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Intermittent Auscultation for Intrapartum Fetal Heart Rate Surveillance

American College of Nurse-Midwives



Fetal heart rate surveillance is a standard component of intrapartum care. The fetal heart rate can be evaluated using intermittent auscultation or electronic fetal monitoring. Research that has compared these 2 strategies found them to be equivalent with respect to long-term neonatal outcomes. The purpose of this clinical bulletin by the American College of Nurse-Midwives is to review the evidence for use of intermittent auscultation and provide recommendations for intermittent auscultation technique, interpretation, and documentation.

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Keywords: fetal heart rate, intermittent auscultation, electronic fetal monitoring, intrapartum fetal surveillance

INTRODUCTION

Standard evaluation of fetal well-being during labor includes the periodic assessment of the fetal heart rate (FHR), the FHR pattern, and FHR response to intrapartum stimuli and events. Effective methods of evaluation and meaningful interpretation of FHR data have long been the subjects of clinical debate. Continuous electronic fetal monitoring (EFM) is the most common method of intrapartum fetal surveillance in current use, but this method has not been shown to be more effective than intermittent auscultation (IA).

The recommendations of most professional organizations regarding FHR assessment during labor are based upon protocols used in randomized controlled trials (RCTs) in which the authors compared IA and EFM.^{4–7} Guidelines based on evidence-based application of IA during labor are not available. This clinical bulletin reviews the evidence for use of IA and presents recommendations for use that are based on the best available scientific data.

INTERMITTENT AUSCULTATION

IA is a method of FHR surveillance that involves counting the FHR for a specified amount of time at specified intervals in relation to uterine contractions. IA may be done with a fetoscope, which uses bone conduction to assist in hearing the opening and closing of the valves of the fetal heart, or with a handheld Doppler ultrasound, which is used to detect fetal heart motion and convert it to sound. Newer models of the handheld Doppler include a paper print out of the recorded heart rate.

Researchers who evaluated the reliability and validity of IA have not reported consistent results. 8,9 However, it appears that IA using a multiple-count strategy to assess the FHR during and after a contraction can be used to detect heart rate, rhythm, accelerations, and decelerations reliably 10,11

but cannot be used to differentiate between types of decelerations or determine baseline variability with accuracy (Table 1).^{5,8,10–15} Despite these limitations, researchers who have compared the 2 fetal surveillance strategies found them to be equivalent with respect to long-term neonatal outcomes.^{3,16–18} Therefore, the inability to consistently determine the FHR variability or type of deceleration in labor using IA does not appear to be clinically significant when monitoring women who are at low risk for uteroplacental insufficiency or who have fetuses with normal baseline heart rates.

ELECTRONIC FETAL MONITORING

With EFM, an ultrasound or a fetal spiral electrode records the fetal electrocardiogram (ECG) to produce an auditory and visual representation of the FHR that is continuously recorded as the FHR tracing. Continuous EFM is used to detect and document the baseline rate, FHR variability, accelerations, and periodic or episodic decelerations. The presence of moderate FHR variability, accelerations, and a normal baseline rate are highly predictive of a well-oxygenated fetus at the time of observation. However, the relationship between variant FHR patterns and fetal acid-base status is highly variable. Most variant FHR patterns have a low positive predictive value for identifying fetal acidemia.

RESEARCH COMPARING INTERMITTENT AUSCULTATION AND ELECTRONIC FETAL MONITORING DURING LABOR

Since the adoption of continuous EFM as the standard of care, multiple RCTs and subsequent meta-analyses designed to determine the effectiveness of EFM have been performed. 3,16–18 The Cochrane Database of Systematic Reviews published a meta-analysis of 13 RCTs in which investigators compared maternal and neonatal outcomes after continuous EFM versus

This Clinical Bulletin was developed under the direction of the Clinical Standards and Documents Section of the Division of Standards and Practice, as an educational aid for midwives. This Clinical Bulletin is not intended to dictate an exclusive course of management or to substitute for individual professional judgment. It presents recognized methods and techniques for clinical practice that midwives may consider incorporating into their practices. The needs of an individual patient or the resources and limitations of an institution or type of practice may appropriately lead to variations in clinical care.



