From Paper to Practice.

An evaluation of the impact of the 1989 NACI guidelines for universal hepatitis B screening in pregnancy.

by

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ABSTRACT

BACKGROUND:

The development and release of clinical practice guidelines continue unabated. Yet the question remains: do practice guidelines guide practitioners? This study examines the implementation of guidelines published by Canada's National Advisory Committee on Immunization (NACI) on hepatitis B screening in pregnancy.

Hepatitis B is transmitted to infants from their chronic carrier mothers during the perinatal period. Asymptomatic HBsAg positive mothers are at risk of transmitting their infection to their newborns at a rate of 20 to 30%. Mothers who are also HBeAg positive transmit the infection at a rate of 70-90%. Ninety percent of infants infected in the perinatal period will become chronic carriers. Such infants have an increased risk for chronic active hepatitis, cirrhosis and hepatocellular carcinoma. Twenty-five percent will die of chronic liver disease in early adulthood. The use of hepatitis B immune globulin and vaccine after birth can prevent up to 90% of hepatitis B infections in infants.

Successful immunoprophylaxis of an infant requires that her carrier mother be identified prior to giving birth. In 1989, after years of recommending screening on a selective high risk basis, NACI recommended screening all pregnant women for hepatitis B surface antigen (HBsAg). If testing was not done during pregnancy it was to be done at the time of delivery.

The objectives of this study were as follows:

Objective 1:

To determine the impact over time of the 1989 NACI hepatitis B screening guidelines on the proportion of pregnant women who had their HBsAg status available at the time of birth of an infant in the Ottawa-Carleton area.

Objective 2:

To determine if lack of screening for hepatitis B surface antigen is related to patient, physician or hospital characteristics.

METHODS:

A retrospective chart review was performed on a random sample of 1288 women giving birth to live infants at the five hospitals with maternity services in Ottawa-Carleton. Using an interrupted time series design, charts were sampled from one year before the guidelines (1988-1989), two years after the guidelines (1989-1990 and 1990-1991) and a more current year (1993-1994). The impact of the NACI guidelines was assessed by examining the change over time in the availability of antenatal HBsAg screening results on a woman's hospital chart. Change over time in the proportion of women admitted without HBsAg results who had in-hospital screening was also examined. Logistic regression was used to determine if lack of availability of HBsAg was related to maternal, physician or hospital characteristics.

RESULTS:

There was a significant increasing trend in the proportion of women with HBsAg results available over time ($p<.0001$). A significant change was noted in the first year after the guidelines. Availability of antenatal HBsAg results increased from a preguideline rate of five percent (1988-89) to 43% in 1989-90. The proportion of women with antenatal HBsAg screening results available increased further from 65% in 1990-91 to 81% in 1993-94. There was however little change in in-hospital screening, which remained low over time. As a result, the overall rate of hepatitis B screening in either the antenatal or intrapartum period was still only 83% in 1993-94. The prevalence of hepatitis B chronic carriers in the study sample was 1.2%.

Maternal age, marital status, gravidity, parity and being transferred from one hospital to another were not associated with availability of HBsAg results at the time of giving birth. Women giving birth at 34-36 weeks were more likely than women giving birth at term to be lacking their HBsAg results. Women giving birth at the larger teaching hospitals were more likely than women giving birth at the smallest community hospital to be lacking HBsAg screening results. Women cared for by family doctors were just as likely to be screened for HBsAg as women cared for by obstetricians. Older physicians were slower than their younger colleagues in increasing their HBsAg screening rates over time.

Of the five hospitals examined, the one hospital with a written policy on HBsAg screening had the largest proportion of women with HBsAg screening

(96%). At the hospital with no policy, only 74% of women had HBsAg results available. Other hospitals had non-written policies which involved calling physicians' offices for results if the antenatal HBsAg results were unavailable. These hospitals tended to be less firm than the hospital with a written policy about screening women admitted without HBsAg test results.

CONCLUSION:

The NACI guidelines on routine hepatitis B screening in pregnancy had a major impact on physicians' screening behavior over time. A significant increase occurred within the first year after guideline release. This finding is different from the general literature on physician compliance with clinical practice guidelines, which shows disappointing results. Screening for hepatitis B carriers is a simple intervention that requires adding HBsAg testing to other prenatal blood work. It appears to have been adopted more rapidly and completely than other recommendations.

However in 1993-94, 17% of the maternal population did not have HBsAg results available at the time of giving birth. This problem appears to be due to a combination of incomplete antenatal screening in the community and low rates of in-hospital screening of women admitted without HBsAg results. The solution lies in the development of hospital policies that promote and maintain high HBsAg screening rates during the antenatal period and ensure in-hospital screening of women admitted without HBsAg results.

The producers of clinical practice guidelines should assess and address the barriers to timely implementation of their recommendations. Instructions on

the implementation of their recommendations should be an integral part of the original guidelines.

I. INTRODUCTION:

In the nineties, physicians are under increasing pressure to ensure both quality of care and the appropriate use of limited resources. This pressure has intensified with the publication of studies documenting unexplained variation in practice among physicians treating the same condition.[1] Demonstration of a poor correlation between research evidence on effective practices and the actual practices of clinicians in their offices has led to calls for intervention by both the government and the profession.

Clinical practice guidelines have emerged as the solution to the challenge of practice variation and as a vehicle for introducing evidence-based medicine into the daily routine of the practising physician. Clinical practice guidelines are defined as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific circumstances."[2] Guidelines may be produced by provincial or national medical associations, advisory committees, licensing bodies, or hospitals. There has been a recent explosion in the number of guidelines available, with over 600 guidelines published in Canada since 1990.[3]

Can guidelines attain the goal set by the United States Institute of Medicine's Committee on Clinical Practice Guidelines?

> "Scientific evidence and clinical judgement can be systematically combined to produce clinically valid, operational recommendations for appropriate care that can and will be used to persuade clinicans, patients

and others to change their practices in ways that lead to better health outcomes and lower health costs."[4]

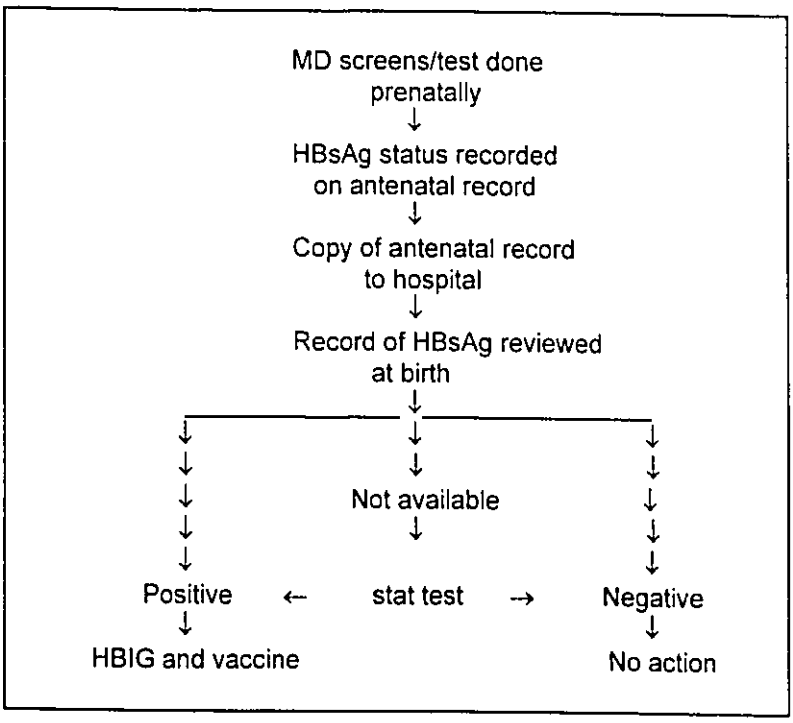
Can guidelines change physician behavior? Interest is increasing in the question of how guidelines impact on actual physician practices. Guidelines that have been assessed have shown disappointing results and highlight the difficulties in modifying physician behaviors.[5,6] There are multiple influences on physician practice patterns and even the best intentions to be guided by the evidence can be derailed by administrative, economic, and regulatory barriers. There is an evolving consensus that many factors influence a physician's clinical behavior beyond the message of the guidelines, including patient characteristics and characteristics of the physician and their practice environment. Simply distributing guidelines to the appropriate physicians and publishing them in widely available and reputable journals may not be enough to change practice habits.[7,8] Such reports highlight the complexity of implementing guidelines in the "real" world and the importance of monitoring physician compliance with recommendations.

