Consultation Report 06-01C-1

Review of Rapid Fetal Fibronectin Assay in the Management of Suspected Preterm Labour:
Consultation Report
Review # 4
AHTDP# 03-13

June 2006

Prepared by:
Charis Management Consulting Inc.
Table of Contents

Background ................................................................................................................................... 1
Response Rate ................................................................................................................................ 1
Results ........................................................................................................................................ 1
Summary .................................................................................................................................... 8
Appendix A: ................................................................................................................................. 9
Appendix B: ................................................................................................................................. 14
Background

On April 25, 2006 the Assistant Deputy Minister, Program Services Division of Alberta Health and Wellness issued a request for feedback on fetal fibronectin testing (fFN) for the diagnosis of preterm labour. The consultation was based on work undertaken through the Alberta Health Technology Decision Process culminating in the production of a Synthesis Report\(^1\). The Synthesis Report was distributed with the invitation letter and consultation questions (Appendix A).

The Synthesis Report was based, in large part, on work undertaken through the Alberta Heritage Foundation for Medical Research Health Technology Unit\(^2\) and the Institute of Health Economics\(^3\).

Response Rate

The invitation for feedback was issued to the Chief Executive Officer of each of Alberta’s nine regional health authorities (RHAs) and to select organizations and committees, such as the Alberta Medical Association, Alberta Perinatal Health Program and Diagnostic Services Advisory Committee. A copy of the letter was also sent to all members of the projects, Expert Advisory Group. A full list of those receiving the invitation letter, along with an indication of those responding to the invitation is presented in Appendix B.

In summary, responses were received from eight of nine health regions, six organizations/committees and three individuals. Two RHAs and three organizations indicated they had no feedback to make. Thus, the results reported in the next section of this report represent the feedback received from 12 of 17 organizations and individuals from whom a response was received.

Results

Feedback is presented according to questions posed in the consultation package.

1. In the Policy Options section of the synthesis report four options are presented:
   (a) do not provide fFN testing, (b) provide in Levels 2 and 3 hospitals only, (c) provide in all Level 1, 2 and 3 hospitals, and (d) provide in Level 2, 3 and Level 1 hospitals with >100 births and 1 hour or more from Level 2 or 3 hospitals.
   
a. Are there additional significant advantages or disadvantages associated with any of the options that were not identified in the Synthesis Report?

   Advantages
   
   - One RHA representative mentioned that an additional advantage for Option C is that this option would provide equal access to the test for all patients and their care providers regardless of location in the province.
   
   - Another RHA respondent stated that the four options identified are practical choices for organizing the implementation of the fFN testing.

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Disadvantages

- One organization noted concern that the highest risk population appears to be aboriginal women, women on welfare and women receiving premium support, many of whom may be in communities that do not have a Level 2 or 3 hospital.
- One RHA representative noted concern about the risks related to acting on the basis of false negative test results.

General comments

- One RHA respondent noted that decisions for implementation of new tests should be based on non-financial considerations and the effectiveness of therapy. This respondent noted that guidelines from the Society of Obstetricians and Gynecologists of Canada (SOGC) for the use of this test are either not established or were not reported in the review report. This respondent emphasized that initial and ongoing physician education must be addressed and a commitment to use the clinical guideline (not yet developed) would be required. The need for an active auditing and reporting mechanism (probably quarterly to the Obstetrics and Gynecology group) would be essential.
- One individual stated that the reviewers did not address the issue of infrequent use of the test in hospitals with small numbers of births, potentially outdated specimen kits, lack of expertise, etc.

b. Which is your preferred option? Why?

Ten respondents indicated a preferred choice as indicated in Table 1.

Table 1. Preferred option by respondent category

<table>
<thead>
<tr>
<th>Respondent Category</th>
<th>Preferred Option</th>
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<tr>
<td></td>
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<td>Total (n = 12)</td>
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Only one of the three organizations/programs/committees offered a preferred option. The others felt that the decision would best be made by the health regions or with the assistance of expert opinion.

The two respondents choosing option 1 based their choice on the lack of research evidence demonstrating the benefits of fFN testing and the effectiveness of therapy.
Reasons for choosing option 2 included the economic benefits of implementing fFN testing only in high volume sites (level 2 and 3 hospitals); these sites were also felt to be able to better provide care related to testing and diagnosis.

Reasons for choosing option 3 included the savings in transfer and treatment costs if fFN testing was available in level 1 hospitals, as well as the larger, tertiary care hospitals. Another reason for supporting option 3 was more equitable access. Notably, one respondent supporting option 3 also suggested that, as a “compromise,” option 4 should be used to begin with in anticipation of possible demand to expand testing to all level 1 hospitals.

