had.

I would be most grateful for your advice.

With kindest regards.

Yours sincerely,

GABRIELE MEDLEY,
DIRECTOR.

c.c. Gillian Edney
Onella Stagoll

VCSACK

VICTORIAN CYTOLOGY (GYNAECOLOGICAL) SERVICE
236-254 St. Kilda Road, Melbourne, 3004

P.O. BOX 253B
MELBOURNE
VICTORIA 3001
AUSTRALIA
Telephone (03) 614-6822

Director GABRIELE MEDLEY
MB BS FRCPA FIAC

20th January, 1989

## REGISTRY OF CERVICAL SMEARS

In order to plan the logistics of this Registry it is important to specify precisely what the Registry wishes to achieve, to delineate the staged nature of such implementation and to define the exact relationship between the V.C.(G.)S. and the Registry.

### AIMS OF REGISTRY:

1. To provide a central data base which encompasses all cervical smears performed in Victoria, giving accurate detail of number of women screened (i.e. individual identification of women), results of smears, and follow-up information of abnormal smears.

   Note: Full Name, Date of Birth, Address and Doctor's name are specified as minimal entry criteria.
   (? Subsequent addition of Medicare/Tax File/I.D. Number).

   To improve compliance and thereby facilitate "matching" of patients I believe a Newsletter to all users*should be sent prior to the commencement of the Registry and thereafter, perhaps 4 x year. Such a newsletter series dealing with matters such as importance of accurate identification, making the smear a "comfortable" experience for women, sampling the cervix, fixation, labelling of smears, reporting philosophy, current problems in cervical pathology etc., is currently under preparation for V.C.(G.)S. users.

2. To provide participating laboratories with details of history of which they may be unware, of previous abnormality for cases notified, thereby improving the quality of assessment and appropriate recommendation.

### METHODOLOGY:

Both the notification to the Registry and the flow of information from the Registry may be -

a) By electronic transfer with provision to referral laboratories of a V.D.U., slave printer and communication device.

b) By hard copy (FAX) from a print-out of cervical smears generated once or twice daily by the referring laboratory.

---

* User: person taking smear eg. referring doctor, family planning clinic etc.

...2

VCSAAB

I believe that during Phase 1. of the implementation process an initial period of transfer of all data by FAX in both directions would be appropriate to establish a knowledge of numbers of cases reported by various referring laboratories, and put in place appropriate protocols.

Subsequently electronic transfer methodology would be brought online for those laboratories referring more than 50 cases per day.

The method of electronic transfer would depend on the data processing facility of the referring laboratory. Its function would be -

a) To immediately access from the Master File "perfect matches" of patients utilizing given name, surname and date of birth and to receive back the appropriate history link* for such patients. Such perfect matches would enter the file.

b) To list patients from whom such "perfect match" is not available; such list to be processed by Registry staff as a manual operation, to be reported back to the laboratory and entered by Registry staff to file.

c) To transmit reports of smears as they are completed, to the Registry File.

d) To receive reports of incomplete transactions after a "specified" period. Such reports would be monitored by Registry staff.

e) To transmit follow-up information to the Registry so that a manual correlation can be performed and entered by Registry staff.

f) To receive print-outs of statistical data.
eg. Rate of Abnormal Smears.
Correlation rates.
Other Quality Control data - eg. comparison with other coded laboratories.

It would NOT be possible for peripheral users directly to access the Master File (except for pefect match), to amend any patient details on the existing file, or to access any of the programmes run by the Registry. Security must be maximal.

Smaller users would continue to transmit and receive information by non-electronic methodology.

* History Link: Known cytological history of matched patient.

...3

## SUBSEQUENT STAGES TO BE CONSIDERED:

1. Generation of stationery for follow-up smear requests and requests for histology reports, treatment history etc. for those patients where this does not occur spontaneously.

   a) Directly from Registry → users of cytology services.
   b) From Registry → pathology service.