This study evaluates the guidelines for antenatal screening of pregnant women for hepatitis B surface antigen (HBsAg) produced by Canada's National Advisory Committee on Immunization (NACI). These recomendations were published in April 1989 in the "Canadian Immunization Guide".[9] Evidence from several American studies demonstrated that prior recommendations for selective screening of pregnant women in high risk groups were ineffective in identifying

HBsAg positive mothers.[10,11] The new evidence-based guidelines called for antenatal screening of pregnant women and in-hospital screening of those who had not received prenatal care. Infants of HBsAg positive mothers were to be given active and passive immunization immediately following birth to prevent the development of hepatitis B.[12]

In March 1990, the Ottawa-Carleton Health Department became aware of two infants who had not received hepatitis B immune globulin or vaccine although they were born to hepatitis B carriers. One woman had been identified as a hepatitis B carrier on antenatal screening but her HBsAg status was not available at the hospital upon the birth of the infant. In the other situation the mother had not been screened. Both newborns failed to receive immunoprophylaxis. The Ottawa-Carleton Health Department recommended that all five hospitals adopt a policy for urgent testing at the time of delivery if the HBsAg status of the women was not available. As a result the HBsAg status would be available on all pregnant women prior to delivery, allowing for appropriate immunoprophylaxis of an infant born to a hepatitis B carrier. The following diagram outlines the process that should occur in clinical practice:

Figure 1: Process for Hepatitis B Screening in Pregnancy



In 1994, a recommendation by the Hepatitis B Working Group for universal immunization of children aged 9 to 13 was followed by a school-based vaccination program for adolescents in Ontario.[13] This mixed newborn-adolescent strategy for controlling hepatitis B will not be successful without high rates of HBsAg screening of pregnant woman and immunoprophylaxis of infants at risk. Although perinatal HBV transmission accounts for only five percent of all infections in a birth cohort it produces 34% of the chronic infections within that cohort. [14]

A review of the literature failed to identify any studies that evaluated physician's compliance with the NACI guidelines for universal HBsAg screening

in pregnancy. This study will examine the change in HBsAg screening before and after the guidelines and will look at the rates of screening in 1993-1994 at the five hospitals with obstetrical services in the Ottawa-Carleton area. Characteristics of hospitals, physicians and patients will also be examined to identify potential barriers to hepatitis B screening in pregnancy.

II. LITERATURE REVIEW:

A. Hepatitis B Disease:

1) Search method:

Articles for review were obtained from searches of the U.S. National Library of Medicine data base (MEDLINE) for 1980 to 1996 using the search terms "hepatitis B", "pregnancy" and "hepatitis B vaccine". Relevant citations in the English language articles retrieved were also reviewed.

2) Hepatitis B infection:

Hepatitis B virus (HBV) is one of several viruses that causes hepatitis. HBV is a double-stranded DNA virus that has three major associated antigens; surface antigen (HBsAg), core antigen (HBcAg) and e antigen (HBeAg). The average incubation period for hepatitis B is 120 days. HBsAg can be detected in serum 30-60 days after exposure. HBeAg in the serum is associated with viral replication and high infectivity. Resolution of infection is indicated by the disappearance of HBsAg and the appearance of antibody (anti-HBS) which confers long term immunity.

Hepatitis B infection may be asymptomatic in up to 50% of cases. Acute symptomatic infection can last up to three months and has a case-fatality rate as high as one percent.[12] Both symptomatic and asymptomatic infection may lead to the chronic carrier state. A chronic carrier is defined as a person who remains positive for HBsAg on two tests separated by 6 months or has a single serum positive for HBsAg and negative for IgM anti-HBc.

HBV infection is usually transmitted by contact with HBsAg positive blood or body fluids. Common routes of exposure include sexual contact, injection drug use, and perinatal transmission.

3) Perinatal transmission of hepatitis B:

Vertical transmission of hepatitis B occurs from the carrier mother to the infant during the perinatal period. Asymptomatic mothers who are HBsAg positive are at risk of transmitting the infection to their newborn at a rate of 20 to 30%. Mothers who are HBsAg positive and HBeAg positive transmit their infection at a rate of 70 to 90%.[15,16]

There have been cases of acute fulminant hepatitis in infected newborns but the majority have asymptomatic infection.[17] The risk of becoming a chronic carrier is inversely related to age at infection and is highest in infants. Ninety percent of infants with asymptomatic infection will become chronic carriers. Infants who become chronic carriers have an increased risk of developing chronic active hepatitis, cirrhosis and hepatocellular carcinoma.[15] Twenty five percent of these carriers will die of chronic liver disease in early adulthood.[18]

If a child is not infected during the perinatal period, there is still a risk of horizontal transmission during childhood from the hepatitis B carrier mother. Twenty-five to 50% of children infected within the first five years of life will become chronic carriers. Infants and children who become hepatitis B carriers serve as the source of future infection in the community.

4) Hepatitis B vaccine:

Hepatitis B is unique: there was an increase in reported disease rather than a decline in the years following introduction of a safe and effective vaccine. Hepatitis B vaccine which became available in Canada in 1982, has mainly been distributed to people at high risk of exposure to hepatitis B. This high risk approach had little impact on the disease. From 1980 to 1989, the reported annual incidence of hepatitis B in Canada increased 2.5 fold, from 5 to 13 cases per 100,000 while the annual death rate increased from 0.5 to 1.5 per one million population.[19] Although this increase may be explained in part by increased testing or reporting, it occurred despite the high-risk immunization programs started in 1982. Similar trends have been documented in the United States.[20] It has been estimated that over 80% of the vaccine issued in the first ten years was used to immunize health care workers, a group that account for only five percent of acute hepatitis B cases.[21]

The use of hepatitis B vaccine and immune globulin after birth can prevent over 90% of HBV infections in at risk infants.[15,22] The HBsAg carrier mother must be identified prior to giving birth in order to provide effective immunoprophylaxis to the infant. Hepatitis B immunoglobulin (HBIG) should be given to infants as soon as possible after birth to provide immediate passive protection. A three dose series of hepatitis B vaccine should follow to induce active immunity. The initial dose of the vaccination series can be given with the HBIG at birth or within the first seven days of life.

B. Hepatitis B Screening in Pregnancy:

1) Search method:

Articles for review were obtained from searches of MEDLINE using the terms "hepatitis B" and "antenatal screening" from 1985 to 1996. Relevant citations in the English language articles retrieved were also reviewed.

2) Screening strategies:

Prevention of perinatal transmission of hepatitis B requires the identification of hepatitis B carrier mothers through screening. The approach to screening for hepatitis B in pregnancy has evolved over the years from selective screening of women at high risk to routine screening of all pregnant women.

A selective screening approach was recommended in "The Guide for Immunization for Canadians" published in 1984. Pregnant women who belonged to population groups known to have high hepatitis B carrier rates were to be screened. This would include birth in a country where hepatitis B is endemic, injection drug use, or multiple sexual partners. Vaccine was recommended for "infants born to HBsAg positive mothers whose contact with a carrier mother will continue." [23]

The selective screening approach requires that physicians know the risk factors, question women and correctly identify and screen women at high risk. Okum et al looked at the program for HBsAg screening in Edmonton from 1985 to 1987. [24] Risk factors were identified in 86% of multiparous HBsAg positive women. These women should have been screened in a previous pregnancy, yet

only seven percent had been identified as carriers in the past. A study in Manitoba also demonstrated that physicians were not identifying and screening women with risk factors.[25] Seventeen carriers were identified in a group of women who had not been screened, sixteen of these women were in high-risk groups. Both studies indicated that there were problems with the selective screening approach.