The argument in favour of option 4 was that it made the most sense, considering reduction in unnecessary transport and hospitalization.

One urban RHA offered an alternate response that considered the question in light of their own situation only. They suggested they would make the test available throughout the region by having test capability located at one Level 2 and one Level 3 hospital. This response is most closely aligned with option 2.

c. If option 2, 3 or 4 is preferred, should fFN testing be available to some or all Albertans as a publicly funded health service?

Five RHA representatives, one organization and two individuals responded to this question. Seven of the eight respondents answered in the affirmative, stating that the test should be available to Albertans. One of these seven respondents stated it should be available only to Albertans presenting at Level 2 or 3 hospitals (consistent with their response to question 1b). The eight respondent had indicated a preference for option 1 in question 1b, but stated that if option 2, 3 or 4 is chosen, then it must be additionally funded – “trying to shift the potential savings from decreased lengths of stay would be a difficult business case for us as high risk patients would be transferred out of our region.”

d. For RHAs only: If your preferred option would involve the introduction of fFN testing in hospitals in your health region, would your region be prepared to introduce it as a publicly funded service within the coming year?

All four of the six RHA respondents stating a preference for introducing fFN (in question 1b) stated they would be willing to implement within the coming year. One indicated they had already implemented the test in their region; two stated they would be willing to implement “as resources allow” or “with increased funding from Alberta Health and Wellness.”

2. What are the operational and implementation challenges with your preferred option?

Seven respondents answered this question (5 RHA, 1 organizational representative and 1 individual).

One respondent stated there were no issues and one suggested the RHAs needed to work out the details. The issues or challenges raised by the others were:

- Education of medical and nursing staff
- Three RHA respondents and one individual mentioned the training of medical staff, residents and/or nurses in the appropriate use of the test.
• Trying to help the specialists understand about the effectiveness of the assay, the changes in treatment options due to the introduction of such a test. We have had limited opportunities to discuss alternate options with them. Their understanding of “point of care” quality assurance programs is limited as they have been somewhat mislead by the manufacturers of these kits (i.e. it is as simple as a urine dip stick test). They also do not understand the burden of accreditation standards placed on laboratories to train, implement and monitor point of care programs.

• Education of medical staff, residents and nursing staff regarding the appropriate use of the fFN test.

• Education and training of medical staff on the proper collection of cervical swabs (and test incubation times, etc.) to avoid false positive and negative test results.

• The challenge will be training and maintaining best practices to prevent false positives.

Protocols/clinical practice guidelines and ongoing quality assurance

• Three RHAs mentioned the need for protocols or clinical practice guidelines:
  • Developing protocols, acquiring equipment and designing test protocols for the laboratory.
  • The benefits from providing this test will be realized by a thorough implementation plan using clinical practice guidelines, knowledge transfer and change management processes with physicians and staff, as well as a monitoring and evaluation plan.
  • See comment regarding point-of-care quality assurance under Education section above.

Resources

• Three RHA respondents mentioned funding and resources as a challenge:
  • It would be difficult to implement the test in our rural hospitals. The limited resources available in rural labs are stretched and adding additional equipment and testing must be well considered.
  • Ensuring that funding is comprehensive, to include not only the test kits themselves, but also quality control and proficiency testing materials, preparation and maintenance of written procedures, building and editing of lab computer reports where appropriate.

3. If fFN testing were to be implemented, should there be a provincial approach to the introduction of the test or should introduction be left to the discretion of each region?

Eight respondents answered this question.

Two RHA representatives and one organizational respondent advocated for a provincial approach to implementation, with the primary rationale being equal or equitable access for all. A second reason for supporting this option was reduction of impact on metro
hospitals. One RHA respondent suggested the need for provincial coordination with a laboratory council, similar to the approach used for Urea breath tests [while not directly answering the question, this answer implies a provincial approach].

Two RHA representatives stated the implementation of the test should be left to the discretion of the region. One gave as rationale the costs for implementation being absorbed by regions. This respondent noted that real costs related to practice (change management) is missing from the analysis, but [are] considerable. The second RHA representative stated the RHAs should have the discretion to implement based on their priorities, needs and available resources.

An additional RHA respondent not advocating the introduction of fFN, stated that “if fFN were to be implemented, we do not believe it should be implemented in each health region” [implying discretion on the part of RHAs to adopt the test].