Question: Where would the responsibility for follow-up reside?

2. Repeat Smear reminders for normal women.

Question: What interval would be recommended?

eg. Currently private laboratories - 1 year
V.C.(G.)S. - 2 years
Consensus - 3 years ?

Would reminders be sent directly to women, to "user" or to referring pathology laboratory.

3. Recruitment of unscreened women from other data bases of Victorian women eg. Medicare, Electoral Roll etc.

Further refinements which would need modifications of input and therefore consideration of uniform cytology request slips may be considered from the beginning, or at any subsequent time.

eg. Clinical Data - parity
contraceptive use
country of origin etc.

However - compliance by users is generally poor and a preliminary educational newsletter informing all users of the Registry and its aspirations (as stated under "Aims") will be needed.

## RELATIONSHIP BETWEEN V.C.(G.)S. and REGISTRY:

If the Registry is to utilize the V.C.(G.)S. data base and data processing facility, there will require to be detailed discussion to define precisely the staff structure of the Registry in relation to V.C.(G.)S. and the channels of authority, responsibility and reporting.

VCSAAB

VICTORIAN CYTOLOGY (GYNAECOLOGICAL) SERVICE
236-254 St. Kilda Road, Melbourne, 3004

P.O. BOX 253B
MELBOURNE
VICTORIA 3001
AUSTRALIA
Telephone: (03) 614-6822
FAX NO: (03) 629-7510

Director: GABRIELE MEDLEY
M.B., B.S., F.R.C.P.A., F.I.A.C.

27th January, 1989

31 JAN 1989

Ms Gillian Edney,
25 Thompson Street,
ORMOND, 3204, Vic.

Dear Gillian,

RE: CENTRAL REGISTRY OF CERVICAL SMEARS.

Following our discussion the other day I wrote to Dr. Gray indicating my areas of anxiety, and also wrote a short document on my ideas about the functioning and staging of the Registry. Since I am not on the interim committee and will thus not have any direct input to the discussions, (although the ultimate responsibility of maintaining the V.C.(G.)S. day to day performance will presumably remain mine,) I would be grateful if you could arrange to table these at the meeting.

With kind regards.

Yours sincerely,

GABRIELE MEDLEY,
DIRECTOR.

c.c. Onella Stagoll
Dr. Nigel Gray

A member of the Australian Cancer Society
Director: Dr Nigel Gray A.M. MB. BS. Hon. LL.D. FRACP, FRACMA
**Anti-Cancer Council of Victoria**

6 January 1989

49-775

The Hon. D. White
Minister for Health
G.P.O. Box 4057
Melbourne 3001

Dear Minister,

Thank you very much for your letter of December 23 in which you invite me to become Chairman of the Interim Project Management Group of the Victorian Cervical Cytology Registry.

I'm naturally delighted that you've established this group and will be very pleased to chair it.

I will need to ask my Executive Committee's permission to do this job - I've already asked my Chairman and he's agreed and therefore I believe you can assume that the Executive Committee will ratify it at the end of February. In summary, I'm delighted to be invited and will be available straight away (although I will be out of the country during February).

Best wishes and Happy New Year.

Yours sincerely,

Nigel Gray
Director

KEOGH HOUSE, 1 RATHDOWNE STREET, CARLTON SOUTH, AUSTRALIA 3053 ☎ (03) 662 3300
Facsimile: (03) 663 3412 Telex: ACCV AA 34158

VICTORIA
MINISTER FOR HEALTH

PLEASE ADDRESS
CORRESPONDENCE TO
BOX 4057
MELBOURNE, VICTORIA
AUSTRALIA, 3001

555 COLLINS STREET
MELBOURNE
TELEPHONE 616 7777
(AREA CODE 03)

-3 JAN 1989

23 DEC 1988

Dr Nigel Gray
Anti Cancer Council of Victoria
1 Rathdowne Street
Carlton South 3053

Dear Dr Gray,

**Re : Victorian Cervical Cytology Registry**

As part of the National Cervical Cancer Screening Strategy, the Commonwealth Government has allocated funds to pilot a statewide Cervical Cytology Registry in Victoria.

