Chapter 5. Future Research

According to national birth certificate data, almost 18 percent of pregnancies (702,000 women) in the United States extend beyond 41 weeks, and over 7 percent (288,000 women) extend beyond 42 weeks (Ventura, Martin, Curtin, et al., 2000). Better data on optimal management of these women would have significant public health benefit.

Estimation of Risks Associated with Prolonged Gestation

Perinatal Mortality

The most precise data available come from the United Kingdom. Estimates in U.S. populations, preferably with the ability to control for the presence of other risk factors for mortality and the use of antepartum testing, are needed. Potential studies include:

- Detailed analysis of U.S. birth certificate data.
- Detailed analysis of U.S. hospital discharge data, although this will necessarily miss deliveries performed outside the hospital, such as those performed at freestanding birth centers and home births.
- Detailed analysis of administrative or computerized clinical data from large provider organizations, such as health maintenance organizations.

Because of the inherent limitations of these data sources, validation with detailed clinical records ultimately will be needed to systematically determine and describe causes of death. These data also would allow determination of the impact of various methods of dating pregnancy on perinatal mortality.

Perinatal Morbidity

Similar methods need to be applied to estimations of the risks of perinatal morbidity:

- Careful attention should be given to case definitions; again, validation of the accuracy of administrative data is needed.
- We did not identify any recent publications providing followup data on infants born after prolonged gestation. Ultimately, long-term outcomes are most important, and better data on the long-term consequences of various management strategies are needed.

Maternal Morbidity

- Again, better estimation of the risks, given current obstetric practice, is needed.

- Recently, attention has been drawn to the risks of long-term maternal consequences of labor and delivery, especially pelvic floor dysfunction. It is unclear if any of the management strategies used for prolonged pregnancy have any impact on the risks of subsequent development of pelvic floor dysfunction.

Testing Methods

Because many outcomes associated with prolonged gestation are rare, evaluations of individual tests and testing strategies will always be either limited in power or forced to rely on surrogate measures. Further research is needed on:

- Identification of surrogate measures of fetal compromise that are less susceptible to bias or observer variation.

- Study designs that could eliminate or substantially reduce the potential for verification bias because of clinician knowledge of antepartum test results.

- The optimal timing of antepartum testing.

Data on currently available tests strongly suggest that test specificity is much better than test sensitivity. In order for expectant management to compare more favorably to elective induction, research into new testing strategies should focus on improving the negative predictive value of tests by improving test sensitivity.

In addition, detailed data are needed on the medical and nonmedical costs associated with specific tests and testing strategies.

Planned Induction versus Expectant Management

Based on the available trial data, planned induction after 41 weeks appears to reduce the risk of perinatal mortality at lower cost and at no risk of increased cesarean section rates compared with expectant management. The strongest and largest trial was completed a decade ago. Whether these conclusions are still valid given current management strategies and interventions (such as misoprostol) is unclear. It also is unclear whether the extra knowledge to be gained by yet another large trial justifies the costs of such a trial. The following points should be considered:

- Decision analysis and cost-effectiveness analysis may help quantify our current degree of uncertainty. In order to be useful, modeling will require more precise data on risks, test characteristics, the effectiveness of induction, and costs in the specific population of interest. Some of these data could be provided by the research agenda discussed above. Decision and cost-effectiveness analyses will also need to consider subtle issues such as the potential

effects of increased induction rates on staffing needs for labor-and-delivery and postpartum units.

- Again, data on patient preferences for both outcomes and process are needed. For some women, the degree of certainty provided by a scheduled induction may be preferable to repeated visits for antepartum testing and uncertainty about when labor may begin. For other women, the desire to minimize intervention in the pregnancy may take precedence. How these preferences interact with patients' attitudes and preferences about risks to both themselves and their babies is an unexplored area of research with substantial implications for individual patients, clinicians, and policymakers.

Interventions for Induction

- Despite a number of randomized trials of methods for inducing labor, our ability to draw conclusions about the efficacy of various agents in women with prolonged pregnancy is limited because of the diversity of indications for induction and the diversity of gestational ages in these trials. Data on outcomes specific to the two groups of interest—women induced electively at a specific gestational age and women with prolonged pregnancy induced because of abnormal fetal heart rate testing—are needed. These data could be obtained either by performing a meta-analysis using pooled data from previous, ongoing, or future trials in these specific subgroups or by performing trials limited to these two groups.

- Sample size estimates for trials should be based on clinically relevant outcomes. Although time from beginning of induction to delivery is an important resource outcome, there are no data available on how women value this outcome compared with others. When sample size estimation is based on time-related variables, power to detect clinically relevant differences in other outcomes is diminished.

- Use of primary outcomes limited by inherent lack of reliability, such as Bishop score or abnormal fetal heart rate tracings, should be avoided. If used as secondary outcomes, consideration should be given when feasible to the use of research techniques designed to minimize the effects of observer variation, such as review by blinded outside experts (an approach often used in trials where data sources such as electrocardiograms, radiology films, or pathology slides are required).

- Patient preferences and quality-of-life measures, using standard techniques and methods for measuring these attributes, should be included in all studies. Attention should be focused not only on patient preferences for outcomes, but on process as well. All women value a healthy baby, but there may be strong preferences for the way in which this outcome is achieved.

- Detailed data are needed on medical and nonmedical costs associated with different interventions for the induction of labor in prolonged gestation and for promoting labor in women at term.

- Given that from some perspectives elective induction of labor may be preferable to expectant management, research on establishing reliable estimates of the relative safety, effectiveness, and costs of available induction agents in this particular patient population should be a high priority.

Special Populations

Preliminary analysis of administrative data suggests that additional research into possible differences in the epidemiology and outcomes of prolonged pregnancy in different ethnic and socioeconomic groups is warranted:

- Confirmation of the lack of ethnic differences in the proportion of pregnancies extending beyond 42 weeks—despite higher rates of preterm birth in black women—using data sources where confirmation of gestational age is available, would be important.

- Confirmation of the higher rate of low birthweight and other diagnoses consistent with uteroplacental insufficiency in black women with prolonged gestation is needed. If confirmed, clinical, epidemiological, basic science, and genetic studies might provide insight into the causes of this association.

- Further exploration of the potential interaction of ethnicity and economic status is needed.