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Utility of and indications for the transfer of samples to the anatomical pathology laboratory for analysis

The placenta

English summary

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This is the English summary of the guidance entitled Pertinence et indications de transmission des prélèvements au laboratoire d'anatomopathologie aux fins d'analyse - Le placenta - published in May 2019.

The complete version of this guidance (in French) is available on the website of INESSS in the Publications section.

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SUMMARY

Introduction

Anatomopathological examination of placental tissues may provide information pertinent to the diagnosis of various undesirable fetomaternal conditions and the medical management of future pregnancies.

However, the majority of placentas are normal and originate from full-term births following a normal pregnancy without complications for either the mother or the newborn. The systematic transfer of placentas to the anatomical pathology laboratory for analysis thus raises the question of whether diagnostic resources are being used optimally.

In the absence of provincial guidelines and considering the lack of an established practice for the handling of placental tissues in Québec institutions, the MSSS mandated INESSS to formulate, for health professionals and the Conseils des médecins, dentistes et pharmaciens (CMDP) and Conseils des sages-femmes (CSF) of Québec, recommendations on the utility of and indications for the transfer of placentas to the anatomical pathology laboratory for analysis.

Methods

The MEDLINE (Pubmed) database, Embase, evidence-based medicine (EBM) reviews, including Cochrane Library, and the International Network of Agencies for Health Technology Assessment (INAHTA) database were consulted. The research material was complemented by consulting the websites of scholarly, professional, regulatory and governmental organizations of interest, as well as hospitals and universities in Canada, the United States, the United Kingdom, Australia and New Zealand. Documents containing guidelines, health technology and intervention methods assessment reports, clinical practice guidelines, regulations and policies were retained.

Québec experts were consulted using a modified Delphi Method in order to compile a list of clinical conditions for which the transfer of the placenta to the anatomical pathology laboratory for analysis is indicated.

A cost analysis was also performed from the anatomical pathology laboratory perspective, to compare the costs associated with the systematic transfer of placentas to the anatomical pathology laboratory to those of selective transfer based on clinical indications deemed pertinent.

Experts and stakeholders were invited, at various stages, to critique the research questions, to comment on the information collected and to participate in the formulation of recommendations. They also enabled researchers to identify the primary challenges of clinical practice and the organizational, ethical, social and legal concerns associated with the formulated recommendations.

Results

Positions of scholarly, professional and regulatory organizations

All of the documents retained present a selective model for the transfer or histological examination of placentas based on predetermined clinical indications.

Among others, the College of American Pathologists (CAP, United States) and the Royal College of Pathologists (RCP, United Kingdom) have published guidelines that include non-exclusive lists of maternal, fetal, neonatal and placental clinical conditions for which an anatomopathological examination of the placenta is either recommended, or deemed essential or desirable. In addition, the decision to send a placenta to the pathology department for analysis should be based on the reasonable possibility that such an examination will provide information pertinent to the diagnosis of undesirable fetomaternal conditions or the management of future pregnancies.

The selective transfer of placentas to the anatomical pathology laboratory first requires that a triage of the placentas be conducted. This step must include a review of the maternal, fetal, neonatal and placental conditions that may constitute an indication to transfer the placenta to the anatomical pathology laboratory for analysis. In order to detect placental abnormalities, a first-line visual morphological examination of placental tissues must be performed in the delivery room by the clinician.

In addition, according to the CAP, placentas that do not undergo an anatomopathological examination should be stored for three to seven days at 4°C before disposal, to ensure that placental tissues are available should the health of the mother or newborn unexpectedly deteriorate.

Current situation in Québec

In Québec, procedures for the transfer of placentas to the anatomical pathology laboratory for analysis vary from institution to institution. While some systematically transfer and perform a full anatomopathological examination on all placentas, others follow selective transfer or histological analysis policies based on a list of predetermined clinical conditions.

Indications for the transfer of placentas to the anatomical pathology laboratory for analysis

According to the Québec experts surveyed, 21 maternal conditions, 13 fetal or neonatal conditions and 15 placental conditions constitute indications for the transfer of a placenta to the anatomical pathology laboratory for analysis, a total of 49 indications.

A list of 21 clinical conditions that do not constitute indications for the placenta transfer to the anatomical pathology laboratory was also compiled.