Over the two year pilot period, the project aims to establish a central data base for cervical cytology records and thereby:

- increase epidemiological knowledge about cervical cancer and its precursor lesions at a population level
- increase follow-up rates after abnormal smears & monitor this
- improve the quality of smear reading and reporting
- initiate a range of recruitment strategies to increase the number of women screened for the first time and the number screened at the prescribed interval (recall)
- provide recording and evaluation facilities for other screening projects
- evaluate the effectiveness of the Registry's contribution to reducing the incidence and mortality rates for cervical cancer.

The Registry will be established by extending existing Victorian Cytology (Gynaecological) Service computer facilities and connecting participating pathology laboratories, (eleven have been nominated to date), to its data processing, recording and evaluation services. Ultimately, it is hoped to that the results of all pap smear tests taken in Victoria will be included.

The project is currently in its very earliest stage of development. Its future site is still to be determined pending a decision on the relocation of the VC(G)S. Legislation to facilitate the reporting of confidential smear results to the Registry is presently before Parliament. An interim Project Management Committee and a small staff, are now being appointed.

The Committee will comprise the following representatives :

- Health Department, Victoria
- VC(G)S Board Member
- VC(G)S Epidemiologist
- 2 Anti-Cancer Council of Victoria
- Private pathology services
- a general practitioner
- 2 women health consumers
- a community health nurse from the Victorian Community Based Cervical Screening Pilot Project
- a Family Planning Nurse

The early stages of development, particularly the first six months, will be critical to the project's success. Your contribution during this time, as Anti-Cancer Council of Victoria representative, would be greately appreciated. It is envisaged that in time membership may change to some extent, depending on the interests and time commitments of members, once the project enters its implementation and evaluation stages.

Committee meetings, commencing in January 89, will be held monthly or more frequently if required for particular aspects of the project.

I would be grateful if you would consider chairing this committee during this important developmental stage. I have asked Onella Stagoll, Manager, WHP&PU to contact you to discuss further details regarding Committee membership and the project in general. In the meantime, please feel free to contact her on 616 8047.

I look forward to your positive response to this invitation.

Yours sincerely,

DAVID WHITE
Minister for Health

5 January 1989 49-767

**MEMORANDUM TO:** Executive Committee

**FROM:** Nigel Gray

=====================================================================

The Committee will recall previous discussions on progress towards the establishment of a Victorian Cervical Cytology Registry.

Robin Marks organised the consensus producing discussions which achieved the potential collaboration of the pathologists and also the discussions with the AMA and other interested parties.

This proposal is the subject of legislation which is now on the table of the Victorian house of parliament. The legislation is quite small in content and merely facilitates the establishment of this registry as a voluntary exercise. The legislation was required to confer immunity from prosecution on doctors who notify the confidential details of patients smears to the register. In other words the legislation differs from that covering the Victorian Cancer Registry under which doctors are **compelled** to notify cases of cancer. In the case of pap smears they are **invited** to notify them and given an immunity from prosecution if they do.

Very widespread discussions were held by Robin and Dorothy Reading with the various women's groups who were involved and we have uniform support for the initiative from everybody on the political spectrum including the CWA and the Victorian Council for Civil Liberties. The only grumbles came from the divisions of general practice and obstetrics and gynaecology within the AMA.

It seems likely that the legislation will pass without difficulty, although obviously if any interest group starts to make a fuss about it, it will die.

The state government has been successful in negotiating with the federal government for funding for the registry. This activity arises from the initiative developed by the Health Department of Victoria's working party on the future of the VC(G)S and by Heather Mitchell, epidemiologist to the Victorian Cytology Service, and the Women's Health Policy Unit within the Health Department of Victoria.