Success of the selective screening approach also requires that the risk factors used to identify women at risk can correctly identify HBsAg carriers. Studies published in the mid-1980s showed that questionnaires based on selective screening failed to identify 50 to 60% of carrier mothers.[10,11] This led to revision of the NACI guidelines in 1987 to acknowledge that "not all carrier mothers will be detected if screening is restricted to high-risk groups."[26] Yet the committee stopped short of recommending routine screening of all pregnant women in Canada, due to the low prevalence of hepatitis B in this country. Instead the recommendation was made for routine testing of pregnant women "where demographic and prevalence data warrant."[26]

In the late 1980s, there was recognition that the selective screening approach was failing to identify HBsAg positive mothers and was therefore unsuccessful in disrupting perinatal transmission of hepatitis B. The 1987 recommendation of routine HBsAg screening in areas with ethnic or high risk populations was not solving the problems of the poor sensitivity of risk factor information in identifying carrier mothers. Nor did the high risk approach address

the failure of physicians to correctly identify and screen those at risk. In addition, a study in 1988 demonstrated that a universal maternal prenatal screening program is cost-effective with a HBsAg carrier rate as low as 0.06%.[27]

Several factors such as lack of physicians' awareness of the risk of perinatal transmission of hepatitis B virus and of the recommended guidelines were also felt to have contributed to the failure of the selective screening approach. An American study in 1988 showed that 40% of obstetricians could name only two groups at high risk for HBV infection and only 28% knew the recommended treatment for infants born to HBV carrier mothers.[28]

These factors led to NACI changing its advice on hepatitis B screening in pregnant women. The recommendation was made in 1989 that all pregnant women be routinely tested for HBsAg.[9] If testing was not done during pregnancy it was to be done at the time of delivery. These recommendations were published in 1989 in the third edition of the Canadian Immunization Guide.

3) HBsAg screening rates in a universal screening program:

Introduction of a universal screening program removes the step of having to correctly identify those at risk, but still requires that physicians are aware of the requirement for HBsAg screening and screen all pregnant women. It also requires that the results be available at the time of the infant's birth. Several Canadian studies have evaluated antenatal screening programs for HBsAg but these involved the routine screening of sera submitted to the lab for other prenatal testing so that a physician request for HBsAg was not required.[24,25,29,30]

The ability of universal screening to succeed where selective screening failed depends on achieving high screening rates in the pregnant population. There are no Canadian studies that examine the success of implementation of the NACI universal HBsAg screening recommendations. In Ontario, a physician must order HBsAg screening, which allows for the assessment of the impact of the NACI guidelines on physician behavior. Several cross-sectional studies in other countries have determined the HBsAg screening rate at a point in time after release of recommendations for universal screening in pregnancy. Other studies looked at changes in screening over time during organized hepatitis B screening programs.

Universal screening of all women for HBsAg in pregnancy was recommended by the American Immunization Practices Advisory Committee (ACIP) in 1988.[31] The American College of Obstetricians and Gynecologists officially recommended routine HBsAg screening in 1990.[32] The Centers for Disease Control (CDC) studied the progress in implementing universal HBsAg screening in pregnant women by conducting surveys in three states - California, Connecticut and Kansas, plus a sample of hospitals in the U.S. from 1991 to 1993.[33] This cross-sectional study looked at the availability of maternal HBsAg status prior to the birth of an infant.

In all areas over 80% of women were screened for HBsAg. Rates were highest in California in 1991 (98%) where hepatitis B screening is required by law. Screening rates were lower in Connecticut in 1993 than in California in

1991. HBsAg results were available on 90% of maternal records (range by hospital 86%-99%). Kansas had the lowest screening rate of 84% in 1992 (95% CI 80-88%). The CDC study also involved a survey of 183 hospitals across the U.S. in 1993. The hospital study involved review of the medical records of 3982 infants. If HBsAg results were unavailable on the infant's medical record then the maternal hospital chart was reviewed. Overall, maternal HBsAg screening results were identified for 84% of infants.

California achieved almost complete screening of the maternal population (98%) in 1991 whereas in other areas of the country as many as 16% of the maternal population were not being screened for HBsAg in 1993. Failure to consistently screen women admitted to the hospital without antenatal HBsAg results was identified as one of the problems.

4) In-hospital screening for HBsAg:

Successful and timely immunoprophylaxis of an infant requires that the HBsAg status of the mother is known at the time of delivery of the infant. If antenatal screening has not been performed NACI recommends that HBsAg screening be done at the time of admission to hospital (perinatal screening). The U.S. guidelines on screening for hepatitis B in pregnancy made the same recommendations in 1988. In 1991, although 81% of Washington hospitals were aware of the recommendations only 51% routinely tested women with no prenatal care upon hospital admission.[34] Other studies have identified poor compliance with perinatal screening as contributing to the failure to achieve

complete screening coverage of the maternal population.[33,35] In the Netherlands, a multicenter study conducted from 1982-1989 showed that screening rates were maximized to 97% after including the ten percent of women who were screened in hospital.[35]

The problem of poor rates of in-hospital screening is compounded by the fact that the prevalence of chronic hepatitis B infection is higher in women who have not been screened or who have not had prenatal care. A study in an inner-city hospital in Philadelphia found that the rate for hepatitis B positivity was eight times higher (6.7%) for pregnant women without antenatal care compared to women registered with the hospital clinic (0.8%).[36] In a hepatitis B screening program in the Netherlands, the prevalence of chronic carriers was twice as high (4%) in the group screened in hospital as in the group screened antenatally (1.8%).[37] Thus failure to test women who have not had antenatal HBsAg screening will result in missing women at high risk for chronic hepatitis B infection.

In-hospital screening is an essential component of any program hoping to achieve high hepatitis B screening rates of the maternal population. There will always be some women missing antenatal screening results and some women with no prenatal care. Timely immunoprophylaxis of an infant requires that the results be available prior to discharge from hospital of an infant and mother. In the Netherlands, if a HBsAg test result is unavailable at the time of an infant's birth then a rapid hemagglutination test for HBsAg is performed. CDC has

recommended that if the maternal HBsAg status is unknown at the time of birth, an infant should receive the first dose of hepatitis B vaccine within 12 hours.[33]

The CDC study looked at other risk factors associated with lack of availability of maternal HBsAg results at the time of an infant's birth.

5) Risk factors for lack of HBsAg screening:

a) maternal characteristics:

In the Connecticut survey maternal risk factors for lack of hepatitis B screening results included no prenatal care (RR, 3.4; 95% CI, 2.0-5.7) and living in a rural area (RR, 2.2; 95% CI, 1.2-4.2). In the larger U.S. hospital survey, woman who gave birth in a rural hospital were also less likely to have HBsAg screening (RR, 1.5; 95% CI, 1.3-1.7).[33]

The number of antenatal visits to a physician was not related to availability of HBsAg on the hospital chart in both the Connecticut and Kansas surveys. In the Kansas study, maternal characteristics such as age, gravidity, education level, and timing and number of antenatal visits were not related to lack of HBsAg screening. White women in Kansas were more likely than women of other races to lack screening results, suggesting that some physicians were continuing to use a selective screening approach based on ethnicity as a risk factor.

b) physician characteristics:

In the Kansas survey, physicians' age and board certification did not influence their HBsAg screening rates. The Connecticut survey found that

source of prenatal care was not a factor in lack of screening. In contrast, the Kansas study showed that women who were cared for by general practitioners were less likely than those cared for by obstetricians to have HBsAg status available (RR, 3.5; 95% CI, 2.3-5.4). The U.S. hospitals study looked at the specialty of the infant's medical care provider. As this study examined infants' charts for maternal HBsAg status they looked at pediatricians, family practitioners and "other" medical care providers. Infants cared for by family practitioners were 1.7 times more likely to be lacking information on maternal HBsAg status than infants cared for by pediatricians.

c) hospital characteristics:

The CDC study examined three scenarios; a hospital had a written policy on HBsAg screening in pregnancy, a hospital had a nonwritten or verbal policy, or there was no policy at all. Women who gave birth at hospitals with no policy on maternal hepatitis B screening were almost seven times more likely to lack HBsAg results than women who gave birth at a hospital with a written policy (RR, 6.6; 95% CI, 5.4-8.2). Women who gave birth at hospitals with a nonwritten policy were still twice as likely to be lacking HBsAg as women delivering at hospitals that had adopted a written policy (RR, 2.1; 95% CI, 1.6-2.). Women giving birth in states with hepatitis B screening laws were twice as likely to have HBsAg screening as women delivering in states without such laws.

