

FETAL HEALTH SURVEILLANCE IN LABOUR

This guideline was developed by the Working Group on Fetal Health Surveillance in Labour and approved by Executive and Council of the Society of Obstetricians and Gynaecologists of Canada.

It has also been reviewed by the Maternal-Fetal Medicine Committee, the Clinical Practice Obstetrics Committee, the ALARM Committee, and the Canadian Medical Protective Association.

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Abstract

Objective: This guideline defines the standards pertaining to the application and documentation of fetal surveillance in labour that will decrease the incidence of birth asphyxia while maintaining the lowest possible rate of obstetrical intervention. Both high- and low-risk obstetrical populations are considered. It is intended that this guideline could be used by all persons providing intrapartum care in Canada, including nurses, physicians, and midwives.

Options: Consideration has been given to methods of fetal surveillance currently available in Canada, including intermittent auscultation, electronic fetal monitoring (alone and when paired with vibro-acoustic or scalp stimulation and fetal scalp blood sampling), the "admission strip," computerized heart rate analysis, fetal oxygen saturation monitoring, fetal electrocardiogram analysis, and near-infrared spectroscopy.

Outcomes: Short- and long-term outcomes were considered that may indicate the presence of birth asphyxia. The associated rates of operative or other labour interventions were also considered.

Evidence: A comprehensive review of randomized controlled trials performed from 1995 to date and a search of the literature using Medline and the Cochrane Database of all new studies on fetal surveillance. The level of evidence has been determined using the criteria described by the Canadian Task Force on the Periodic Health Examination.

Recommendations:

Part I: Standard Fetal Surveillance in Labour

1. Women in active labour should receive continuous close support from an appropriately trained professional. One-to-one nursing is recommended. (I-A)
2. Intermittent auscultation following an established protocol of surveillance and response (Figure 1) is the preferred method of fetal surveillance in healthy pregnancies in the active phase of labour. (I-A)
3. Labour induction requires close monitoring of uterine activity and fetal heart rate. (III-B)
4. In the presence of abnormal fetal heart rate characteristics detected by intermittent auscultation and unresponsive to resuscitative measures, increased surveillance by continuous electronic fetal monitoring or fetal scalp sampling or delivery should be instituted. (I-A)
5. Continuous intrapartum electronic fetal monitoring is recommended:
 - a) for pregnancies where there is an increased risk of perinatal death, cerebral palsy, or neonatal encephalopathy (III-C)
 - b) when oxytocin is being used for augmentation of labour (I-A)
 - c) when oxytocin is being used for induction of labour (III-C).
6. With respect to continuous electronic fetal monitoring, all professionals must be familiar with the paper speed used in each case to avoid misinterpretation. The correct time should be recorded on the electronic fetal monitoring record. (III-C)

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7. Electronic fetal monitoring records should be inspected and documented every 15 minutes in the active phase of labour and at least every 5 minutes in the second stage of labour. (III-C)
8. The timing of electronic fetal monitoring patterns should be determined in association with uterine contractions. The contraction frequency, duration, intensity, and resting tone should be assessed and documented. Abdominal palpation, a tocodynamometer, or an intrauterine pressure catheter may be used to facilitate the assessment. (III-C)
9. Practitioners should use standard terminology when describing fetal heart rate characteristics of an electronic fetal monitoring record. (III-C)
10. Fetal scalp blood sampling is recommended in association with electronic fetal monitoring patterns that are uninterpretable or non-reassuring, such as sustained minimal or absent variability, uncorrectable late decelerations, increasing fetal tachycardia, and abnormal FHR characteristics on auscultation. (II-3B)
11. The limited knowledge available on the use of labour admission tests warrants further research to establish the usefulness of this screening approach. (III-C)