Table 1. Fetal Heart Rate Characteristics Determined via Auscultation versus Electronic Monitor					
FHR Characteristic ^a	Fetoscope	Doppler without Paper Printout	Electronic FHR Monitor		
Variability	No	No	Yes		
Baseline rate	Yes	Yes	Yes		
Accelerations	Detects increases ^b	Detects increases ^b	Yes		
Decelerations	Detects decreases	Detects decreases	Differentiates types of		
			decelerations		
Rhythm ^c	Yes	Yes	Yes		
Double counting or half-counting FHR	Can clarify	May double count or half count	May double count or half count		
Differentiation of maternal and fetal	Yes	May detect maternal heart rate	May detect and record maternal		
heart rate			heart rate		

IA during labor for more than 37,000 women.³ The women in the continuous EFM group had an increase in cesarean births (relative risk [RR], 1.63; 95% confidence interval [CI], 1.29-2.07; n = 18,861; 11 trials) and operative vaginal births (RR, 1.15; 95% CI, 1.01-1.33; n = 18,615; 10 trials) but no difference in perinatal mortality (RR, 0.86; 95% CI, 0.59-1.23; n = 33,513; 11 trials) or rates of cerebral palsy (RR, 1.75; 95% CI, 0.84-3.63; n = 13,252; 2 trials).³ There was a 50% decrease in the incidence of neonatal seizures in the continuous EFM group compared to the IA group (RR, 0.50; 95% CI, 0.31-0.80; n = 32,386; 9 trials).³ However, in a follow-up study of the infants who had seizures at 4 years of age, the researchers found an equal number of children in each group with cerebral palsy, leading them to conclude that continuous EFM offers little, if any, benefit. 21,23 In practice, the reduction in the incidence of neonatal seizures must be balanced against the morbidity associated with cesarean and operative vaginal births. Cesarean birth significantly increases the incidence of maternal morbidity and mortality when compared to vaginal birth.

Use of EFM as an initial admission test for laboring women has also been studied in 5 RCTs and a subsequent meta-analysis of more than 13,000 low-risk women in labor.²⁴⁻²⁸ The EFM admission test is usually a 20-minute continuous recording of the FHR that is evaluated for any characteristics that may increase the risk for fetal acidemia. Use of an EFM admission test increased the incidence of continuous EFM during labor (RR, 1.30; 95% CI, 1.14-1.48; n = 10,753; 3 trials), and there was a trend toward an increase in the rate of cesarean birth (RR, 1.00; 95% CI, 1.00-1.44; n = 11,338; 4 trials).²⁴ There were no significant differences in other labor interventions such as amniotomy, labor augmentation, or epidural analgesia. Similarly, there were no differences between the groups in adverse neonatal outcomes. The authors concluded that continuous EFM as a labor admission test has no clear benefit when compared to IA in women who do not have any known risks for fetal acidemia at the onset of spontaneous labor at term.²⁴

METHOD OF INTERMITTENT AUSCULTATION

IA can be used to determine the baseline FHR and detect periodic FHR changes. Most professional associations have made

recommendations on the frequency of IA based on protocols used in RCTs comparing EFM to IA.4-7 However, the timing of IA with regard to uterine contractions must also be consid-

Evaluation of Baseline Fetal Heart Rate

To determine the baseline FHR, the FHR is auscultated between contractions and when the fetus is not moving. At the same time, the mother's radial pulse is palpated to ensure that the fetal heart rate is auscultated, not the mother's. 6,29 After establishing the baseline rate, the FHR is auscultated for 15 to 60 seconds at recommended intervals between contractions and when the fetus is not moving to assess the baseline rate.

Evaluation of Periodic FHR Changes

Listening for FHR accelerations and decelerations is the second component of IA. Typically, the provider auscultates the FHR for a period of time (eg, 15 to 60 seconds) and notes any audible increase or decrease in rate. Methods have been devised to validate this information⁹⁻¹³ based on studies primarily done with women who were not in labor or via use of simulated data such as FHR recordings. 14 Therefore, although the techniques may be utilized in the intrapartum setting, they have not been specifically validated for use in the intrapartum setting. In most of the studies, investigators used a multiplecount strategy whereby the observer counted the FHR during several 5- to 15-second increments. 11-15 An increase in the number obtained from each 5- or 15-second count in subsequent intervals indicated an acceleration; a decrease in the rate indicated a deceleration. These rates can be plotted on a graph for documentation as described by Paine et al. 12,13 If there is a question as to whether accelerations or decelerations have been auscultated, continued auscultation during the course of a uterine contraction may provide clarification. The multiplecount strategy is likely to be more accurate than a single-count strategy.14

Frequency of Intermittent Auscultation

To date, investigators have not determined the optimal frequency of IA during labor. The current recommendations of

Abbreviation: FHR, fetal heart rate. $^{\rm a}$ Definitions of each FHR characteristic based on those reported in Macones et al. $^{\rm 20}$

bPer method described by Paine et al. 12 and Paine et al. 13 (Determined as regular or irregular. None of these devices can diagnose the type of fetal arrhythmia.