6) Changes in screening rates over time:

The typical model for the diffusion of innovations involves a s-shaped curve with change that is not instantaneous or constant.[38] Studies in several countries showed varied results on the uptake of HBsAg screening by physicians over time. Some national programs achieved screening rates of 80% or higher within three years of initiating a program while others achieved rates as low as 51% during the same period.

A seven year multicentre hospital trial of routine screening for HBsAg at several large city hospitals and in a rural region in the Netherlands achieved high compliance rates in the first year.[35] Screening rates in the first year ranged from 85% in the rural area to 95% in two large urban hospitals. This program involved educational campaigns aimed at the health professionals in participating centers and a designated person at each center responsible for implementation of HBsAg screening. In 1989 this program was adopted on a national basis and a nationwide program for HBsAg screening in pregnant women was initiated. This national program achieved screening rates of 84% within three years.[37] Screening rates increased yearly from 46% in 1989, to 73% in 1990, 80% in 1991 and 84% in 1992.

In 1989 in Taiwan where the prevalence of HBsAg carriers is one of the highest in the world (18%), screening rates similar to those achieved in the Netherlands were obtained in a hepatitis B screening program in pregnancy.[39] This program involved education of the public and health professionals up to one

year prior to implementation. Various healthcare professionals were targeted through training courses and physicians received an information booklet one year prior to the program. In the two months prior to the start of the program instruction manuals were distributed to all health professionals and the public was targeted through a media information campaign. An explicit flow chart outlining the steps in the program was adopted. In the first 15 months, 78% of the maternal population were screened for HBsAg.

A nationwide program for hepatitis B vaccination in Italy targeted infants born to HBsAg positive women.[40] Women were screened for HBsAg in the last trimester of pregnancy. This program did not achieve high coverage. The screening rates only increased from 32% in 1984 to 51% in 1986. The authors attributed the failure of this program to poor cooperation from obstetricians and lack of awareness of the program. Future plans for implementation were to focus on providing information to the public and physicians.

The results of these studies suggest that compliance with guidelines is increased if there is an accompanying program that increases awareness and enables and reinforces screening behavior.

C. Impact of Guidelines on Physician Practice:

1) Search method:

Articles for review were obtained from searches of MEDLINE using the terms "physician's practice patterns", and "guidelines", "pregnancy" and "prenatal care" from 1985 to 1996. Relevant citations in the English language articles retrieved were also reviewed.

2) Physician compliance with guidelines:

In general, studies on physician compliance with clinical practice guidelines have shown disappointing results. Lomas looked at ten studies that evaluated the impact of consensus recommendations on practice behavior; six found no impact, two found minor impact and two found major impact.[41] In eight studies that measured the percent conformity with recommendations it was less than 67% for all but one. The study that did demonstrate a high compliance with the guidelines (97%) was already well accepted in practice with 83% of practitioners following the guidelines prior to their being published.

In the past much of the focus has been on developing carefully written evidence-based guidelines intended to maximize health outcomes. Little attention has been paid to dissemination or implementation strategies. Dissemination was simply a matter of publishing the guidelines in widely available journals. Traditional diffusion models relied on the physician to seek out the information and adopt the recommendations. Increasingly studies have shown that the traditional model is flawed. Even if the information reaches the

physician awareness of the accepted norms of practice does not necessarily translate into modification of behaviour.[4,6]

Characteristics of the guidelines that are thought to influence their adoption into practice include complexity of the guideline; trialability (extent to which a physician can try a procedure on a limited basis prior to adopting it); and observability (the extent to which the results can be seen).[38] A study examining these factors in application to 23 practice guidelines found that guidelines that were low on complexity and high on trialability had higher compliance rates.[42]

Many factors beyond aspects of the guidelines themselves are now believed to influence physician behavior. Lomas's Coordinated Implementation Model considers the administrative, educational, community and economic environments and their influences on the practitioner.[43] Others talk of the various stages in the adoption of guidelines into practice. The Implementation and Maintenance stages require that "infrastructure must be established to make the practice environment conducive to ongoing application of the guidelines".[44]

3) Physician compliance with prenatal care guidelines:

Guidelines are not new to obstetrics. The first "Standards for Obstetric-Gynecologic Services" was published by the American College of Obstetricians and Gynecologists in 1959.[45] To date, there is little information available on the degree of adherence of obstetric providers to recommendations for prenatal care.

Compliance with recommended prenatal care guidelines was assessed using a cross-sectional design in several of the studies identified. This study design makes it difficult to determine the impact that guidelines had on physician practice patterns because the pre-guideline compliance is unknown. They do however give a view of the conformity of practice with recommendations at a point in time after the guidelines are released. Other studies looked at changes in the rate of compliance before and after the guidelines. This methodology allows for better determination of the impact of the guidelines on physician practices. Several studies that surveyed obstetricians' practice patterns in response to guidelines had poor methodology, including a questionnaire that was not validated or piloted,[46] and response rates that were approximately 20% or less.[46,47]

Baldwin et al did a cross-sectional study of adherence of various prenatal care providers (urban and rural obstetricians, urban and rural general practitioners, urban certified midwives) to the ACOG standards in 1988-89 in Washington state.[48] Retrospective information was abstracted from the prenatal care records of 2357 low risk obstetrical patients. Certified midwives had the highest compliance rates with recording of ACOG recommended tests and manoeuvres on a woman's chart. Compliance with recommended prenatal lab testing was over 90% by all providers for hematocrit, Rh factor, VDRL, rubella and urinalysis. All these interventions are low on complexity. Tests with lower provider compliance included those recommended more recently, and those

which involved controversy (e.g. group B streptococcal cultures). Older physicians were significantly less likely than younger physicians to adhere to three of the guidelines, recording of fetal activity and presentation and ordering serum alpha fetal protein (AFP).

A survey of Norwegian physicians' compliance with national guidelines for routine iron supplementation in pregnancy also found that recommendations that are controversial have poor compliance rates.[49] In 1990 only 36% of general practitioners routinely prescribed iron in pregnancy as recommended. The authors felt this low rate of compliance with routine iron supplementation in pregnancy was due to the contentious nature of the guidelines and lack of evidence that iron supplementation in pregnancy is beneficial. They did not however survey physician attitudes or explanations for non-compliance with the recommendations.

Lomas et al looked at the impact of the Canadian guidelines on cesarean birth on the knowledge and practices of obstetricians in Ontario.[7] They found that although awareness of the guidelines was good (87-94%), and there were significant changes in self-reported practices, there was not a substantial decrease in the cesarean section rate two years after release of the guidelines. The authors demonstrated that although dissemination of the guidelines appeared to impact on physician knowledge and attitudes and to predispose them to change, this failed to translate into a dramatic decrease in the cesarean section rate. They point to other educational, administrative, medico-legal,

economic and patient-centered barriers that need to be considered if clinical practice guidelines are to have an impact on physician practices.

A study by Kosecoff et al on the impact of the National Institutes of Health consensus conferences on physician practice appears to confirm this hypothesis.[5] Although there was evidence of increased trial of labor and vaginal delivery rates among woman with a previous cesarean section after release of the U.S. guidelines, there was no decrease in the cesarean section rates of women with infants in the breech position or an overall significant decrease in the cesarean section rate. The authors suggested that physician factors, such as skill and experience with breech deliveries, and institutional factors, such as availability of 24-hour anesthesiology for emergency cesarean sections, played a role in the adoption of the recommendations.

In contrast to the two previous studies, Myers and Gleicher reported on a study at an inner-city hospital that achieved its goal of decreasing the cesarean section rate from 17.5% of deliveries in 1985 to 11.5% of deliveries in 1987.[50] The voluntary program involved an obligatory second opinion on most sections, established criteria for the most common indications for section and a detailed review of all cesarean sections. Factors within the hospital were established to facilitate and support a reduction in the cesarean section rate. Both full-time academic faculty and private practitioners significantly decreased their cesarean section rate.

4) Summary:

Do prenatal care guidelines guide providers? Overall the studies show mixed effects of guidelines on practice. Cross-sectional studies of antenatal screening in several states in the U.S. showed good compliance with HBsAg screening several years after the guidelines. In other studies, hepatitis B screening rates appeared to increase more rapidly when there was a program designed to increase awareness and enable change. Other complex manoeuvres such as decreasing the cesarean section rate have shown disappointing results without establishing programs that enable and reinforce the necessary behavior change and address other factors such as institutional and medicolegal issues. This supports the evolving consensus that factors beyond characteristics of the guidelines, such as the practice environment influence physician clinical behavior.