Part II: New Technologies for Fetal Surveillance in Labour

12. The use of computer-based algorithms alone to interpret fetal heart rate patterns is not recommended as a standard of care at the present time. (III-D)
13. Fetal pulse oximetry as an adjunct to electronic fetal heart monitoring in patients with non-reassuring FHR status is not recommended as a standard of care at the present time. (III-D)
14. ST waveform analysis technology is under development but is not recommended as a standard of care at this time. (III-C)
15. Near-infrared spectroscopy as an adjunct to electronic fetal monitoring is currently not recommended as there is insufficient evidence to assess its efficacy in fetal surveillance. (III-D)

16. Further study of fetal pulse oximetry, ST waveform analysis, and near-infrared technology in clinical research settings is encouraged. (III-B)

Validation: This guideline was reviewed by the SOGC Clinical Practice Obstetrics Committee, Maternal Fetal Medicine Committee, and ALARM Committee, as well as by the Canadian Medical Protective Association.

Sponsor: The Society of Obstetricians and Gynaecologists of Canada.

PART II: NEW TECHNOLOGIES FOR FETAL SURVEILLANCE IN LABOUR

The quality of evidence reported in these guidelines has been described using the Evaluation of Evidence criteria outlined in the Report of the Canadian Task Force on the Periodic Health Exam (Table 1).¹

COMPUTERIZED FETAL ANALYSIS

Computerized fetal monitoring generally refers to two different applications: feature detection and interpretation. Feature detection is the identification, labelling, and measurement of the patterns used clinically to describe a fetal heart rate tracing: baseline, accelerations, decelerations, and variability.² Interpretation refers to some assessment of the clinical significance of these features with respect to fetal well-being. Commercial software that provides these functions in central monitoring systems or in electronic fetal monitors is regulated by the Therapeutic Product Programme of Health Canada and the

TABLE I QUALITY OF EVIDENCE ASSESSMENT ¹	CLASSIFICATION OF RECOMMENDATIONS
<p>The quality of evidence reported in these guidelines has been described using the Evaluation of Evidence criteria outlined in the Report of the Canadian Task Force on the Periodic Health Exam.</p> <p>I: Evidence obtained from at least one properly randomized controlled trial.</p> <p>II-1: Evidence from well-designed controlled trials without randomization.</p> <p>II-2: Evidence from well-designed cohort (prospective or retrospective) or case-control studies, preferably from more than one centre or research group.</p> <p>II-3: Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category.</p> <p>III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.</p>	<p>Recommendations included in these guidelines have been adapted from the ranking method described in the Classification of Recommendations found in the Report of the Canadian Task Force on the Periodic Health Exam.</p> <p>A. There is good evidence to support the recommendation that the condition be specifically considered in a periodic health examination.</p> <p>B. There is fair evidence to support the recommendation that the condition be specifically considered in a periodic health examination.</p> <p>C. There is poor evidence regarding the inclusion or exclusion of the condition in a periodic health examination, but recommendations may be made on other grounds.</p> <p>D. There is fair evidence to support the recommendation that the condition not be considered in a periodic health examination.</p> <p>E. There is good evidence to support the recommendation that the condition be excluded from consideration in a periodic health examination.</p>

Food and Drug Administration (FDA) in the United States. Approved software has undergone successful review by these agencies where the data supporting the claims of the companies are analyzed. Ideally, the performance of a new diagnostic test is compared to a gold standard, but there is no recognized gold standard collection of fetal heart rate patterns against which one can test computerized detection algorithms.

Assessing the performance of feature detection for intrapartum use has been reported.³ The results apply to the particular device under study and should not be generalized to others. Measuring the agreement between a computer and clinical experts is challenging because of the well-described^{4,5} variation in clinical opinion. In one study,³ the feature detection algorithms were evaluated by four clinicians from varied backgrounds, including an obstetrical nurse, a certified midwife, an obstetrical resident, and a maternal-fetal medicine specialist. One-hour segments of tracings divided into 10-minute windows from the first hour of the active phase of labour from 50 women were analyzed.

