Maternal-Fetal Risk Assessment and reference Values in Pregnancy

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Background and Importance

The ultimate objective of high quality maternal-fetal care is the uncomplicated birth of a healthy baby to a healthy mother at term. Both maternal mortality ratios and fetal mortality rates have plummeted in the industrialized countries. In the first decade of the 20th century, the maternal mortality ratio in the USA was 850 deaths per 100,000 live births and fetal mortality was around 1000 per 1,000 live births.[1] By around 1995, maternal mortality in the USA was 7 per 1000,000. In Canada total obstetric deaths/year between 1993 –1997 was 4.4 per 100,000 live births. Infant mortality had dropped during this time to around 6-7 per 1,000 births in Canada and the USA. Similar improvements have occurred in most industrialized countries but in many parts of the world, the maternal mortality ratio and perinatal mortality rate remain high.

As maternal and perinatal mortality has decreased in many countries, the focus of perinatal medicine has expanded to improving critical quality indicators for maternal and fetal health. Comprehensive national, state or provincial perinatal surveillance systems have been introduced that monitor a variety of indicators, including occurrence rates for specific select adverse occurrences, behavioral risk factors and medical practices. These systems gather data that form a basis for sophisticated risk assessment and management programs for maternal-fetal health.

An example of such a system is the Canadian Perinatal Surveillance System (1). Within these systems, the most important indicators of perinatal health are determined, a system of monitoring is instigated and data collected to provide a basis for assessing future intervention strategies.

Risk Assessment in Maternal – Fetal Health. Definitions and Principles.

Risk management is a process whereby risk is defined and assessed in order that adverse outcomes may be prevented. Table I defines terms used in risk management.

Table I. Definitions of term used in risk management	
Risk	An undesired event that has adverse consequences
Risk impact	the loss associated with the risk (life, health, economic, social)
Risk probability	the likelihood that the event will occur (0 to 1)
Problem	when risk probability = 1, the risk is identified as a problem
Risk exposure	risk impact X risk probability (used to quantify risk)

Risk sources may be specific, or generic i.e. common to all pregnancies. For example there is a generic *a priori* risk that a woman will have a multiple pregnancy. However some families have a higher risk for multiple pregnancies. Following in-vitro fertilization, the risk is also increased. There is thus a specific increased risk for

multiple pregnancy over and above the generic or background risk. Risk exposure may be voluntary such as the use of alcohol or illicit drugs, or Involuntary, such as unanticipated exposure to an infectious agent

Principles of Risk Management

1. Identify risk of adverse outcome
2. Assess risk impact and probability
3. Quantify the importance of risk
4. Implement surveillance system for specific risks
5. Identify cause or causes
6. Identify modifiers or interventions
7. Determine target risk reductions
8. Implement interventions
9. Utilize surveillance to evaluate efficacy of interventions
10. Review and modify strategic approach as necessary to meet targets

Evidence based approach to risk reduction

Outcomes selected for risk reduction must be based on evidence that clearly demonstrates the efficacy of the reduction strategy. Levels of evidence based assessment range from interventions with benefits clearly demonstrated by evidence from controlled trials, through those where evidence of benefit is strong though not established by randomized trials, to those in which there are insufficient evidence on which to base a recommendation. For other intervention strategies the balance

between demonstrated benefits and risk of adverse effects must be carefully evaluated (2). Suggested interventions during pregnancy are discussed in later sections of this guideline.

We recommend that risk assessment intervention strategies must be based on clearly demonstrated benefits through evidence from controlled trials or where evidence of benefit is strong though not established by randomized trials.

Maternal-Fetal Risk Assessment and the Laboratory

The laboratory role in risk management strategies varies with the strategy and the time of pregnancy in which it is important. Table II indicates examples of such strategies.

Table II. Example of laboratory based gestation specific risk reduction strategies: Decreasing perinatal risk in diabetes

Time sensitivity	**Intervention**	**Outcome objective**
Pre-conception	Controlling blood glucose in known diabetics	Decrease risk of congenital abnormality
Second Trimester 16 - 20 weeks	Maternal Serum Screen	Detect possible neural tube defect or other congenital

		anomalies
8 weeks	Glucose Screen	Detect and manage abnormal glucose tolerance
Third trimester	Assess fetal lung maturity	Decrease neonatal respiratory distress syndrome
Post Natal	Monitor neonatal glucose, calcium	Prevent and manage neonatal metabolic problems

Maternal-Fetal Medicine and Reference Values

The laboratory is important as generator of clinical pathology data on which risk assessment and management decisions are based. The marked physiological changes that occur as pregnancy progresses cause correspondingly marked changes in pregnancy reference ranges (3 -6). Similarly great differences are seen in the fetus and the neonate, born at different l stages on maturity. The range of different reference intervals that must be understood and accounted for in the pediatric and obstetric population is unlike that in of a normal adult population. Maternal-Fetal and Pediatric Laboratory Medicine is therefore a laboratory service where utilization of reference values appropriate for gestation and developmental age assumes the greatest importance.

Although development and validation of reference intervals is an activity undervalued by funding agencies, method and population specific reference data should be a fundamental requirement for interpretation of clinical data and for institution of any risk management program. Published intervals can serve as a guideline, providing an indication of the magnitude and direction of change in reference intervals for a given analyte in a pediatric or obstetric population (3-6). However it is incumbent of laboratories testing specimens from these unique populations, to validate their own reference data according to the specific methods is use in their facilities.

We recommend that any laboratory testing specimens from pregnant women or pediatric patients must develop or validate gestation and age specific reference intervals for every analyte offered.

References:

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