This study will add to the growing body of literature on practice guidelines by evaluating the progress in implementing the 1989 NACI guidelines on routine screening for hepatitis B in pregnancy in the Ottawa-Carleton region. The Canadian Immunization Guide containing the NACI guidelines is disseminated via mailings to all physicians practising in Ontario. Guidelines and updates are published in Canada Communicable Disease Report and in the Canadian Medical Association Journal (CMAJ). Implementation becomes the responsibility of the practitioner in the community. Have the NACI guidelines had an impact on hepatitis B screening in pregnancy? Are there barriers to attaining complete screening coverage of the maternal population in Ottawa-Carleton?

III. OBJECTIVES:

Objective 1:

To determine the impact over time of the 1989 NACI hepatitis B screening guidelines on the proportion of pregnant women who had their HBsAg status available at the time of birth of an infant in the Ottawa-Carleton area.

Objective 2:

To determine if lack of screening for HBsAg is related to patient, physician or hospital characteristics.

IV. METHODS:

A. Study Population:

The study population consisted of women who gave birth to live infants at the five hospitals with maternities in the Ottawa-Carleton area from April 1, 1988 to September 30, 1991 and from October 1, 1993 to September 30, 1994. Although women who delivered at home were not included, the study population included almost all women who gave birth in the region. Midwives were only licensed in 1994, and only ten women gave birth at home in the Ottawa-Carleton area during 1992, with the rest of the population giving birth at one of the five hospitals.

B. Study Design:

This study is a retrospective medical chart review using an interrupted time series design. The impact of the guidelines was measured by examining the change over time in the proportion of women who had their HBsAg status available at the time of delivery in the Ottawa-Carleton area.

Lack of the HBsAg result on the mother's hospital chart means that test results were not available to make the decision on giving immunoglobulin and vaccine to the newborn at birth. Charts were reviewed for written evidence of HBsAg screening. Antenatal HBsAg screening results should be indicated on the provincial antenatal record. If prenatal HBsAg screening has not been done or the results are unavailable at the time of admission to the hospital, then stat

in-hospital testing should be performed. In-hospital screening for HBsAg should be indicated on the physician's order sheet. Therefore availability of HBsAg results at the time of giving birth was separated into:

i) the proportion of women with live births who had their antenatal screening HBsAg results available on the antenatal record in the hospital chart.

ii) the proportion of women who did not have the results of antenatal screening on their hospital chart who had urgent HBsAg testing done in hospital prior to giving birth.

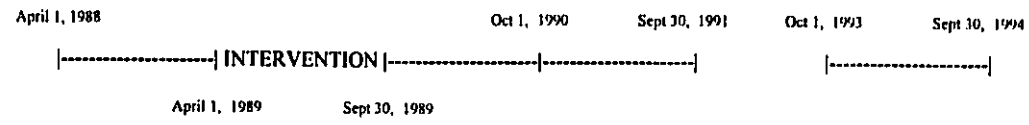
Randomly selected charts from the five hospitals that provide obstetrical services in the Ottawa-Carleton area were reviewed. A total of 1288 charts were selected. Four years were included in the study; the year before NACI recommendations (April 1, 1988 - March 31, 1989), two years after (October 1, 1989 - September 30, 1990 and October 1, 1990 - September 30, 1991) and a more current year (October 1, 1993 - September 30, 1994).

Choice of the time periods is based on the study of the diffusion of innovations in medicine which demonstrated that at one year physician awareness of guidelines, attitudes toward them, and knowledge of their content reaches a maximum.[51] During the second year changes in practice should be detectable. Previous studies have looked at changes in practice during the second year.[5,7]

The "Communicable Disease Weekly Report" published the revised recommendations on April 22, 1989[52] and the "Canadian Medical Association Journal" reprinted the recommendations on August 1, 1989.[53] The guidelines were published in the third edition of the "Canadian Immunization Guide" which was mailed to all Canadian medical practitioners in May 1989.[9] In order to allow for time for receipt and reading of the guidelines a six month intervention period was chosen from April 1 to September 30, 1989.

The year prior to guideline release (April 1, 1988 to March 31, 1989) was used to determine the baseline proportion of women with antenatal HBsAg results available prior to giving birth. One year time periods were divided into three-month intervals and the proportion with antenatal HBsAg results available during each interval was calculated. This gave four data points in the baseline year, eight points during the 24 months after the guideline intervention period and a further four points in the 1993-1994 period. The period from October 1, 1993 to September 30, 1994 was used to assess the most current HBsAg screening rates available at the time of data collection. The following diagram outlines the time frame:

Figure 2: Study Time Frame:



A total of 80 charts were to be collected from each three-month time interval giving a sample size for each year of 320 charts. The 320 charts were divided between the hospitals based on the percentage of the total births in the Ottawa-Carleton area that a particular hospital had for each one-year period considered (Table 3.1-3.5). This number was then divided equally between the four three-month intervals in that year. Each three-month interval had 80 charts divided between the five hospitals except for 1993-94. There were 82 charts in each of the four time intervals in 1993-94 due to rounding when calculating the percentage deliveries for each hospital.

As the one-year periods contained intervals from two calendar years (i.e. 1988-89) the percentage of births that each hospital had in the second year (i.e. in 1989) was used in the calculations. For the 1993-94 time period, the percentage of births at each hospital in 1993 was used as this information was not available for 1994 at the time of data collection.

Table 3.1: The number of charts reviewed at Hospital A

Time Period	Percent of Ottawa Carleton births	Number of charts reviewed/year	Number per 3 month interval
1988 - 1989*	6.9	24	6
1989 - 1990*	7.2	24	6
1990 - 1991*	7.4	24	6
1993*-1994	8.5	28	7
Total charts for Hospital A:			100

* year used to calculate % births

Table 3.2: The number of charts reviewed at Hospital B

Time Period	Percent of Ottawa Carleton births	Number of charts reviewed/year	Number per 3 month interval
1988 - 1989*	17.8	56	14
1989 - 1990*	18.9	60	15
1990 - 1991*	20.2	64	16
1993*-1994	20.6	68	17
Total charts for Hospital B:			248

* year used to calculate % births

Table 3.3 The number of charts reviewed at Hospital C

Time Period	Percent of Ottawa Carleton births	Number of charts reviewed/year	Number per 3 month interval
1988 - 1989*	31.5	100	25
1989 - 1990*	29.0	92	23
1990 - 1991*	26.7	84	21
1993*-1994	25.7	84	21
Total charts for hospital C:			360

* year used to calculate % births

Table 3.4: The number of charts reviewed at Hospital D

Time Period	Percent of Ottawa Carleton births	Number of charts reviewed/year	Number per 3 month interval
1988 - 1989*	18.9	60	15
1989 - 1990*	17.8	56	14
1990 - 1991*	19.7	64	16
1993*-1994	19.3	64	16
Total charts for Hospital D:			244

* year used to calculate % births

Table 3.5: The number of charts reviewed at Hospital E

Time Period	Percent of Ottawa Carleton births	Number of charts reviewed/year	Number per 3 month interval
1988 - 1989*	24.7	80	20
1989 - 1990*	27.1	88	22
1990 - 1991*	26.0	84	21
1993*-1994	25.9	84	21
Total charts for Hospital E:			336

* year used to calculate % births

Hospital Medical Records Institute (HMRI) monthly and annual reports for each hospital were used to identify all women who had live births in the time periods under study. All obstetrical deliveries are coded under Service 51. Cases with diagnostic codes V27.1 and 656.4 were excluded in order to remove stillbirths. For each hospital, all woman giving birth were grouped into the three-month time intervals based on the date of discharge. The chart numbers in each three month time period were then numbered. Epi-info was used to generate a list of the required number of random numbers. Charts with the corresponding number were selected for review. Twenty-five (1.9%) charts could not be located; five were misfiled, eight were missing, eight were active and four had been damaged by flooding. They were replaced by randomly chosen charts from the same interval.