Adapted from: Lyndon A, Ali LU, eds. Fetal Heart Monitoring Principles and Practices. 4th ed. Dubuque, IA: Kendall-Hunt Publishing Company; 2009. Used with permission from the Association of Women's Health, Obstetric and Neonatal Nurses.

Table 2. Recommendations of Professional Organizations for Frequency of Fetal Heart Rate Auscultation for Women who are Low Riska **During Labor**

		Active Phase	Second Stage
Organization	Latent Phase	Minutes	Minutes
American College of Nurse-Midwives		15-30	5
American College of Obstetricians and		30	15
Gynecologists			
American College of Obstetricians and		15	5
Gynecologists and American Academy of			
Pediatrics Joint Guidelines for Perinatal Care			
Association of Women's Health, Obstetric And		15-30	5-15
Neonatal Nurses			
Royal College of Obstetricians and		15 ^d	5 ^d
Gynaecologists			
Society of Obstetrics and Gynaecologists of	At time of assessment and	15-30	5°
Canada ^b	approximately every hour		

^aNone of the guidelines of the professional organizations included here specifically define low risk. For the purpose of this bulletin, low risk refers to women who have no medical or obstetric conditions that are associated with uteroplacental insufficiency or conditions that are associated with an increased incidence of umbilical artery pH of less than 7.1 at birth.

professional organizations representing maternal-fetal health care providers are summarized in Table 2. In the absence of evidence-based parameters to define the optimal interval for auscultation, an interval ranging between every 15 to 30 minutes during the active phase, every 15 minutes during the second stage prior to expulsive efforts, and every 5 minutes after initiation of pushing may be reasonable as long as the auscultated FHR is normal and there are no other labor characteristics that would suggest a need for more frequent monitoring.

The frequency of auscultation should be individualized based upon the contraction pattern, level of maternal activity, and institution interventions that may affect the FHR. In addition to listening to the FHR with IA at regular intervals, it is recommended that the FHR be assessed before and after vaginal examinations or rupture of membranes.5

Timing of Auscultation in Relation to Uterine Contractions

The timing of auscultation varies among protocols but can include auscultation throughout and after contractions or between contractions. Evidence for the best technique is limited. Although one can listen and count the FHR throughout a contraction and for a short time after the contraction resolves, this is technically difficult to do. One of the primary goals of listening throughout the contraction and for a brief time after the contraction ends is to ensure the listener can detect periodic FHR decelerations if they are present. If one listens between contractions only, there is the potential to miss clinically important decelerations that can increase the risk for fetal acidemia. Thus, the best technique for detecting decelerations is to listen during the last portion of a uterine contraction and for a short period after the contraction is complete. A Doppler with speaker and/or printer functions has advantages over a fetoscope for this purpose, including ease of use in several maternal positions and during water immersion. Audibility allows for validation and collaboration with the woman and other members of the caregiving team. The recommended technique for IA is provided in Table 3.

INTERPRETATION OF THE FETAL HEART RATE **DURING LABOR**

The purpose of monitoring the FHR during labor is to detect the development of clinically significant acidemia in the fetus. If the fetus does not have an a priori risk for uteroplacental insufficiency, intermittent decreases in oxygen delivery to the intervillous space that occur during uterine contractions are usually well compensated for during the course of labor. If a previously well-oxygenated term fetus develops clinically significant acidemia during labor, recurrent FHR decelerations will be present, and the FHR baseline will evolve from moderate to minimal and then absent variability. This pattern of recurrent decelerations that become progressively deeper and FHR variability that progressively diminishes is sometimes accompanied by tachycardia.³⁰ In general, the progression from well oxygenated to acidemia takes approximately one hour. 19 Alternatively, acute hypoxic events that do not resolve will be evident as acute fetal bradycardia. Thus FHR characteristics detectable via EFM or IA must be interpreted with regard to their accompanying risk for the presence of fetal acidemia.