The government has now made a decision to establish the registry with the funds made available and has invited me to chair the interim project management committee and invited Robin Marks to be the second representative of the Anti-Cancer Council of Victoria. He and I received identical letters. A copy is attached.

This initiative looks to be a good one and will go a long way towards solving the problem of recruiting the 250,000 never screened Victorian women into an organised program. The activity requires collaboration between the Health

Department of Victoria and the Victorian Cytology Service - who provide the **service** component for reading of pap smears; between the Women's Health Policy Unit of the Health Department who provide the **budget** for the registry and also take those **service** initiatives available to the Health Department which include provision of pap smear services through community health centres (many of which will be staffed by non-medical people!); and the Anti-Cancer Council which has traditionally occupied the territory of **public and professional education** in this field.

I have been invited to be chairman of the committee and it would seem sensible that, at least for the first year or two, I accept this invitation. In due course it would be logical for either Robin or myself to stand aside for Dorothy Reading. She is the person with responsibility for the public education program. However, initially the government's choice of Robin and myself is probably a wise one and, anyway, is their choice.

Would the committee please ratify our acceptance of the invitation?

Since there is pressure for the committee to start work I have checked this request with the Chairman, who agreed that we should accept.

Att. Letter from the Minister for Health

# VICTORIAN CERVICAL CYTOLOGY REGISTRY

AGENDA for meeting of Interim Management Committee
To be held on 31st January 1989
from 2.30 – 4.30 pm at the
Anti Cancer Council of Victoria
etc etc

1. INTRODUCTION OF MEMBERS
   names – representative nature

2 APOLOGIES

3. BUSINESS
   - 3.1 Committee Procedures
     - 3.1.1 Terms of Reference – To be determined
     - 3.1.2 Membership
       To accept/amend current membership – [illegible]
     - 3.1.3 Meeting Times
       To determine meeting dates, times + location.
       PLEASE BRING YOUR DIARIES

3.2 Project Budget
Based on a proposal submitted in May 1988, to note that $419,000 was allocated to the project as follows:

| | |
|---|---|
| 1987/88 | $132,000 |
| 1988/89 | $150,000 |
| 1989/90 | $137,000. |

3.3 Preliminary Project Plan
Copy of this plan, submitted to the national Screening Evaluation Coordination Unit in November 1988, is attached. Note that a Project Plan and detailed guide to contents of procedures manuals has been provisionally promised to SECU by mid February, 1989.

3.4 1989 Project Timelines
Draft timelines to establish the Registry are attached. working manuals

3.5 Establishing the Registry

3.5.1 Appointment of Co-ordinator
See draft job description, advertisement and timelines attached - selection sub-committee to be appointed.

3.5.2 Appointment of Computer Consultant
Required to design computer specifications, recommend hardware, software and external communication systems, and oversight purchase, installation and test of equipment.

3.5.3 Guidelines for Registry's relationship with the VC(G)S
To be developed.

4. ANY OTHER BUSINESS

5. NEXT MEETING
To be determined.

Tasks

Terms.

Relation with commonwealth.

# PRELIMINARY PROJECT PLAN FOR THE
# VICTORIAN CERVICAL CYTOLOGY REGISTRY
# PILOT PROJECT

CONTENTS :

## INTRODUCTION

Due to the large number of participants involved and the breadth of the project, these specifications will not be finalised until the Project Officer and Management Committee are appointed and fully functional later this year.

A Preliminary Plan, rather than a Project Plan, is submitted which summarises the information currently available. As the Registry Project embraces a unique combination of features from the screening pathway, the structure of the Model Timetable and Procedures Manual have been adapted. Until project protocols are finalised, much of the material presented will remain provisional, particularly the evaluation procedures which require substantial development.

SECU's views on the contents of this Preliminary Project Plan will be welcomed as will its close involvement in developing the various protocols in the near future.