1) The pilot study:

A pilot study was conducted by the principal investigator (R.S.) to revise and refine the data extraction sheet (Appendix A). The pilot study involved reviewing two charts randomly selected in the manner previously described from each of the 16 three month time intervals at all five hospitals. Thirty-two charts per hospital or a total of 160 charts were reviewed.

The data extraction sheet was generally acceptable with a few modifications. It was noted during the pilot study that the Ontario antenatal record was not always available on the inpatient hospital chart. Results of HBsAg testing of pregnant women in the community should be recorded on this form and then made available to the hospital when it is sent in by the woman's physician prior to delivery, or when the woman brings in the form at the time of admission. Therefore a variable was added to measure the number of missing antenatal forms at each hospital. All other areas within the inpatient chart where HBsAg status might be recorded and therefore available to hospital staff at the time of delivery were noted for inclusion in the directions for the data abstractors (Appendix B). Difficulties were noted in the pilot study in abstracting information on the variable "employed" which was poorly recorded. It was decided to abstract data on this variable in the main study while recognizing its limitations.

The pilot study identified differences among the hospitals regarding where information was recorded. Although all hospital charts contained similar information, the name of the sheet or form that contained the information was

often different. The provincial antenatal record is the only standard form at all hospitals (Appendix C). The structure of charts within the same hospital also changed over the four year period. Therefore instruction sheets were produced for each hospital that directed the data abstractor to the appropriate portion of the chart for each variable.

C. Data Collection:

Data were collected by two data abstractors. One data abstractor completed the chart review at two hospitals while the other completed all the charts at a third hospital. Both data extractors collected data at the two larger hospitals. Training was given at each of the five hospitals prior to data collection and the instruction sheet for that hospital was reviewed. Fifteen percent of charts and their corresponding data collection sheet were reviewed by the principal investigator at each hospital at the start of data collection. Any problems encountered were reviewed with the data abstractors.

Data were collected from the maternal inpatient hospital chart. The following forms or records were used:

i) *demographics sheet:* this is located at the front of the chart and contains information such as name of the attending physician, and the address and date of birth of the mother. It had a different name at each hospital ranging from Health Record to Hospital Admission Report.

ii) *addressogram:* the card containing demographic information produced upon admission of the woman to hospital.

iii) *provincial antenatal record*: the standard antenatal form in Ontario. It is updated by the woman's physician at each antenatal visit with such information as weight, blood pressure etc. (Appendix C). The hospitals require that a copy of this record be sent to them prior to the delivery. A woman is also given a copy of this antenatal record to bring with her to the hospital at the time of admission. This record contains information on antenatal blood work including hepatitis B surface antigen.

iv) *delivery record*: this contained information on the progress of the mother and infant during labor and delivery. It is completed by the nurse and/or attending physician during labor and delivery. It had different names at different hospitals, e.g. Obstetrical Record, Labor and Recovery Flowsheet. In one hospital the labor and delivery form was revised in 1994 to include a space for filling in the HBsAg status.

v) *obstetrical admission*: this includes in most cases, a physical exam, vital signs and a brief history of the past medical history and the current

pregnancy. It is completed by the nurse or the clerk, intern or physician in hospital when the woman is admitted.

vi) *physician order sheet*: this is the sheet on which medication and lab tests are ordered. At all five hospitals no lab tests are performed unless they are ordered on these sheets.

vii) *discharge summary*: this summarizes the course in hospital and is dictated by the attending physician after discharge of the woman. Some hospitals had a hand-written summary sheet.

viii) *gynecology observation record*: this contains information on outpatient antenatal visits to the obstetrical clinic at one hospital and was included in the woman's inpatient chart.

D. Study Variables:

The choice of study variables was influenced by the availability of data on the hospital chart and the information required to meet the second objective: to determine if lack of screening for hepatitis B is related to patient, physician or hospital characteristics. The following information was included on the data extraction form:

i) *Chart number*: the chart reviewer obtained this from the list of randomly selected charts.

ii) *Time period*: this indicated the three-month time interval and year during which the delivery took place. This was obtained from the list of randomly selected charts.

iii) *Hospital*: refers to the hospital where a woman gave birth.

iv) *Discharge date (d/m/y):* this was indicated on the demographic sheet. If it was not there it was taken from the discharge summary. In one hospital during 1988 the discharge date was not always clearly indicated. In this case the length of stay was added to the admission date to obtain the discharge date (See instruction sheet Appendix B). If a woman had more than one delivery the separate admissions were bound together in one hospital chart. Therefore in all cases, the date was checked to see that it corresponded with the time period indicated above to avoid the mistake of extracting data from a birth by the same mother during an incorrect year.

v) *Transfer*: this indicated if the woman was transferred from another hospital. This information was collected as indicated on the demographic sheet at the front of the hospital chart.

vi) *Attending Physician*: this is the physician that admits the woman to hospital. She/he may not be the physician who provided care prior to delivery. This information was extracted from the front demographic sheet. If it was not available there it was taken from the addressogram.

vii) *Qualification of Attending Physician*: information was collected on the qualification of the physician, whether they were a general practitioner, had their CCFP, or were an obstetrician and gynecologist. This information was collected from the Canadian Medical Directory for the appropriate year.

viii) *Graduation Year of Attending Physician:* information on the year graduated was collected from the Canadian Medical Directory. This was the year that the physician obtained their medical degree (M.D.).

ix) *Family Physician*: this is the physician indicated as the family doctor on the front demographic sheet or if not available there, then on the antenatal record.

x) *Qualification of Family Physician*: information was collected on whether the physician was a general practitioner or had their CCFP. This information was collected from the Canadian Medical Directory for the appropriate

year.

xi) *Graduation Year of Family Physician*: information on the year graduated was collected from the Canadian Medical Directory.

xii) *Antenatal care physician*: this is the physician involved in antenatal care as taken from the provincial antenatal record. If it was not available here it was taken from the delivery record if available.

xiii) *Qualification of antenatal care physician*: information was collected on whether the physician responsible for antenatal care had a M.D., CCFP, or a FRCPC in obstetrics and gynecology.

xiv) *Graduation year of antenatal care physician*: information on the year of graduation from medical school was collected from the Canadian Medical Directory.

xv) *Shared care*: if a woman receives shared care she sees her family doctor in the early stages of pregnancy and then sees an obstetrician after 28 weeks and for the birth. The antenatal form was checked to see if the family physician was indicated as being involved in shared care.

xvi) *Age*: the age of a woman at admission to hospital was taken from the demographic sheet. If it was not available there it was taken from the admission record. Third choice was the addressogram followed by the discharge summary.

xvii) *Marital status*: this was categorized into seven categories: married, divorced, single, common-law, separated, widowed and not available. This information was obtained from the front demographic sheet, the addressogram or the antenatal record.

xviii) *Postal code*: this was the postal code at the time of hospital admission. This was obtained from the demographic sheet or if not available there from the addressogram.

xix) *Occupation*: information on maternal occupation was obtained from the antenatal record. If it was not available there it was recorded at some hospitals on the demographic sheet. If it was not available in either of these places it was recorded from the admission history. Occupation was classified based on Statistics Canada's Standard Occupational Classification Manual (OCM) that defines an occupation as "a collection of jobs sufficiently similar in their main tasks to be grouped under a common

title".[54] Occupation is divided into 21 categories. The following were applicable in this study:

1. Managerial, administrative and related occupations.
2. Natural Sciences, engineering and mathematics.
3. Social Sciences and related occupations.
4. Teaching and related occupations.
5. Medicine and health related occupations.
6. Artistic, literary, recreational and related occupations.
7. Clerical and related occupations.
8. Sales occupations.
9. Service occupations.
10. Farming, horticultural, and animal husbandry occupations.
11. Processing occupations.
12. Product fabricating, Assembling, and repairing occupations.
13. Transport equipment operating occupations.
14. Occupations not classified elsewhere (e.g. factory workers).