Using any one of these experts as a standard, the percentage agreement by the other clinicians for accelerations or decelerations ranged from 43.1% to 66.5%.³ The agreement among clinicians for the actual baseline value was 98.3%.³

On average, these clinicians disagreed with about 46% (range 37.7–50.5%) of the defined accelerations and with 54% (range 48.9–64.2%) of the defined decelerations.³ The clinicians disagreed with the computer-defined baseline value in 14.6% of the windows.³ Computerized alerts were programmed to be given on the basis of more severe patterns or combinations of patterns over time. Agreement by the clinicians that these portions of tracing were “non-reassuring” was better than the agreement rates for the isolated features; however, they disagreed on average with 22.4% (range 20.8–23.1%) of the computer alerts.³ As the performance of these feature detection algorithms has been assessed in only one study,³ and in that study assessed only in early labour tracings (where the fetal heart rate is more stable than later in labour), and as there is no information regarding the numbers of clinician-identified events that were missed by the computer, this approach, while suggesting potential, is not sufficiently validated to be considered a standard of obstetrical care.

Determining the association between fetal heart rate features and some meaningful clinical outcomes requires an accurate method to detect the features, a large sample of cases in each outcome category that is truly representative of the population, and modelling techniques suited to handling this kind of complex data set. Failure to find associations between fetal heart rate patterns and outcome can be due to limitations in any one or all of these steps, as well as to the inherent limitation of fetal heart rate patterns to predict newborn status.

There are no commercially available computer systems that make interpretations. On a research basis, Keith *et al.*⁶ have

created a computer system that detects fetal heart rate features and synthesizes one of five possible management suggestions. An extensive analysis comparing the computer system to 17 clinical experts showed good agreement between the computer and the experts, both in terms of the actual recommendation and the time at which it was made.⁷

RECOMMENDATION

12. The use of computer-based algorithms alone to interpret fetal heart rate patterns is not recommended as a standard of care at the present time. (III-D)

FETAL OXYGEN SATURATION MONITORING

PHYSIOLOGY

The oxygen saturation of arterial hemoglobin can be measured using pulse oximetry, whereby the difference in absorption of light by oxyhemoglobin and deoxyhemoglobin, measured at two wavelengths in the red and infrared spectrum, are determined in systole and diastole.⁷ In addition to the arterial hemoglobin, light is also absorbed by other nonpulsatile elements, such as venous hemoglobin, tissue, and bone.⁷ However, as only the ratio of light absorption between systole and diastole is used, the contribution from other nonpulsatile absorbers is cancelled, so that changes in light intensity only attributable to pulsatile blood elements (primarily arterial hemoglobin) are measured.⁷ After obtaining optical signals at systole and diastole for both wavelengths, the normalized ratio of red to near infrared non-absorbed light is used to determine the ratio of oxyhemoglobin to deoxyhemoglobin. The oxygen saturation of arterial hemoglobin is then calculated using a set of empirically derived calibration coefficients.⁷

Pulse oximetry with transmission sensors has now been well validated for the continuous monitoring of arterial oxygen saturation (SpO₂) in both adult and newborn populations and is used routinely in anesthesia and critical care settings. Recently, application of pulse oximetry with use of reflectance sensors, whereby the light-emitting diodes and the photo detector are housed side by side, has been investigated for the monitoring of fetal oxygenation during the intrapartum period.⁸ The sensor which has been most studied to date⁸⁻¹² is the FS-14 fetal sensor, which uses light absorption measured at 735 and 890 nm.

CRITICAL THRESHOLD VALUE FOR FETAL OXYGEN SATURATION

The fetal oxygen saturation monitor is not an “acidosis detector”; rather, it was designed to indicate whether the fetus is “well oxygenated” or not. The definition of “well oxygenated” is ascribed by the caregiver and is dependent on the agreed-upon “critical threshold.”⁹

