SUMMARY

Introduction

The Quebec Government has decided to legalize and integrate midwifery into the health care system. The results and recommendations from the *Conseil d'évaluation des technologies de la santé (CETS)* presented in this document are aimed at providing useful information to all those involved in an integration process that will promote safe and effective care for Quebec's mothers and newborns.

In June 1990, the Quebec Government adopted the "Act respecting the practice of midwifery within the framework of pilot projects," in order to authorize the practice of midwifery on an experimental basis until September 1998, and to create a *Conseil d'évaluation des projets-pilotes* ("Pilot Project Evaluation Council"). Eight of the 20 pilot projects submitted were accepted and an evaluation process was set up concurrently with their opening. Following the publication of the evaluation report and the recommendations of the Pilot Project Evaluation Council, the Quebec Government decided to legalize the practice of midwifery in Quebec as of September 1999 and to set up a university degree program in midwifery.

The evaluation of the pilot projects raised some concerns about midwifery practice, however particularly regarding newborn resuscitation and stillbirths. In May 1998, the Minister of Health and Social Services commissioned *CETS* to further analyse the situation regarding stillbirths within the framework of the midwifery pilot projects in Quebec. A committee of experts was formed to this end. The current report basically consists in a formative evaluation and highlights the issues to consider in order to facilitate the integration of midwifery into the perinatal care system and to improve the quality of services provided.

Mandate

The mandate received by *CETS* was twofold, consisting of the following:

1) To carry out a meta-analysis of the scientific literature in order to "illustrate what is usually expected in midwifery practice" and

2) To complete "an epidemiological analysis of each stillbirth case, including those identified during and after the evaluation process, up until the date on which the group of experts began their evaluation. This analysis should be carried out by a group of independent experts, without any bias regarding the practice of midwifery in birthing or maternity centres recommended by the Act respecting the practice of midwifery within the framework of pilot projects, nor having any relationship with a recognized professional order. This study should not consider multiple malformation cases which are generally considered to be unavoidable and should, if possible, establish the associations between the practice of midwifery and the characteristics of the clientele."

   It was also specified that "analytical relationships should be explored between the meta-analysis and the results of the analysis of the stillbirth cases."

Selection of the members of the Ad Hoc Committee on the Analysis of Stillbirth Cases in the Practice of Midwifery in Quebec

With a view to its mandate, *CETS* formed a committee of experts composed of professionals selected according to their speciality, expertise in research and clinical practice, recognition in professional milieu, and acceptance of participation on the committee. This committee consisted of eight members including two

obstetrician-gynecologists, two midwives, two general practitioners, a neonatology specialist and a pediatrician and epidemiologist who chaired the Committee. Five members of the Committee were selected from outside Quebec: both obstetrician-gynecologists, both midwives and one of the general practitioners. The recruitment of professionals both from within and outside Quebec responded to the mandated requirements concerning the formation of the expert Committee.

Review of the Literature

Methods

In order to address the first part of the mandate, articles published on the subject since 1966 were located with a computerized search of several literature databases and by consulting reference lists of published reports and articles. Articles were divided into two categories: 1) randomized controlled trials, and 2) other studies, including observational comparative and descriptive studies. Two members of the Committee reviewed the randomized controlled trials in order to ensure that they met pre-established meta-analysis inclusion criteria. Results from the retained studies were combined with meta-analysis techniques, using the relative risk (RR) with its 95% confidence interval (95% CI) as the measure of effect.

Randomized Controlled Trials: Results

Available data allow neither the confirmation nor the invalidation of an association between stillbirth[1] and midwife-led perinatal care as compared to physician-led care (RR=1.54; 95% CI: 0.77 – 3.06). As for perinatal mortality,[2] the meta-analysis of six studies indicates a trend towards a risk increase bordering on statistical significance in the group under midwife-led care (RR=1.63; 95% CI: 0.99 – 2.69). However, this increase does not significantly hold when the meta-analysis includes only low-risk women (RR=1.11; 95% CI: 0.15 – 1.35).

In interpreting the results of these studies, certain limitations must be taken into account such as differences in the definition of stillbirth and the impossibility of determining the moment of stillbirth, either antepartum or intrapartum. Finally, although the review of the literature includes relevant international studies on midwifery practice in birthing centres, none of the reviewed studies involved midwives practising in a context comparable to that in which birthing centres were introduced in Quebec.