Four categories were added: housewife/homemaker, student, those who reported themselves as "self-employed" without indicating a profession, and those who had the company for whom they worked named, but no profession given.

xx) *Employed*: whether or not the person was employed was abstracted from the antenatal record, the demographic sheet or the obstetrical admission.

xxi) *GPA*: the maternal status for gravidity, parity and abortus were recorded. This was obtained from the antenatal record. If it was not available there it was obtained from the delivery record, or the discharge summary.

xxii) *Last normal menstrual period (d/m/y)*: information on the LNMP was obtained from the antenatal record as it was recorded by the physician. If it was not available there it was obtained from the delivery record.

xxiii) *Number of antenatal visits*: this information on the number of visits made to the physician's office prior to delivery was abstracted from the Ontario antenatal record. In the one hospital that included inpatient charts in some women's hospital files, information on visits was also taken from here when available.

xxiv) *First and last visits and gestational age at visit*: the date of the first and last recorded visits and the gestation in completed weeks at each of these visits was obtained from the antenatal record.

xxv) *Antenatal hepatitis B status (HBsAg)*: the information on a woman's antenatal HBsAg status was obtained from the provincial antenatal record. Prenatal blood work is usually done after the woman's first antenatal visit and the results are later written on the antenatal record.

xxvi) *HBsAg order on chart*: if the HBsAg status was not on the antenatal record or the antenatal record was not available, the chart was checked to see if testing was done in the hospital. The physician order sheet was checked for an order for serological testing for HBsAg. All lab test results on the chart were also checked for evidence of HBsAg testing.

xxvii) *Result of HBsAg*: whether the result of the HBsAg test was positive, negative or in some cases recorded as "immune" was obtained from the antenatal record. If the testing was done in hospital, this information was collected from the hospital chart. The clinical history and physical when available was checked for HBsAg results. In 1994, one hospital included a space on the labor and delivery record for HBsAg. As the purpose was to ascertain whether HBsAg status was available to clinical staff, this sheet was also checked at this hospital.

xxviii) *Gestation at birth*: the gestation at birth was obtained from the delivery record. If it was not available there it was obtained from the discharge summary or the clinical history.

xxix) *Delivery type*: information on whether an infant was delivered by cesarean section (C/S) or vaginally was extracted from the delivery record or if unavailable here, from the discharge summary or summary sheet.

E. Sample Size:

The sample size required for the study was calculated using the method for estimating a population proportion with a specified absolute precision.[55] The population estimate for the anticipated proportion of women being screened for HBsAg later in the study (1993) was based on data provided by the Virology Laboratory at the Ministry of Health.[56] It was postulated that in 1993, four years after the NACI guidelines, screening would have reached a stable rate and that the proportion of women screened in prior years would be lower. Sample size was calculated so that the screening rate during a three-month interval in 1993-1994 could be estimated within ten percentage points of the true value with 95 percent confidence.

In June 1993, antenatal HBsAg testing was centralized, with all blood specimens going to the Ministry of Health Laboratories. Statistics were available for the Ottawa-Carleton region for the three month period from October 1 to

December 31, 1993. During this time 1700 women from Ottawa-Carleton had antenatal HBsAg screening. Based on this, it was estimated that 6800 such tests were done for the year of 1993. Approximately 10,000 women from the Ottawa-Carleton region gave birth in 1993, implying that approximately 68% of women were tested prenatally for HBsAg during 1993.

Using the estimate that 70% of pregnant women were being screened antenatally in 1993 with 95 percent confidence that this estimate was within ten percentage points (i.e. 60-80%) of the true value gave a required sample size of 80 charts per three-month period. The study was designed to make point estimates of the screening rate in three-month intervals during the four years under study. The required sample of 80 charts per three-month interval gives a total sample size of 1280 or 320 charts per study year.

The 320 charts to be sampled each study year were divided between the five hospitals based on the percentage of deliveries that each hospital had for that study year. Due to rounding the final sample size was 1288 with the first 12 three-month intervals (1988-1991) having a sample size of 80 each and the final four intervals (1993-1994) having a sample size of 82 each.

There was no information available on the preguideline rates of screening for HBsAg in Ottawa-Carleton. Since a selective high risk screening strategy had been recommended for several years prior to the 1989 recommendations it was unlikely that the antenatal screening rates were zero. The sample size of 320 in the year before and for each year after was considered satisfactory to

detect even a small change in the screening rate. Even if 60% of women were being screened for HBsAg in pregnancy during 1988-1989, then detecting a 15% increase after the guidelines (75%) would require only 216 charts before and after with a power of 90% and a p of .05.

F. Ethical Considerations:

The chiefs of the obstetrical department at the five hospitals were informed of the study. Ethics committees at all five hospitals reviewed the proposal and gave their approval for the study.

G. Data Quality:

Two data abstractors were used in the study. Interobserver reliability in chart abstraction was assessed by having both complete data forms on the same randomly selected 30 charts. Each data extractor reviewed 15 charts that had previously been done by the other person. Discrepancies were found in eight entries (1.1%); once in extracting chart number, once in discharge date, twice in obstetrical care physician, once in occupation, once in last normal menstrual period, once in number of antenatal visits, and once in recording gestational age at first visit. There were no other differences. There were no discrepancies in recording hepatitis B status.

The validity of information taken from the hospital chart was not assessed by comparison to any other source. There was no reason to expect that chart

information would be unreliable in terms of date of birth, gestation at delivery or other variables. Although it could be argued that absence of hepatitis B status on the inpatient chart does not mean that testing did not occur, the purpose of this study is to look at the information available for clinical decision making in the hospital at the time of delivery. If the HBsAg result is not available then it is unlikely that an infant of a carrier mother will receive hepatitis B immune globulin and vaccine at birth.

Information that was not available was recorded as missing data. The chart reviewers were instructed to record "?" if this was what was written on the chart (i.e. in the case of last menstrual period) and this was subsequently coded as missing on data entry (see Appendix B).

H. Data Analysis:

The data were entered onto microcomputer and descriptive analyses were done using SPSS-PC version 6.1. Chi-square for trend was done using Epi-info and logistic regression was done with SPSS-PC version 6.1. Data were checked for inconsistencies prior to analysis. Dates were checked for logical time sequence; eg. charts in which the woman's last visit to the physician occurred after the discharge from hospital (7) and charts in which the first visit occurred before the last menstrual period (19) were highlighted. In the latter the majority of errors (73.7%) were in recording the year of the last menstrual period (LNMP). Many of these were initial errors on the chart (e.g. physician seeing patient in

January 1990 and recording LNMP as November 1990 instead of November 1989). The inconsistencies identified were corrected.

The data analysis used to achieve each of the objectives is described below:

Objective 1:

To determine the impact over time of the 1989 NACI hepatitis B guidelines on the proportion of women who had their HBsAg status available at the time of giving birth in the Ottawa-Carleton area. This objective had two components:

a) *the proportion of women with live births who had their antenatal HBsAg screening results available on the antenatal record in the hospital chart.*

This component was approached using two separate analyses.

i) *trend over time*:

To determine if there was a significant trend over time in the proportion of women delivering who had their antenatal screening HBsAg results available, the proportion of women with this information was calculated for each of the 16 time periods. Chi-square for trend was then used to determine if there was a significant trend over time with a 5% chance of making a type I error.

ii) *impact of the NACI guidelines:*

To determine if the NACI guidelines had an impact on the proportion of woman with antenatal HBsAg screening results available before and

after the guidelines. The proportion of women with this information was calculated for each one year time period. The year prior to the guidelines (1988-89) was then compared to each one year period after the guidelines. The following three comparisons were made:

1988-1989 to 1989-1990

1988-1989 to 1990-1991

1988-1989 to 1993-1994

The z-test was used to determine if there was a statistically significant difference between the proportion of women screened before and after the guidelines using the following formula;

$$z = \frac{(p_1 - p_2) - 0}{SE\ (p_1 - p_2)}$$

b) *the proportion of women who did not have the results of antenatal screening available and who had HBsAg testing done in hospital prior to giving birth.*

To determine if there was a significant trend over time in the proportion of women without results of antenatal screening available who had HBsAg testing done in hospital prior to delivery, the proportion of women who had in-hospital testing was calculated for each of the 16 time periods. Chi-square for trend was then used to determine if there was a significant trend over time with a 5% chance of making a type I error.

Objective 2:

To determine if lack of maternal HBsAg screening was related to:

a. patient characteristics (age, marital status, gravidity, parity, occupation, number of antenatal visits, gestation at birth, or if a patient was transferred from another hospital)

b. physician characteristics (family practitioner or specialist, year graduated)

c. hospital characteristics (hospital A,B,C,D,or E, size, and whether the March 1990 Health Department recommendations were adopted as written policy.)