A critical threshold appears to exist for a lowering of oxygen saturation in the fetus in relation to the onset of metabolic

acidosis,⁹ which would then provide a further means of assessing the need for delivery in the patient with a non-reassuring fetal heart rate pattern. Study in the ovine fetus, with stepwise lowering of maternal inspired oxygen over several days, demonstrated the fetal pH to begin decreasing when productal arterial oxygen saturation was close to 30%.¹³ A second study in the ovine fetus, with stepwise lowering of oxygenation over several hours, again showed that fetal pH and base excess values only began to decrease below an oxygen saturation of 30%.¹⁴

In a study of a large tertiary referral hospital population,¹⁵ it was shown that calculated umbilical vein and artery oxygen saturation measured at birth was significantly correlated with pH ($r = 0.46$) and umbilical artery base excess, albeit weakly ($r = 0.18$ to 0.22). Furthermore, the correlations were better described using cubic rather than linear regression models,¹⁵ again supporting the concept of a critical threshold or threshold range for umbilical oxygen saturation values in relation to measures of acidosis.¹⁵ Further support for the critical threshold level of 30% comes from a study of fetal pulse oximetry in human fetuses compared with scalp blood pH.¹⁰

NON-RANDOMIZED CLINICAL STUDIES

In an observational study, Alshimmiri *et al.*⁸ monitored 54 patients labouring at term with non-reassuring FHR patterns, intrauterine growth restriction, or thick meconium, using the FS-14 fetal oxygen sensor. Fetal SpO₂ values showed little overall change as monitored through labour and averaged 44% for the total period of monitoring. An SpO₂ of less than 30% for the last 30 minutes of labour had a positive predictive value of 40% and a negative predictive value of 90% for an umbilical artery pH less than 7.13 at birth.

In the French multicentre observational study, Goffinet *et al.*¹¹ and Carbonne *et al.*¹⁶ reported on 174 patients labouring at term with non-reassuring FHR patterns, using the FS-14 fetal oxygen sensor. An SpO₂ of less than 30% for the last 30 minutes before fetal scalp sampling had a positive predictive value of 43% and a negative predictive value of 87% for an umbilical artery pH less than 7.15 at birth, which was similar to the predictive value of fetal scalp sampling at a threshold of 7.20 for fetal scalp pH. An SpO₂ of less than 30% during the second stage of labour had a positive predictive value of 43% and a negative predictive value of 88% for an umbilical artery pH less than 7.15 at birth.

In the German multicentre observational study, Seelbach-Gobel *et al.*⁹ reported on 400 patients labouring at term with reassuring and non-reassuring FHR patterns, using the FS-14 fetal oxygen sensor. An SpO₂ of less than 30% for more than 15 minutes had a positive predictive value of 58% and a negative predictive value of 90% for a decline of scalp pH by greater than 0.05 between fetal scalp blood samples,⁹ indicating the importance of duration of low fetal oxygenation, as well as the level of low oxygenation.

RANDOMIZED CONTROLLED TRIALS

There has only been one randomized controlled trial (RCT) of fetal oxygen saturation monitoring, the U.S. multicentre RCT, from which Garite *et al.*¹² reported on 1010 patients labouring at term with non-reassuring FHR patterns, who received electronic FHR monitoring alone (control group) or combined with fetal pulse oximetry (study group), using the FS-14 fetal oxygen sensor. Study group patients with a fetal SpO₂ greater than 30% were allowed to continue labouring, while the management of those with a fetal SpO₂ less than 30% depended on the continuing FHR pattern, with the option of fetal scalp sampling (the same management for control patients). Study group patients had a 50% reduction in Caesarean section rate for non-reassuring FHR. However, the overall Caesarean section rate in the study group was no different from that in the control group because of an increase in Caesarean section for dystocia in the study group. Among women undergoing operative delivery of any kind for non-reassuring fetal status, the addition of SpO₂ was a more accurate predictor (sensitivity and specificity) of acidosis than EFM alone.¹² There was no difference in overall neonatal outcome between the two groups. Acidosis was defined as cord arterial pH < 7.05 or a cord arterial base excess ≤ -10 .