Two RHA and one individual respondent advocated for a provincial approach to the development of practice guidelines:

- Realizing that fFN is already available in Capital Health and Calgary Health regions, I support the development of provincial clinical practice guidelines for the assessment of preterm labour that would include use of the fFN test (if available). The development of such a guideline would provide an opportunity to promote consistent practices with those already performing the test and also those still gaining experience with the test.
- If the province is funding the fFN then there should be a provincial approach to practice guidelines (implementing and maintaining).
- It may be helpful to encourage adoption of standardized guidelines for patient selection and standardized test processes across the province.

4. **Do the contents of the synthesis report provide the information you need to offer an informed opinion? Is there additional information you believe is necessary to consider?**

Six of nine respondents were satisfied that the synthesis report provided the information they needed to offer an informed opinion.

- The process of literature review appears thorough and considered expert clinical opinion, as well as the scientific literature.
- The analysis of risks and benefits to the relevant populations seems appropriate.
- The synthesis report was well researched and informative.
- This is a very helpful and useful review of the literature.

Those that suggested additional information would have been helpful, mentioned the need for more explicit information on the sensitivity, specificity or positive predictive value of the test; more background on the program drivers and system-level issues; and need for more detailed information than was readily available (but may have been available in the detailed reports).

- In regards to the statistics, the only thing we are told is that the negative predictive value is 99% (only 1% of women with a negative test actually had premature labour). We are not told the sensitivity, specificity or positive...
predictive value. The study does indicate that false positive results could have serious repercussions on treatment, but we are not told what this number is. Thus, it makes it impossible to construct a 2 by 2 table to indicate whether the negative predictive value is itself of value. For an extreme example of this in this situation, let’s assume the test we want to use is a pregnancy test. If this test is negative, the negative predictive value for premature labour is even higher – 100%. However, there is ABSOLUTELY no value of this negative test in this instance as obviously, when we look elsewhere in the table, there are other significant things to consider about these tests.

- The assessment in this report surrounded the evaluation of a technology (the fetal fibronectin test) without fully evaluating the clinical program drivers, as well as the systems, personnel and training needed to use the technology effectively (comparative to the clinical centres that published reports in the literature used in this review). The documents cited in Appendix A could not be found by searching the website of Alberta Health and Wellness or the AHFMR that were required in order to assess concerns surrounding potential incomplete economic impact analysis. Considering the very limited time available for this review, it would have been expedient if the reports mentioned in the appendix were available online.
- Monitoring the compliance of post-test collection of the clinical guideline would be a resource issue for the abstraction group in Health Records. We are unclear from the document if a well designed scientific and medical utility study has been performed and if the effectiveness of therapy was also traced as part of the study.
- Additional information on test methodology and costing would add additional information.

5. Provide any additional comments or feedback on the findings of the review or on the policy options.

Six people provided additional comments. Of these, three reiterated or expanded on their positions for or against test introduction:
- We completed a pilot project with fFN which demonstrated its effectiveness in detecting spurious vs. real preterm labour. Providing access to this test using evidence-based clinical guidelines would improve patient care and system efficiencies.
- With limited funding available for implementing new methodologies and testing, we feel it would be best spent on items that have been proved to be effective such as colorectal cancer screening.
- The RCT studies do not show an ability to reduce health care utilization and unnecessary treatment (page 9). Observational studies have not shown usefulness (page 8). My conclusion is that this is a very helpful and useful review of the literature. There needs to be better studies in my mind before one adopted this test in our region or even provincially.
- The recommendation to provide fFN assay testing for women with access to level 2 or 3 care centres will be disappointing for physicians in rural Alberta with a level 1 designation. It will also be disappointing for families in rural areas who are already concerned with lack of access to best practice technologies. It is also
paradoxical that women close to level 2 or 3 centres usually have the benefit of specialists with superior assessment skills while women with access at level 1 centres do not have the benefit of this expertise.

- While fFN testing does not offer economies of scale in rural areas, it would be equally beneficial to women in a level 1 care centre, not only for its diagnostic accuracy, but also to decrease travel and disruption of family life, the significant costs of which are not fully factored into economic modeling for the technology.

Two respondents mentioned limitations of this study relating to the narrow focus of fFN as the only test option, or the lack of region-specific information and lack of emphasis on application of the test in remote settings.

- There are new tests becoming available to assess risk of premature rupture of membranes (eg. Cervical IGF-BP2). The emphasis of this document has been on a single product, the Adeza fFN. It may be appropriate to consider that by the time funding is approved, Health Regions may be able to select alternate technologies to assess risk of premature rupture of membranes.