## A. PROJECT TIMETABLE (Provisional)

| Milestone/Documentation/Data | Date of Delivery to SECU |
|---|---|
| REGISTRY SERVICES (Stage 1) | |
| · Detailed guide to contents of procedures manuals | With Project Plan mid February 1989 |
| · informed consent legislation | March/April 1989 |
| · commence service functions | May 1989 |
| · submit procedure manual updates | August 1989 |
| RECRUITMENT STAGES* (Stage 2 & 3) (length of recall & call to be determined) | |
| · pilot recall using pre-existing VC(G)s data | July 1989 |
| · submit procedure manual updates | September 1989 |
| · call* | |
| · submit procedure manual updates | May 1990 |

* In the event of pilot initiatives within Victoria which utilise individualistic call procedures from a pap registrar being undertaken, the register will assist in the event of such research efforts.

SUBMISSION OF DATA SECU

| Data covering the period : | Last date of delivery to SECU |
|---|---|
| 1 May 1989 to 31 October 1989 | 31 December 1989 |
| 1 November 1989 to 31 March 1990 | 30 April 1990 |
| 1 April 1990 to 20 June 1990 | 30 June 1990 |

EVALUATION

| | |
|---|---|
| . times and dates to be advised with Project Plan | mid February 1989 |

## B. PROCEDURES MANUAL GUIDE TO CONTENTS

## B.1 SUMMARY OF THE PROJECT

### 1.1 GOALS

To establish a statewide computerised data base for cervical cytology records and thereby :

- increase epidemiological knowledge about cervical cancer and its precursor lesion at a population level.
- increase follow-up rates after abnormal smears
- improve the quality of smear reading and reporting
- initiate a range of recruitment strategies to increase the number of women screened at the prescribed interval (recall) and screened for the first time (call)
- provide recording and evaluation facilities for other screening projects
- evaluate the effectiveness of the Registry's contribution in reducing the incidence and mortality rates for cervical cancer.

### 1.2 DESIGN

The project will be implemented in three consecutive stages.

Stage 1 consists of establishing the data base by extending VC(G)s computer facilities and connecting participating laboratories with its data processing, recording and evaluation services.

Stage 2 (Recall) involves increasing the number of women screened at the prescribed interval* by :

- selecting a target population from the Registry's records for individual recall by letter of invitation
- supported by public awareness/educational strategies.

Stage 3 (call) involves recruiting previously unscreened women to participate in a regular screening program by :

- selecting a target population from a suitable population register (cross referenced with Registry records) for individual recruitment by letter of invitation
- supported by public awareness/educational strategies

This stage will only be proceeded with if there is community and professional acceptance of it after pilot studies.

Each stage of the project, and its overall performance will be evaluated on an ongoing and survey sample basis using a variety of relevant methodologies.

## 1.3 LOCATION

The Registry will be located within the Victorian Cytology (Gynaecological) Service currently housed at Prince Henry's Hospital Melbourne. Due to the planned relocation of the VC(G)S, the Registry will move to a new Melbourne site within the life of the project. Negotiations to determine the VC(G)S's new host hospital are soon to be finalised.

---

* Prescribed interval will be set at 3 years for the purposes of this study

## 1.4 STAFFING

Project Staff will comprise :

Epidemiologist shared with the VC(G)S
Project Manager
Assistant Epidemilogist (1/2 time)
Medical Records/Administrative Officer
2 VDU Operators
Computer and Statistician Consultancies

## 1.5 ORGANISATIONAL/INSTITUTIONAL AFFILIATIONS

The Registry's principal organisational affiliation will remain with the VC(G)S and through it to the host public hospital. The Registry will also negotiate contractual relationships with the individual cytology laboratories participating in the project.