CONSIDERATIONS AND LIMITATIONS

The accuracy of pulse oximetry in the measurement of arterial oxygen saturation may be affected by methodologic issues, including sensor placement and contact, tissue blood volume and edema, venous pulsation, and variable signal penetration.¹⁷ Another variable affecting the utility of the method is the decrease in cutaneous blood flow in association with hypoxia.¹⁷ Lastly, on the steep part of the hemoglobin oxygen dissociation curve, small changes in pO₂ result in large changes in O₂ saturation.¹⁷ Studies in animals indicate that reflectance pulse oximeters, of the type currently under clinical trial, are more precise across a range of values than transmission pulse oximeters, which are calibrated for oxygen saturation greater than 70%.¹⁷

Low SpO₂ values as a measure of fetal oxygenation may be well tolerated, with no clinically significant increase in anaerobic metabolism, depending on the duration of continuing labour and the ability to initiate compensatory mechanisms. This ability of the fetus to compensate would account for the low positive predictive value of 40–50% for SpO₂ values less than 30% and significant acidosis at birth.¹⁸ Conversely, normal fetal SpO₂ values may occasionally be associated with significant metabolic acidemia at birth, as evidenced by the false negative rate of 5–10% in clinical outcome studies.¹⁸ This false reassurance may be related to a deterioration in fetal oxygenation after removal of the oxygen sensor or during the delivery process, thus leading to a degree of metabolic or respiratory acidosis at birth that is not predicted by SpO₂ values through labour.¹⁸ It is also possible that periodic decreases in fetal oxygenation during uterine

contractions with umbilical cord compression may give rise to a cumulative acidosis over time that is not predicted by SpO₂ values, either between or during contractions.¹⁸

RECOMMENDATION

13. Fetal pulse oximetry as an adjunct to electronic fetal heart rate monitoring in patients with non-reassuring FHR status is not recommended as a standard of care at the present time. (III-D)

FETAL ELECTROCARDIOGRAM ANALYSIS

Fetal ECG monitoring is a technique used in combination with standard electronic fetal monitoring (EFM). A specialized monitor with proprietary software collects both the standard fetal heart rate and uterine activity signals and the fetal ECG.¹⁹ Interpretation is based on the observation that the fetal QRS and T wave change in relation to the metabolic state of the fetal heart.¹⁹ By analyzing changes and trends in the ST segment and the T/QRS ratio, in conjunction with a three-level classification of the fetal heart rate patterns, a more precise interpretation regarding the need for intervention can be made.¹⁹

Use of this technology requires considerable training, as thresholds for intervention change depending upon the classification of the fetal heart rate patterns (three classes), the

T/QRS ratio (two levels), and the shape of the ST segment (three grades).^{19,20} The impact of this type of monitoring compared to standard electronic fetal monitoring has been evaluated in two prospective randomized clinical trials.^{19,20} Both randomized clinical trials were conducted in Europe and the data are summarized in Table 2.^{19,20} Rates of Caesarean section for the indication of non-reassuring fetal status were lowered in the U.K. study only.²⁰ However, total Caesarean section rates were constant.^{19,20} Instrumental vaginal delivery rates for the indication of non-reassuring fetal status were reduced in the U.K. study²⁰ but this was not statistically significant at the $P = 0.05$ level in the Swedish study.¹⁹ Statistical significance was achieved when these rates of Caesarean delivery and instrumental vaginal delivery were combined and compared in the two groups.^{19,20}

A reduction in Caesarean rates for a single indication that is not reflected in the total Caesarean rate raises the concern that Caesareans continued to be done and that another indication was recorded by the clinicians. The same concern might be applied to instrumental vaginal delivery rates. Nevertheless, metabolic acidosis was reduced in the Swedish study group,¹⁹ total Caesarean rates were not increased, and there were fewer combined interventions for non-reassuring fetal status.²⁰

Use of single parameters such as PR interval or the T/QRS ratio has not been shown to be superior to standard EFM.^{21,22}