Interpretation of the Fetal Heart Rate via **Continuous Electronic Fetal Monitoring**

In 2008, a workgroup of the National Institute of Child Health and Human Development (NICHD) and American College of Obstetricians and Gynecologists recommended a 3-tier system of categories for interpretation of FHR patterns based

bIntermittent auscultation should only be used by practitioners with experience in the technique of auscultation, palpation of contractions, and auditory recognition of pertinent fetal heart rate changes.

CWhen pushing has been initiated.

dFor a minimum of 60 seconds after a contraction.

Table 3. Technique for Performing Intermittent Auscultation

- 1. Perform Leopold's maneuvers to identify the fetal presentation and position.
- 2. Assist the laboring woman into a position that maximizes audibility and preserves comfort.
- 3. Assess frequency and duration of uterine contractions.
- 4. Determine the maternal pulse rate.
- 5. Place the fetoscope or Doppler over the fetal thorax or back.
- 6. Determine the baseline fetal heart rate by listening between contractions and when the fetus is not moving. Verify maternal pulse rate if necessary.
- 7. Subsequently, count the fetal heart rate starting at the peak of the uterine contraction and for a short period of time after the contraction resolves every 15 to 30 minutes in active labor and every 5 minutes in the second stage of labor.
- 8. Note increases (accelerations) or decreases (decelerations) from the baseline rate by counting and recording the fetal heart rate using a multiple-count strategy agreed upon by practice protocol.^a

on the relationship between the FHR pattern and the risk for concomitant fetal acidemia. FHR characteristics that are termed Category I (normal) indicate the fetus does not have acidemia. These patterns include moderate FHR variability, an FHR baseline of 110 to 160 beats per minute, and absence of late or variable decelerations. The presence of accelerations is not required for interpreting the findings to be Category I, but accelerations are a sign that the fetus has a pH higher than 7.19 at the time the acceleration is detected and are therefore important to note when observed. The absence of accelerations is not indicative of a nonreassuring fetal status. Similarly, early decelerations may be present.

Category III (abnormal) FHR patterns are those with absent variability in the presence of recurrent late or variable decelerations, bradycardia, or a sinusoidal pattern. Recurrent late or variable decelerations with minimal or absent variability have a 23% positive predictive value for the presence of fetal acidemia. Abnormal FHR patterns are termed Category III, and they warrant immediate evaluation and an urgent plan for birth.

Category II (indeterminate) FHR characteristics include all those patterns not identified as either Category I or Category III. These FHR patterns are termed indeterminate because they are not predictive of abnormal fetal acid-base status, and there is insufficient evidence to classify them as either Category I or Category III.

INTERPRETATION OF THE AUSCULTATED FETAL HEART RATE

Auscultated FHR patterns can be interpreted as either Category I or Category II and are summarized in Table 4. These 2 categories are consistent with the 3-tier system of 3 categories. Despite limited research substantiating the use of these 2 categories, the FHR descriptions have been adapted to reflect the FHR characteristics obtainable via IA (ie, baseline rate, accelerations, decelerations, irregular rhythm, but not type of deceleration) in order to facilitate clinical management and documentation. 5 Category III FHR patterns are not technically detectable when using IA because one is not able to determine baseline variability using this technique. Category I auscultated FHR characteristics are normal and reflect

Table 4. Interpretation of Auscultation Findings

Category I

Category I FHR characteristics by auscultation include the following:

Normal FHR baseline between 110 and 160 bpm and, Regular rhythm and,

Absence of FHR decreases or decelerations from the baseline Note: Presence of FHR increases or accelerations from the baseline may or may not be present in a FHR auscultated and determined to be Category I. Accelerations should be assessed for and documented if present. If present, FHR accelerations signify fetal well-being at the time they are noted.