## 1.6 FUNDING SOURCES AND LEVELS OF FUNDING

It is expected that the project will be funded by the Commonwealth and State Governments according to the schedule below. The timing of the State's Capital contribution is provisional at this stage, pending relocation. VC(G)S is a publicly funded laboratory at the cost to HDV of $2 million. HDV will make available appropriate space and provide for utilities and overheads.

| | 1987/88 ($1,000) | 1988/89 ($1,000) | 1989/90 ($1,000) |
|---|---|---|---|
| C/wealth | 132 | 150 | 137 |
| State (Operating) | *52 | 52 | 52 |

## 1.7 MANAGEMENT STRUCTURE AND OVERSIGHT STRUCTURE

The Registry Project will be developed and implemented by a Management Committee accountable through the VC(G)S Board of Management to the Health Department, Victoria. The Management Committee will also closely liaise with the Women's Health Policy & Program Unit of the Health Department and the Anti Cancer Council of Victoria. Members will be appointed in November and comprise:

. Health Department, Victoria

---

* Epidemiologist Salary

- VC(G)S Board Member VC(G)s and Epidemiologist
- Anti-Cancer Council of Victoria
- A Cyto-pathologist from a participating private and public laboratory
- A representative of private pathology services
- a general practitioner
- 2 women health consumers
- a Family Planning Nurse

The Committee will be supported by a Project Officer, accountable to the Management Committee.

## B.2 MAJOR FUNCTIONS AND PROCEDURES OF THE PROJECT

### 2.1 LIST OF PARTICIPATING LABORATORIES

- the VC(G)S
- private laboratories (see Attachment 1 for provisional list

### 2.2 DATA SUPPLIED BY PARTICIPATING LABORATORIES

| VC(G)S | External Laboratories |
|---|---|
| Names/previous surname | Name/previous surname |
| Birthdate | Birthdate |
| Address | Address |
| Date of Smear Receipt | Date of Smear Receipt |
| Referring Practitioner Code | Referring Practitioner Code |
| Parity<br>Hormonal Status<br>Contraception<br>Appearance of Cervix<br>Relevant Past History (pelvic irradiation etc) | (Note : additions to this minimum dataset to be negotiated with the Laboratories) |
| Smear results (coded according to the classifications recommended by the Epidemiological Workshop) | Smear results |
| Follow up Action Recommended (Coded according to the type of further investigation/treatment recommended) | Follow up Action Recommended |
| Results of Follow-up Action (as per smear results code) | Results of Follow-up Action |

Note : Details of codes used are yet to be determined.

## 2.3 DATA SUPPLIED TO PARTICIPATING LABORATORIES

- summary of women's past smear tests (dates and results) matched to current smear identification, where previous records exist
- follow-up reminder notices when expected dates for further results from recommended action have elapsed
- various reports on each laboratories own performance in processing smears, reporting results, quality control procedures etc
- links with the Cancer Registry
- other information as requested

N.B. (As per project Proposal)

## 2.4 DATA TRANSMISSION/PROCESSING PROCEDURES

VC(G)S data will be keyed directly into the Registry from VC(G)S cytology request forms. External laboratories will extract the prescribed data set from their own records (computerised) and submit batch data to the Registry via modem.

Once the initial identifying data is received, the Registry will search its data base and return details of any matches (i.e.previous smear records held) together with patient histories to the relevant laboratory via modern linkage.

On receipt of smear results, the Registry will update its records (update existing files or create new ones) and establish follow up flags where further diagnosis/treatment is recommended. These follow-up flags will be activated at a prescribed time after the recommended date for follow-up services has elapsed.

## 2.5 NOTIFICATION PROCEDURES

Responsibility for promptly advising women and their practitioners of smear results (positive and negative will remain with the laboratory concerned. Similarly responsibility for issuing reminder follow-up notices rests with the laboratories. However, the registry will provide a follow-up reminder service directed initially to the laboratories and subsequently to the women and/or service providers. A schedule specifying the time intervals and targets for these notices is yet to be finalised.

## 2.6 LEGISLATIVE PROVISIONS

Legislation to amend the Victorian Cancer Act 1958 will be presented to the Autumn Session of Parliament, beginning in March 1989.