Differential cost analysis

Based on an analysis of medico-administrative data, it was estimated that 75 to 79% of placentas could be exempt from transfer to the anatomical pathology laboratory for analysis.

According to preliminary experimental data from an institution that recently implemented a selective transfer policy, roughly 35% of placentas were sent to the anatomical pathology laboratory. Based on this information, nearly 53,800 macroscopic examinations could be avoided every year by adopting a selective placenta transfer policy, which represents savings of approximately 9,000 to 18,000 hours of analysis time in anatomical pathology departments in Québec.

Following the adoption of a selective placenta transfer policy, cost reductions of approximately $352,000 to $3.1M are predicted, across the province, based on the models and assumptions considered.

Summary of data collected during meetings with experts and stakeholders

The experts and stakeholders consulted were in favour of adopting a selective placenta transfer policy based on relevant clinical indications. However, they brought up challenges in clinical practice and organizational and ethical concerns.

Among other issues, concerns were raised about transferring responsibility for triage of placentas to clinicians, traceability of placentas not sent to the anatomical pathology laboratory and their temporary storage, as well as time limits and accessibility of placental examination reports for the professionals charged with the medical care of the child. Some of these concerns are addressed by suggestions, but not recommendations, for implementation and are listed under “Other considerations.”

The recommendations issued by INESSS will promote wise use of anatomopathological resources, taking into account clinical utility and aspects related to distributive justice. They will facilitate province-wide standardization of procedures for the handling of placental tissue.

Observations and recommendations

Considering that:

- the majority of placentas do not present any morphological abnormalities and originate from normal pregnancies, with no fetal anomalies, that lead to full-term births with no complications for the mother or the newborn;
- scholarly societies suggest implementing a triage system for placentas and a selective model for anatomopathological examination of placental tissues based on predetermined clinical indications;
- the clinical indications considered in the guidelines examined sometimes diverged in terms of exhaustiveness and potential interpretation;
- a multidisciplinary committee of Québec experts formulated, by consensus decision-making, a list of maternal, fetal, neonatal and placental clinical indications that require the transfer of a placenta to the anatomical pathology laboratory for analysis;

- these lists are non-exclusive and must be used as tools when determining whether to order an anatomopathological examination of a placenta, based on one's own clinical judgment;
- some neonatal indications for the anatomopathological examination of a placenta may appear in the hours or days following the birth;
- some Québec institutions have already adopted a selective placenta transfer policy to improve the efficiency of anatomopathological resources.