TABLE 2

CAESAREAN SECTION RATES FOR NON-REASSURING FETAL STATUS^{19,20}

		EFM	EFM & STAN	P value
Number of women	UK	1215	1219	
	Sweden	2447	2519	
	Sweden*	2164	2228	
% Caesarean for the indication of non-reassuring fetal status	UK	2.5	1.2	0.03
	Sweden	4.0	4.0	0.38
	Sweden*	2.9	1.9	0.04
% Caesarean for all indications	UK	24.8	24.4	0.85
	Sweden	9.0	9.0	0.38
	Sweden*	8.0	6.5	0.07
% Instrumental vaginal delivery for the indication of non-reassuring fetal status	UK	6.7	3.8	0.001
	Sweden	5.0	4.0	0.08
	Sweden*	6.1	5.6	0.49
% Caesareans and instrumental vaginal delivery for the indication of non-reassuring fetal status	UK	9.1	5.0	0.001
	Sweden	9.0	8.0	0.047
	Sweden*	8.0	5.9	0.008
% with cord blood gas evidence of metabolic acidosis pH < 7.05 and base deficit > 12.0 mmol/L	UK	1.06	1.4	0.09
	Sweden	2.0	0.7	0.02
	Sweden*	1.4	0.6	0.01

* Analysis done after removing data where there was a protocol violation, which means analysis as treated rather than analysis as randomized, which reduces the level of evidence to that of an observational study and has major impact on the proper interpretation of results in this setting.

RECOMMENDATION

14. ST waveform analysis technology is under development but is not recommended as a standard of care at this time. (III-C)

NEAR-INFRARED SPECTROSCOPY

The concentration of oxyhemoglobin and deoxyhemoglobin within tissue vascular beds can be measured using near-infrared spectroscopy (NIRS). This measurement depends upon the change in absorption of near-infrared light transmitted through the tissue during a change in hemodynamic conditions such as blood flow, blood volume, blood oxygenation, and application of the modified Beer-Lambert law.²³ This technology has been studied as a non-invasive means of monitoring cerebral oxygenation in the newborn and in the fetus during the intrapartum period. In an observational study, Aldrich *et al.*²⁴ monitored 41 patients labouring near or at term, using the NIRO-500 spectrophotometer, and demonstrated a significant correlation between fetal cerebral oxygenation values within 30 minutes of delivery and subsequent cord blood gas and pH values at birth. A second observational study compared NIRS to fetal pulse oximetry and found a positive correlation between changes in fetal cerebral oxygenation values and pulse oximetry values.²⁵ However, study to date in the fetus also indicates continuing technical difficulties with probe positioning and as yet there are no published trials assessing the usefulness of NIRS in the monitoring of fetal condition during labour.

RECOMMENDATION

15. Near-infrared spectroscopy as an adjunct to electronic FHR monitoring is currently not recommended, as there is insufficient evidence to assess its efficacy in fetal surveillance. (III-D)

FUTURE RESEARCH

The goals for future research in fetal surveillance methodologies should include the study of more specific markers of impending fetal compromise, which could lead to reduced rates of intervention for suspected fetal compromise and lower rates of significant metabolic acidosis at birth.

The evaluation of any method of intrapartum fetal surveillance should address the accuracy of the method, ideally obtained from randomized clinical trials. The accuracy in the real world of clinical practice (effectiveness) as opposed to that in an idealized environment (efficacy) needs to be determined. When new fetal surveillance technologies are approved for use in Canada it would seem advisable to evaluate them in pilot programs under careful supervision prior to their widespread distribution. Such steps should reduce the likelihood of an ineffective technology becoming established as a part of routine practice.

RECOMMENDATION

16. Further study of fetal pulse oximetry, ST waveform analysis, and near-infrared technology in clinical research settings is encouraged. (III-B)

This Clinical Practice Guideline, Fetal Health Surveillance in Labour (Part I: Standard Fetal Surveillance in Labour, and Part II: New Technologies for Fetal Surveillance in Labour), supersedes the previous guidelines on Fetal Health Surveillance published in 1995/1996.

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