Specifically, the Bill will :

- enable medical practitioners, including pathologists and radiologists to report the results of cancer tests to the central register without the specific consent of the person tested.
- indemnify doctors against any action to which they might otherwise be subject for reporting confidential information
- restrict access to identifying data in the Registry to doctors seeking information to assist them in interpreting test results, or when a test is due, or upon supply of a consent form signed by the woman concerned for other information.
- permit epidemiologist access to Registry data subject to the written approval of the Chief General Manager of the Health Department Victoria for each particular study.

Women having smear tests will have the right to :

- prevent their test result being sent to the Registry, and
- have identifying data related to their results deleted from the Registry.

The legislation has been extensively discussed with representative and community bodies. These include the Australian Medical Association, Royal Australian Nursing Federation, Royal College of Pathologists of Australia, Royal College of Obstetricians and Gynaecologists and the Victorian Civil Liberties Council as well as a wide variety of womens interest groups such as Health Sharing Women, Victorian Womens Health Network National Council of Women and the Health Issues Centre.

It is intended that all women are made aware of their rights through education programs to promote the legislation.

## 2.7 SELECTION OF TARGET POPULATIONS FOR RECRUITMENT

The project will specify different target populations for its different services and recruitment strategies as follows :

STAGE 1 Ultimately the target population will cover all women screened in Victoria.

STAGE 2 Target groups for recall procedures will be identified and drawn from existing VC(G)S records as the projects evaluation lifespan will not permit the inclusion of screening records processed after 1986 (to comply with the recommended 3 year interval)

The size and characteristics of these target groups are yet to be determined.

STAGE 3 Target groups for call recruitment will be identified by cross referencing the Registrys database with other nominated population registries to determine which women do not have a known screening history in Victoria.

## 2.8 OTHER SCREENING PROJECTS

The Registry will also service a Pilot Community Based Cervical Screening Project currently being developed. The geographic localities will be determined once pilot Community Health Centres are selected. The project will target under and unscreened women in high risk categories i.e. women over 40 years old, rural, non-english speaking and aboriginal women.

Note : For Stage 2 and 3, the project will adopt the age eligibility and screening intervals recommended by the Interval Consensus Conference and current epidemiological opinion on those women considered most at risk. To date the distribution of eligible women by age is available (see Attachment 2), but distribution by ethnic background and educational level is yet to be obtained.

## 2.9 QUALITY ASSURANCE

Final details on the quality control procedures related to:

- technical quality control
- detection rates for inadequate & abnormal smears
- documentation & reporting
- follow-up rates, etc

are subject to negotiations with participating laboratories. Minimum quality assurance procedures will be specified in the contracts between the Registry and participating laboratories.

## 2.10 REVIEW BY INSTITUTIONAL ETHICS COMMITTEE

It is proposed that all protocols related to research activities, will be submitted to the Prince Henry's Hospital Research Advisory and Ethics Committee (and new host hospital) for approval.

## 2.11 WOMENS VIEWS

### Information Supplied to Women

Information on the purpose, nature and recommended intervals of the pap smear test should be supplied by the women's practitioner prior to taking the smear. Practitioners using participating laboratories will be asked to advise women of the services provided by the Registry and their right to opt out, see Legislative rights to refuse participation.

Information supplied at the point of service will be supported by public awareness/educational campaigns promoted through mass media and local networks/media outlets.

### Recording and Following up Complaints

The Registry will establish a complaints procedure to resolve complaints received from women, practitioners, pathology laboratories or any other party.

The Registry will liaise with the recently established Health Services Commissioner and complaints office to review complaints about any aspect of the screening pathway as part of its quality control/consumer satisfaction monitoring functions.