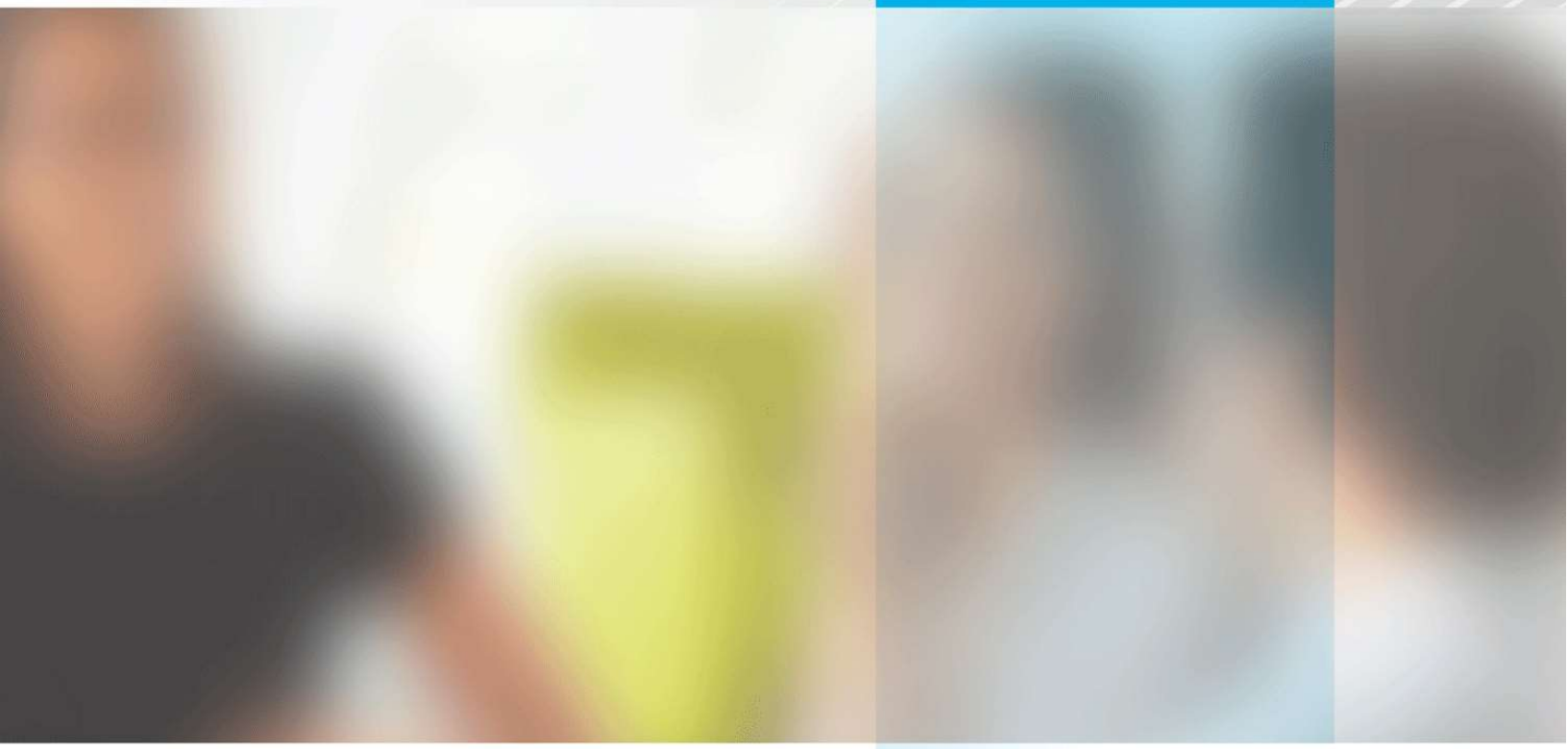
RECOMMENDATIONS OF INESSS

- INESSS is of the opinion that it would be fair and reasonable to adopt a province-wide selective procedure for sending placentas to anatomical pathology laboratories for analysis.
- INESSS recommends that a placenta be sent to the anatomical pathology laboratory when at least one of the maternal, fetal, neonatal or placental conditions, as enumerated in the list of 49 indications for anatomopathological examination of a placenta, is present.
- If a placenta does not present any of the established maternal, fetal, neonatal or placental indications, it may be exempted from transfer to the anatomical pathology laboratory.
- This implies that every placenta must undergo a triage examination performed by a competent birth professional or, otherwise, by a pathologist. The information from the triage examination must be duly recorded in the mother and child's file, ideally in a standardized form.
- Beyond the established indications, a health professional must be able to order the transfer of a placenta to the anatomical pathology laboratory for analysis if, in their clinical judgment, there is any level of uncertainty or concern for the health of the mother or child.
- In extenuating circumstances, to facilitate change management and the implementation of such a measure, triage may be performed for a limited period within the pathology laboratory in order to ensure the utility of an anatomopathological examination.
- Placentas not requiring an anatomopathological examination must be kept cold (not frozen) at 4°C for seven days before disposal, to ensure that placental tissue is available should the health of the newborn unexpectedly deteriorate.

Other considerations

INESSS is of the opinion that the following should be considered:

- The creation of training programs for clinicians and other health professionals charged with documenting the procedure for first-line placental examinations, in order to standardize practices.
- A progressive implementation of these recommendations (for example, over a period of 12 to 18 months) to validate the triage procedure followed by birth professionals through internal audits, including the accuracy of procedures and measurement methods for first-line placental examination.
- A tool to measure compliance with recommendations and quality of practice, as well as the mobilization of the Conseils des médecins, dentistes et pharmaciens (CMDP), Conseils des sages-femmes (CSF) and managers responsible for quality during the implementation process and the transition for risk management and quality assurance.
- The application of sample labelling standards to all placentas, including those not sent to the anatomical pathology laboratory and stored for seven days at 4°C, to ensure traceability as needed.
- The application of biological and biomedical waste disposal protocols to placentas neither sent to the lab nor returned to the parents.
- A procedure for prioritizing urgent neonatal cases.
- The introduction of reasonable clinical targets concerning time frames for the submission of placental examination reports.



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