Among the other results obtained, the meta-analysis of two studies indicates a reduction in newborn resuscitation among the clientele receiving midwife-led care. There is no significant difference in the mean Apgar score between groups. As for the meon admission of newborns to neonatal intensive care units, results of studies were not combined because of study heterogeneity.

Other Comparative and Descriptive Studies: Results

The observational comparative studies examined were cohort studies conducted either on entire populations, with the impossibility of evaluating the risk level of the clientele or identifying transfer cases, or on groups in which women chose to be under midwife or physician care. The results of these studies do not indicate a significant difference between the group of women under midwife care and the group

[1] In Quebec, a stillbirth is defined as the birth of a stillborn, i.e., a fetus weighing 500 g or more and which, after complete expulsion, shows no signs of life. The literature refers to the week of gestation when defining a stillbirth, such as the birth of a stillborn having a gestational age of 20 weeks or more, 22 or more, or 24 or more.

[2] Perinatal mortality includes stillbirths and early neonatal deaths within the first seven days of birth.

followed by physicians. Descriptive studies of midwifery practice describe well-organized programs, with clearly established protocols for specialist consultation and transfer in case of complications. The studies confirm the quality of care provided by these programs.

Stillbirth in Quebec

In Quebec, a stillbirth is defined as the birth of a stillborn, i.e., a fetus weighing 500 g or more which, after complete expulsion, shows no signs of life. The provincial stillbirth rate was 4.2 per 1,000 births in 1995 and 3.9 per 1,000 births in 1996, including stillbirths due to congenital malformations that are incompatible with life, as well as high-risk pregnancies.

Stillbirths Within the Framework of Pilot Projects

The Committee studied the 19 stillbirth cases that occurred among pregnancies under midwifery care in Quebec birthing centres, from their opening until August 30, 1998, the date on which the Committee of experts was formed. During this period, there were 3,379 births in birthing centres for a stillbirth rate of 5.6 per 1,000 (19/3,379). This rate is not statistically different from the 1995 and 1996 provincial stillbirth rates after standardization based on the mother's age (SMR[3] = 1.37; 95% CI: 0.75 – 1.99).

The Committee considered 11 stillbirth cases to be unavoidable. Care was deemed inappropriate in 10 cases, either during the antepartum or postpartum periods, for which stillbirth was considered possibly avoidable in 3 cases and probably avoidable in 5 cases. In 2 cases, inappropriate care was not related to the deaths. The notion of appropriate or inappropriate care refers to the overall management of the pregnancy involving several types of professionals including midwives and physicians.

A thorough review of the files indicates that inappropriate care seems to be related to the following factors: difficulty in recognizing an abnormal condition or failure to act appropriately following identification of a problem; communication problems between professionals; delays encountered when faced with emergency situations; an ambiguous definition of professional responsibilities when transfer of care and joint follow-up have taken place; and the lack of documentation of the information provided to the pregnant woman on recommended interventions during the care process.

Conclusion

Available scientific literature is not conclusive regarding the association between stillbirth and midwifery practice. It has now been established that midwifery in Quebec will go beyond pilot project experimentation, since the "Midwives Act" was sanctioned on June 19, 1999 and became fully effective on September 24, 1999. The Committee of experts has therefore examined the various underlying causes of inappropriate care at length. Information gathered suggests important points to consider regarding the integration of midwives into the perinatal health care system.

Based on the work and analysis of its Committee of experts, *CETS* makes the following recommendations:

Recommendations

1. Comprehensive Approach to Perinatal Care

The file review shows that the midwives provided comprehensive care which was responsive to the individual needs of the women

[3] The standardized mortality ratio (SMR) is the ratio of the number of cases observed to the number of cases expected or calculated.

and their families, and that the attention and counseling provided by the midwives appeared to be of a high quality.

- *Within this context and considering that perinatal health care professionals recognize the benefits of caring for all aspects of the woman, CETS recommends that this comprehensive approach be maintained.*

2. Documentation of Informed Choice

Our review of cases indicates that the principle of informed choice is a fundamental aspect of midwifery practice that is increasingly sought by women. In some of the cases studied, it would have been more appropriate to make and document clear recommendations for medical follow-up, rather than to simply share observations and information in a non-directive manner. While the refusal of advised diagnostic tests or treatments by women is well documented in the cases analysed, file notes are not explicit or detailed enough about communicating the possible medical consequences for mother or baby of not following recommendations.