## C. EVALUATION PROTOCOL

### C.1 SERVICE PROVISION

Evaluation of Registry will focus on the following areas:

1. Degree of use of the Registry by laboratories reporting on Pap smears within Victoria.
2. Profile of women currently being screened and variations in this consequent upon specific campaigns to increase participation.
3. Abnormality rates among screened women by age, screening history (where known), postcode of residence, type of practitioner taking smear, laboratory, presence/absence of endocervical component.
4. Quality assurance measures for laboratories including :
    - (a) sensitivity for the detection of squamous cell carcinoma (i.e. false negative rate)
    - (b) positive predictive value of an abnormal cytology report
    - (c) interval cancer rate among screened women
5. Time trends in the above

The importance of the above evaluation to developing a national strategy for cervical cancer should not be minimised. Currently there is a complete lack of the above data at a population level, and yet such information is vital to an appreciation of what is currently achieved by our opportunistic approach to cervical cancer screening and, more importantly, to determining what could be achieved by a more formally organised program.

No specific behavioural science studies are considered appropriate to the establishment phase of a Registry, but when Stage 2 (recall) and Stage 3 (call) are implemented relevant studies will be undertaken. It is not envisaged that either of these Stages will be fully operational during the lifetime of the "New Initiatives for Women" funding, unless this is extended. Pilot studies will be evaluated as per SECU protocols.

The economic evaluation will determine the establishment and ongoing costs of

1. maintaining a Register
2. following women with abnormalities
3. instituting a call and recall system.

ATTACHMENT 1

# PARTICIPATING PATHOLOGY LABORATORIES

* Indicates Private Sector

* Dr Abe Dorevitch
693 Bourke Road
Camberwell 3124

* Dr Gabrielle Medley
Director
Victorian Cytology Service
Prince Henry's Hospital
St. Kilda Road
Melbourne 3004

* Dr Peter Wallis
Melbourne Diagnostic Laboratories
32 Smith Street
Collingwood 3066

* Dr Robert Brown & Ms Sarah Gray
C/- Mrs Helen Mayer
Laboratory Manager
BPMS, 10 Chapel Street
Windsor 3181

* Mrs Helen Mayer
Laboratory Manager
BPMS, 10 Chapel Street
Windsor 3181

* Professor W De Boer
Regional Pathology Laboratories
155-157 Victoria Street
Abbotsford 3067

* Dr A Bodie
Box 125
Caulfield East 3145

* Dr D W Fortune
Director of Pathology
Royal Women's hospital
Gratten Street
Carlton 3053

* Dr Malcolm Traill
Aldor Pathology
244 Cheltenham Road
Keysborough 3173

* Dr Collin Laverty
P.O. Box 21
East Wood NSW 2122

* Dr Jack Hobbs
Mercy Maternity Hospital
Clarendon Street
East Melbourne 3002

* Dr Gertie Hiller
Monash Medical Centre
Clayton Road
Clayton 3168

* Mr Ed Wilson
693 Bourke Road
Camberwell 3124

* Dr Ruth Davoren
Royal Women's Hospital
Gratten Street
Parkville 3052

Dr G Kovacs
Family Planning Association
270 Church Street
Richmond 3121

as220

## DATA ON WHICH THE CALCULATIONS HAVE BEEN BASED

| Age (Years) | 1986 Census Women | Proportion with intact uterus+ | Eligible Women | Applying WA* Age specific rates to this population |
|---|---|---|---|---|
| 15-19 | 173,564 | 1.00 | 173,564 | 19,092 |
| 20-24 | 165,175 | 1.00 | 165,175 | 47,900 |
| 25-34 | 327,735 | 0.97 | 317,903 | 104,875 |
| 35-44 | 283,511 | 0.87 | 246,655 | 63,803 |
| 45-54 | 195,611 | 0.76 | 148,664 | 35,209 |
| 55-59 | 94,238 | 0.77 | 72,563 | 8,953 |
| 60-64 | 91,653 | 0.79 | 72,406 | 5,497 |
| 65-69 | 73,826 | 0.81 | 59,799 | 3,322 |
| TOTAL | 1,405,373 | | 1,256,729 | 288,653 |

* Source Armstrong, Rouse and Butler 1987

\+ Holman et al, 1986