Category II

Category II FHR characteristics by auscultation include any of the following:

Irregular rhythm

Presence of FHR decreases or decelerations from the

Tachycardia (baseline >160 bpm >10 minutes in duration)

Bradycardia (baseline <110 bpm >10 minutes in duration)

Abbreviations: bpm, beats per minute; EFM, electronic fetal monitoring; FHR, fetal heart rate; NICHD, National Institute of Child Health and Human Development. a When recurrent decelerations are detected, a transfer to EFM is indicated. EFM will be able to determine if the decreases from baseline are early, late, or variable decelerations and a diagnostic category I, II, or III will then be assigned using NICHD criteria for EFM generated FHR tracings. From Lyndon A, Ali LU, eds. Fetal Heart Monitoring Principles and Practices. 4th ed. Dubuque, IA: Kendall-Hunt Publishing Company; 2009. Used with permission from the Association of Women's Health, Obstetric and Neonatal Nurses.

adequate oxygenation in the fetus. These characteristics are predictive of fetal well-being when observed. 4,5,19,20

Category II auscultated FHR characteristics include all FHR characteristics that are not Category I. These FHR characteristics may be either indeterminate or abnormal depending on the FHR variability which cannot be determined via IA. EFM should be used to verify or clarify an indeterminate or abnormal FHR pattern and guide management. Management

^aSeveral multiple-count strategies have been tested in studies of auscultation. Note that in some of these studies, researchers evaluated FHR auscultation for nonstress tests and the particular technique has not been tested for intrapartum use: Paine et al, ¹² Paine et al, ¹³ Shifrin, ¹⁴ Daniels and Boehm, ¹⁵ and Miller et al. ¹¹

Table 5. National Institute of Child Health and Human Development Terminology for Fetal Heart Rate Characteristics Determined By Electronic Fetal Heart Rate Monitoring

Electronic Fetal Heart Rate Monitoring			
Term	Definition		
Baseline rate	Mean FHR rounded to increments of 5 bpm during a 10-minute segment excluding periodic or episodic		
	changes, periods of marked variability, and segments of baseline that differ by $>$ 25 bpm. Duration must		
	be ≥ 2 minutes.		
Bradycardia	Baseline rate of < 110 bpm for ≥ 10 minutes		
Tachycardia	Baseline rate of $>$ 160 bpm for ≥ 10 minutes		
Variability	Fluctuations in the baseline FHR of 2 cycles/minute or greater. Visually quantitated as the amplitude of the		
	peak-to-trough in beats per minute		
Absent	Amplitude from peak to trough undetectable.		
Minimal	Amplitude from peak to trough $>$ undetectable and ≤ 5 bpm.		
Moderate	Amplitude from peak to trough 6-25 bpm.		
Marked	Amplitude from peak to trough $>$ 25 bpm.		
Acceleration	Visually apparent abrupt increase (onset to peak is $<$ 30 seconds) of FHR above baseline. Peak is \ge 15		
	bpm. Duration is \geq 15 bpm and \leq 2 minutes. In gestations \leq 32 weeks, peak of 10 bpm and duration of		
	10 seconds is acceleration.		
Prolonged	Acceleration $>$ 2 minutes and $<$ 10 minutes duration.		
Early	Visually apparent gradual decrease (onset to nadir is ≥ 30 seconds) of FHR below baseline. Return to		
	baseline associated with a uterine contraction. Nadir of deceleration occurs at the same time as the peak		
	of the contraction Generally, the onset, nadir, and recovery of the deceleration occur at the same time as		
	the onset, peak and recovery of the contraction.		
Late	Visually apparent gradual decrease (onset to nadir is ≥ 30 seconds) of FHR below baseline. Return to		
	baseline associated with a uterine contraction. Nadir of deceleration occurs after the peak of the		
	contraction. Generally, the onset, nadir, and recovery of the deceleration occur after same time as the		
	onset, peak, and recovery of the contraction		
Variable deceleration	Visually apparent abrupt decrease (onset to nadir is $<$ 30 seconds) in FHR below baseline. Decrease is \geq		
	15 bpm. Duration is \geq 15 seconds and \leq 2 minutes.		
Prolonged deceleration	Visually apparent abrupt decrease (onset to nadir is $<$ 30 seconds) in FHR below baseline. Decrease is \geq		
	15 bpm. Duration is ≥ 2 minutes but ≤ 10 minutes.		

Abbreviations: bpm, beats per minute; FHR, fetal heart rate. Adapted from Macones et al. 20

of indeterminate FHR patterns depends on multiple factors, including whether the pattern is recurrent or resolves. Intrapartum resuscitation techniques such as position change, hydration, and correction of hypotension or hyperstimulation can be instituted as necessary. If the Category II FHR pattern does not resolve, transfer to EFM for further evaluation is recommended.