- *CETS believes it is essential for midwives to clearly communicate their recommendations to pregnant women regarding required diagnostic tests and treatments, including recourse to medical consultation, and to carefully document the patient's refusal and the possible consequences discussed.*

3. Training and Education

The recognition of any problematic situation throughout the woman's pregnancy and the appropriate ways to manage this situation is a crucial element of safe midwifery. Furthermore, midwives will be called upon to work as a team with other professionals in their everyday practice. It is therefore important that training programs for midwives adequately prepare them to face these situations.

CETS recommends that:

- *The midwifery training program should ensure that students are sufficiently prepared not only to provide care for normal births, but also to recognize abnormalities during pregnancy, labour, birth and the postpartum period, and thus to provide appropriate diagnostic tests and treatments and to refer patients to the care of a physician, if necessary;*
- *Training programs should offer students several opportunities to learn to work as a team with other health care professionals in providing care to pregnant women and their babies. The university training program should establish relationships with a number of individual physicians, hospitals and clinics that will provide clinical teaching for midwifery students.*

4. Standards of Care

Some cases of stillbirth analysed highlight a difficulty in recognizing the seriousness of an abnormal condition and ensuring adequate follow-up during the prenatal period or during labour. Moreover, for some cases analysed, the pregnancy was not a low-risk one but presented a moderate or high degree of maternal or fetal risk. These observations lead *CETS* to suggest several elements that could contribute to the continued improvement of midwifery practice :

- *Intrauterine growth restriction should be included in the list of obstetrical risk criteria in the "Regulation respecting obstetrical and neonatal risks."*

- *Continuing education programs for midwives should, in particular, include intrauterine growth restriction, fetal heart rate abnormalities and decreased fetal activity among the topics covered in the identification of pathological conditions.*

- *Standards of care should be established to ensure that midwives' records include clear and detailed information on the ordering of tests, requests for consultation and the results of these tests and consultations.*

- *The sharing of responsibilities between midwives and physicians should be clearly defined in cases of joint follow-up. For each intervention, the provider assuming the primary responsibility for care should be clearly identified in the pregnant woman's file. If it becomes necessary for the pregnant woman to be followed by a different professional, the midwife should document all information concerning this transfer of responsibility.*

- *If stillbirth occurs, the midwife should ensure that the parent(s) are provided with information about the benefits of a complete autopsy. When an autopsy is declined by the parent(s), the midwife should ensure that a macroscopic examination is performed and that the results, including a brief description of the fetus and its weight, are recorded in the file in such a manner as to contribute to an understanding of the cause(s) of death.*

- *The Professional Order of Midwives should ensure that a perinatal morbidity and mortality surveillance system is established. The data compiled could be used to further develop clinical practice guidelines and for practice audits.*

5. Professional Collaboration and Responsibilities

The integration of midwifery into the health care system involves significant changes to the perinatal care system. The experimental framework of the midwifery pilot projects and the characteristics of their implementation, origin and operationalization have had repercussions on the nature of the collaborations that could be developed by the birthing centres. Collaboration between professionals and institutions also greatly depends on the perceptions about the role of midwives held by the various players, and the reconfiguration of professional "territories" required by the arrival of this new care provider.

CETS recommends that:

- *The isolation which presently characterizes the practice of midwifery is not favourable to its integration into the perinatal care system and it is therefore necessary, in order to ensure optimal care for mothers and babies, that midwives and physicians work together as part of a team. The responsibility of successfully integrating midwives into the system is shared by midwives, physicians, health care institutions and the government. A positive model of integration rather than isolation should be central to this new approach in primary care, and should be introduced into all midwifery education and clinical practice environments.*

- *Effective collaboration between the various professionals involved in the care of a pregnant woman is based on the existence of protocols, recognized by all care providers, that clearly identify practice responsibilities, mechanisms of consultation and care transfer, risk factors throughout follow-up for which a transfer is required, as well as means for immediate access to specialized medical and hospital resources. The development and application of these protocols imply that all obstetric and newborn-care professionals and midwives are fully aware of the scope of midwifery practice and recognize their respective skills.*

- *The successful integration of midwifery into Quebec's perinatal care system will depend on the concrete efforts of midwives and physicians to establish collaborative working relationships which are truly continuous and not merely short-term responses to proble-*

matic cases. Effective communication and collegial relationships between care providers will help to promote continuity of care and, most importantly, improvement in the quality of midwifery care in Quebec, in order to ensure the health and well-being of both mothers and their babies

Summary