- On page 4, where the discussion centres around the number of women, I find this section quite confusing for the following reasons: What is the relevance of the percentage threatened PTL of annual births? 846 women had preterm births without PTL and 97 had preterm births with PTL (27% of the 1247 women with PTL who went on to have preterm births). This means only 10% of preterm births had PTL. I take it from this that the relevant population would be the percentage of the 1247 women with PTL who are at a Level 2 or 3 hospital already. We do not know this number in [my region] which for me would be the most relevant number.

- The fFN test is being targeted for use in remote nursing stations in the NWT to assess the need to transfer patients. Application of the test in this remote setting, where testing may be infrequent and therefore experience would be difficult to gain provides an interesting contrast to the options presented in this document.

One respondent expressed a consideration for laboratory accreditation:

- From the medical regulatory perspective, our primary consideration is with respect to laboratory accreditation. We would expect that fetal fibronectin testing procedures would be accredited to the same standard we expect of other laboratory facilities. From a physician practice perspective, we would assume that physicians in practice would use their experience and knowledge and adhere to best practices.

Several points of clarification were made:

- Northern Lights had previously purchased one fFN testing unit and has been waiting for the provincial review and provision of guidelines for use prior to commencing testing.

- The Northern Lights Health Centre is a level 2 care centre. In the review we are erroneously classified as a level 1 care centre.
Summary

In summary:

- The majority of respondents, including the majority of RHA representatives, favour the introduction of fFN as a publicly funded service. However, they are divided as to their preference for implementation province-wide (available in all maternity hospitals) or in Level 2 and 3 hospitals only. They are also divided on the question of whether the implementation approach should be provincial or left to the discretion of health regions.

- The most prevalent implementation challenges were the education and ongoing quality assurance of medical, nursing and laboratory staff; need for clinical practice guidelines or protocols (preferably standardized provincially); and resources needed for implementation.
Appendix A:

Consultation Package and Distribution List
April 25, 2006

Dear <Name>:

Re: Alberta Health Technologies Decision Process: Fetal Fibronectin Testing

Alberta Health and Wellness is interested in obtaining your organization’s input on policy options for providing fetal fibronectin (fFN) testing in Alberta.

A review of fFN testing was undertaken as part of the Alberta Health Technology Decision Process in response to a request from the Alberta Perinatal Health Program. The fFN assay is a diagnostic laboratory test used for women with symptoms of preterm labour to rule out the possibility of delivery in the 7 to 14 days following the test. The test is used to avoid unnecessary interventions with symptomatic women who are experiencing false labour.

The review was conducted through a collaborative effort involving the Alberta Heritage Foundation for Medical Research (AHFMR) Health Technology Assessment Unit and Institute for Health Economics (IHE). An Expert Advisory Group comprised of representatives from the regional health authorities, clinicians with obstetrical practices, Alberta Perinatal Health Program and Alberta Health and Wellness guided the review process.

The synthesis report, Review of Fetal Fibronectin Testing, is attached. It summarizes the findings of the review and presents policy options regarding the introduction of fFN in Alberta.

Prior to presenting a recommendation to the Minister of Health and Wellness regarding whether or not fFN testing should be provided and if so, how, we are consulting with select stakeholders on the findings and policy options outlined in the synthesis report. Please provide a single response from your organization to Henry Borowski by mail, facsimile or email by May 15, 2006. His contact information is:

Henry Borowski, Director
Health Technologies and Services Policy
Alberta Health and Wellness
10025 Jasper Avenue, Box 1360
Edmonton, AB T5J 2N3
Phone: (780) 415 2855
Fax: (780) 415 1704
Email: henry.borowski@gov.ab.ca
Margaret Wanke of Charis Management Consulting Inc. has been asked to compile feedback received in response to the attached consultation questions. Your response will be forwarded to Margaret. Please also feel free to contact Margaret if you have any questions about the synthesis report or would like to access a copy of the AHFMR and/or IHE analyses containing more detailed information.

If you have any questions about Alberta’s Health Technology Decision Process, please do not hesitate to contact me or Henry Borowski, Director of the Health Technologies and Services Policy Branch. I can be reached at (780) 415 1599 or janet.skinner@gov.ab.ca and Henry at (780) 415 2855 or henry.borowski@gov.ab.ca.

Thank you for participating in this consultation. Your feedback will help us in formulating our recommendation to the Minister.

Yours truly,

Janet Skinner  
Assistant Deputy Minister  
Program Services Division

cc: fFN Expert Advisory Group members  
Margaret Wanke, Charis Management Consulting Inc.