DOCUMENTATION

Characteristics of the auscultated FHR that should be documented include uterine activity pattern, counted FHR, rhythm, and presence or absence of accelerations or decelerations. Terms used for each characteristic should be consistent with the terminology defined by the NICHD when applicable to auscultated findings (Table 5).²⁰ If decelerations are detected, documentation should include the nadir rate, whether the decelerations are recurrent or nonrecurrent, and any interventions instituted. If accelerations are documented, they can be detected using the criteria for identifying acceleration via auscultation validated by Paine et al.^{12,13} In addition,

information about the labor course or maternal status that may assist in the interpretation of data by independent observers should be documented in the record, including FHR response to rupture of membranes, maternal position changes, response to scalp stimulation, or results of vaginal examination.

PATIENT SATISFACTION AND CHOICE

In a systematic review of factors contributing to women's satisfaction with the experience of childbirth (N=45,000), investigators identified the 4 most important factors: personal expectations, amount of caregiver support, quality of caregiver support, and involvement in decision making.³² Involving low-risk laboring women in shared decision making and offering informed choice about mode of fetal monitoring may further add to their satisfaction with the experience of labor and birth.^{33,34} Since IA requires a ratio of one care provider to one woman and near constant presence in order to perform auscultation at the recommended frequency, this

method of fetal surveillance during labor may also contribute to improved outcomes and increased patient satisfaction.³⁵

CHALLENGES AND FUTURE RESEARCH

More research is necessary to determine the most effective frequency of auscultation, interobserver and intraobserver reliability, efficacy of the 2-category system, and barriers to the use of IA in labor. Given the current rate of EFM use in healthy, low-risk women and high cesarean rates in the United States, further investigations to identify clinical and nonclinical barriers to the evidence-based use of IA is warranted. Investigations should also evaluate practical methods of incorporating IA into all maternity care provider education programs and busy intrapartum units. Providers and students need opportunities to learn and become comfortable with using IA. ^{36,37}

RECOMMENDATIONS FOR PRACTICE

In Canada and the United Kingdom, IA is the preferred method of fetal surveillance in women who enter labor at term with no medical or obstetric conditions associated with uteroplacental insufficiency and/or conditions associated with an increased risk for fetal acidemia.^{6,7} The American College of Obstetricians and Gynecologists indicate that for monitoring women in labor, IA is "acceptable in a patient without complications."4 The frequency of observations required to monitor labor with IA facilitates other evidence-based labor support practices, and this method of monitoring the FHR should be the preferred method. IA is associated with fewer cesarean and operative vaginal births, procedures that have additional attendant risks for the mother and newborn, than EFM. In addition, equivalent neonatal outcomes are associated with the use of IA and EFM.3,16-18 Finally, IA allows women more mobility, which in turn increases comfort and progress of labor.

Summary of Recommendations

- 1. IA is the preferred method for monitoring the FHR during labor for women at term who at the onset of labor are at low risk for developing fetal acidemia.
- IA should be conducted according to practice guidelines that include criteria for use of IA, criteria for converting to EFM, and protocols for frequency of observation and documentation.
- Multiple-count methods appear to be more accurate and reliable than single-count methods for evaluation of periodic changes.
- Listening through a contraction instead of listening between contractions will likely improve detection of periodic or episodic changes that might suggest conversion to EFM.
- Auscultated FHR characteristics should be documented using approved terminology and descriptive notations as needed.
- 6. Further research is needed to determine the reliability and validity of different IA protocols and barriers to use of IA

as a standard of care for women who enter labor at low risk of fetal acidemia.

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A literature search was conducted and articles published in English between 1986 and 2014 were reviewed. Studies were evaluated for quality using the guidelines recommended by the US Preventative Health Services Task Force in their document titled:

Guidelines for Rating Strength and Quality of Evidence from Research Findings:

Strength of Recommendation

- **A:** There is good evidence to support that the intervention be adopted.
- **B:** There is fair evidence to support that the intervention be adopted.
- **C:** There is insufficient evidence to recommend for or against the intervention, but recommendations may be made on other grounds.
- **D:** There is fair evidence to support that the intervention be excluded.
- **E:** There is good evidence to support that the intervention be excluded.

Quality of Evidence

- **I:** Evidence obtained from at least one properly randomized controlled trial.
- **II-1:** Evidence obtained from well-designed controlled trials without randomization.

- **II-2:** Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.
- II-3: Evidence obtained from multiple time series studies with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.
- **III:** Opinions of respected authorities, based on clinical experience; descriptive studies and case reports; or reports of expert committees.

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