Attachment
RHA/Organization: _____________________________

1. In the Policy Options section of the synthesis report four options are presented: (a) do not provide fFN testing (status quo), (b) provide in Level 2 and 3 hospitals only, and (c) provide in all Level 1, 2 and 3 hospitals, and (d) provide in Level 2, 3 and Level 1 hospitals with >100 births and 1 hour or more from Level 2 or 3 hospitals.

   a) Are there additional significant advantages or disadvantages associated with any of the options that were not identified in the Synthesis Report?

   b) Which is your preferred option? Why?

   c) If option 2, 3 or 4 is preferred, should fFN testing be available to some or all Albertans as a publicly funded health service?

   d) For RHAs only: If your preferred option would involve the introduction of fFN testing in hospitals in your health region, would your region be prepared to introduce it as a publicly funded service within the coming year?

2. What are the operational and implementation challenges associated with your preferred option?

3. If fFN testing were to be implemented, should there be a provincial approach to the introduction of the test or should introduction be left to the discretion of each region? Please provide rationale for your answer.

4. Do the contents of the synthesis report provide the information you need to offer an informed opinion? Is there additional information you believe is necessary to consider? [Note that the Technology Effects and Effectiveness and Costing Analysis are available upon request from the consultant, on behalf of Alberta Health and Wellness]

5. Provide any additional comments or feedback on the findings of the review or on the policy options. We are pleased to consider any feedback that would assist in decision making.

Respondent Signature:    Position:    _____________________________    ___________________________________
## Distribution List

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<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Organization</th>
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<tbody>
<tr>
<td>Mr. Mike Gormley</td>
<td>Executive Director</td>
<td>Alberta Medical Association</td>
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<tr>
<td>Dr. Trevor Theman</td>
<td>Registrar</td>
<td>College of Physicians &amp; Surgeons of Alberta</td>
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<td>Ms. Corine Frick</td>
<td>Director</td>
<td>Alberta Perinatal Health Program</td>
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<td>Dr. Reg Sauve &amp; Mr. Neil MacDonald</td>
<td>Co-Chairs</td>
<td>Alberta Perinatal Health Advisory Committee</td>
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<tr>
<td>Dr. David Dawson</td>
<td>Chair, Council of Medical Directors</td>
<td>c/o HBA Services</td>
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<td>Mr. Tom Seaman</td>
<td>Chair, Diagnostic Services Advisory Committee</td>
<td>c/o HBA Services</td>
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<tr>
<td>Mr. Jack Davis</td>
<td>President and Chief Executive Officer</td>
<td>Calgary Health Region</td>
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<td>Mr. Tom Seaman</td>
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<td>Mr. Steve Petz</td>
<td>President and Chief Executive Officer</td>
<td>East Central Health</td>
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<td>Mr. Dalton Russell</td>
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<td>Mrs. Sheila Weatherill</td>
<td>President and Chief Executive Officer</td>
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<td>Mrs. Pam Whitnack</td>
<td>Chief Executive Officer</td>
<td>Chinook Regional Health Authority</td>
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<td>Mr. John Vogelzang</td>
<td>President and Chief Executive Officer</td>
<td>David Thompson Regional Health Authority</td>
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<tr>
<td>Mr. Cliff Cottingham &amp; Ms. Shelly Pusch</td>
<td>Co-Acting Chief Executive Officers</td>
<td>Aspen Regional Health Authority</td>
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<td>Mr. Bernie Blais</td>
<td>Chief Executive Officer</td>
<td>Northern Lights Health Region</td>
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Appendix B:

List of Respondents
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<th>Affiliation</th>
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<td>1. Chinook</td>
<td>C. McCrank, Vice President</td>
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<td>2. Palliser</td>
<td>T. Seaman, President &amp; CEO</td>
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<td>3. Calgary</td>
<td>Dr. A. Lyon, Calgary Laboratory Services</td>
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<td>4. David Thompson</td>
<td>D. McBain, Senior Vice President</td>
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<td>5. East Central</td>
<td>Dr. O. Olsen, Vice President, Medical Services</td>
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<td>6. Capital</td>
<td>Joanna Pawlyshyn, Vice President and COO Royal Alexandra Hospital/Diagnostic Services</td>
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<td>7. Aspen</td>
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<td>8. Peace Country</td>
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<td>9. Northern Lights</td>
<td>Dr. A. Nicholson, Medical Director and Bernie Blais, CEO</td>
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<td>Dr. W. Hnydyk, Senior Medical Advisor</td>
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<td>Alberta Perinatal Health Program – Ad hoc Prioritization Com.</td>
<td>C. Frick, Director, Alberta Perinatal Health Program</td>
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<td>College of Physicians &amp; Surgeons of Alberta</td>
<td>Dr. T. Theman, Registrar</td>
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<td>Alberta Health and Wellness</td>
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