In order to determine the variables associated with lack of hepatitis B screening, analysis was performed on cases collected from time periods after the guidelines were issued. The 320 cases from April 1, 1988 to March 31, 1989 were excluded, leaving a total of 968 charts used in the univariate and subsequent multivariate analysis. This allows examination of the factors that have come into play since the NACI guidelines and risk factors that are currently important in lack of hepatitis B screening of pregnant women prior to delivery.

1) Univariate analysis:

Univariate analysis was performed using the chi-squared test to identify factors associated with lack of maternal HBsAg screening prior to giving birth. The percentage of missing values in the variable "employed"

(47.1%), "occupation" (27.4%), "gestational age at first visit" (17.8%) and gestational age at last visit (17.5%) precluded their valid use in analysis. Most variables were entered in the form of the original categories. Categories of certain variables with small numbers were collapsed into fewer categories after determining that important distinctions or information would not be lost:

a) the categories in marital status were collapsed from six into three categories by grouping married and common-law into one group, separated, divorced and widowed women into another plus a third category of single women.

b) physician qualification was originally collected in three categories of GP, CCFP, and obstetrician. There were few GPs and this category was combined with CCFP to form one category of family practice (GP and CCFP).

c) the variable delivery type had a third category of both cesarean section (C/S) and vaginal delivery. There was one case in which one twin was delivered by C/S and the other twin delivered vaginally. This case was grouped with C/S.

Other variables were collected as continuous data and then were grouped into categories after descriptive statistics were examined and prior to univariate analysis. The following variables were grouped after data collection:

a) year graduated was grouped into ten year intervals based on the

minimum and maximum values from 1947-1989.

b) age was grouped into the six categories that are used on the physician notice of birth (PNOB) and the standard Statistics Canada groupings.

c) gravidity was grouped into two categories of primagravida (first pregnancy) and multigravida (more than one previous pregnancy). Parity was grouped into primiparous (one live birth including this one) and multiparous (more than one pregnancy resulting in a viable fetus).

d) number of antenatal visits was divided into three groupings of low (<6), moderate (6-11) and standard (12+). This was based on the accepted standard of monthly visits after the first visit and until 30 weeks, followed by visits every 2 weeks until 36 weeks and weekly visits until delivery. A woman who had her first visit at 12 weeks and was seen at the recommended interval until delivery at 40 weeks would have 12 visits. The number and not the timing of the visits was considered.

e) gestation at birth was grouped into the accepted groupings for preterm birth and normal gestation. The three groups were < 34 completed weeks, 34-36 completed weeks and 37+ weeks.

Family physicians' names were collected as previously described. An attempt to identify those receiving shared care (a woman sees her family doctor

in the early stages of pregnancy and then sees an obstetrician after approximately 28 weeks and for the delivery) was made. If shared care was indicated on the provincial antenatal form this was abstracted. Information on shared care was collected to determine if this change in physicians was a factor in availability of maternal HBsAg status. The supposition was that with the change in physicians the screening might get missed. It proved difficult to collect reliable data on shared care as even in the case of definite shared care (i.e. indicated in the discharge summary) it was not always recorded on the antenatal sheet. There were 48 cases identified as receiving shared care. Due to the poor quality of this variable it was not used in analysis.

The HEaLth Planning System (HELPS) Livebirth database was used in making comparisons between the study population and the Ottawa-Carleton population. The HELPS Livebirth database on SPSS is made available to all Health Departments by the Ontario Ministry of Health. This database was used to calculate the rates for specific variables in the Ottawa-Carleton maternal population (age, marital status, parity, and gestation at birth). Information was not available on HELPS for other study variables (e.g. gravidity and number of antenatal visits). The data for HELPs are collected from " Notice of Live Birth or Stillbirth" that is completed by the medical practitioner or nurse attending the delivery. It is supplemented by the "Statement of Live Birth" that is completed by a parent within 30 days of an infant's birth. The data are reported by place of residence and therefore include only women who reside in Ottawa-Carleton.

Women who live in Quebec or elsewhere who gave birth at one of the five hospitals would not be included in the HELPS data for Ottawa-Carleton. There are approximately 2000 births in Ottawa-Carleton each year from women who reside outside the Ottawa-Carleton region. Information on cesarean section rates was obtained from the Ottawa-Carleton Health Department perinatal statistics. This database contains information on all women who gave birth in Ottawa-Carleton and therefore includes the additional 2,000 women from outside Ottawa-Carleton.

2) Multivariate Analysis:

In building the multivariate model, variables with a chi-square test with $p<.25$ in univariate analysis were included in order to identify important variables as recommended by Mickey and Greenland.[57]

The dependent variable was lack of HBsAg results prior to the delivery of a live infant. Variables were coded such that the baseline or referent level was the group with the highest rate for hepatitis B screening. Coefficients would therefore reflect level of excess risk. Hospital was coded differently, such that the referent level was the hospital with the smallest number of deliveries.

The graduation years of both the antenatal care physician and the attending physician were statistically significant in univariate analysis. In most cases the antenatal care physician was also the attending physician upon a woman's hospital admission. In addition the antenatal care physician would be most responsible for ensuring that antenatal HBsAg screening was performed.

Therefore graduation year of the antenatal care physician (gradANC) was the most appropriate variable for inclusion in the multivariate model.

Logistic regression was performed in a forward stepwise manner with the significant variables to select the final subset of variables in the main effects model. Starting with a model that contained only the constant, the variable with the smallest significance level (cutoff of 0.05) for the Score statistic was entered into the model. All variables that were in the model were then examined to see if they met the removal criteria using the likelihood ratio test. The variable with the largest significance level above the cutoff of 0.1 was removed from the model. If no variables met the removal criteria the next variable was entered into the model. This process continued until no variables met the entry or removal criteria or a previously considered model was encountered.

Possible interactions among the selected subset of main effect variables were considered. The two interactions, "graduation year of antenatal care physician" by "timeperiod" and "graduation year of antenatal care physician" by "hospital" were evaluated by running two separate logistic regressions which included the two main effects plus their two-way interaction. A two-way interaction was considered for entry in the final model if its goodness-of-fit p-value was less than 0.10. Two-way interaction terms meeting the above criterion were evaluated by entrance into the final model using forward stepwise logistic regression. The interaction term was accepted if the goodness-of-fit of the model was meaningfully improved.

V. RESULTS:

This study involved the review of 1288 charts of mothers giving birth to live infants at the five hospitals with maternity services in the Ottawa-Carleton region. Twenty-five (1.9%) charts could not be located; five were misfiled, eight were missing, four had been damaged by flooding and eight were active and therefore unavailable. These charts were replaced by randomly chosen charts from the same time interval.

A. Description of the Study Population:

1) Characteristics of the study population:

The age structure of the study population changed over time. The proportion of women in the 30-34 age group delivering live births increased over the six year time span (1988-1994), while the proportion in the 25-29 age group decreased (Table 5.1). These changes were statistically significant ($p<.05$). These changes over time in the study sample reflect the changes that occurred in the Ottawa-Carleton maternal population. The composition of the other age groups remained stable over time.

There were interesting changes in the marital status of the study population that reflect changes occurring in the structure of the Canadian family. The proportion of single women remained fairly constant over time at approximately 11%. However, the proportion of woman reporting common-law relationships increased significantly from 4.4% in 1988 to 9.8% in 1994 ($p<.05$)

(Table 5.1). There was a corresponding decrease from 1988 (83.2%) to 1994 (77.7%) in the percentage of women reporting being married. Yet the proportion of women reporting relationships remained fairly constant (86-88%) and there was no significant difference between the four years in the proportion of woman in the combined married/common-law group. This trend to increased common-law relationships has been documented by Statistics Canada in the General Social Survey.[58] The proportion of common-law families in Canada has doubled from 6% in 1981 to 12% in 1995.

In the study population approximately 43% of women gave birth to their first infant. The proportion of women who were primiparous and multiparous remained fairly constant over time. There were no significant differences in the proportions of primiparous women or multiparous women delivering in the four time periods ($p>.05$).

The majority of infants (89.6% - 92.4%) were born at term (37+ weeks). The proportion of infants born prematurely (<37 weeks) was highest in the 1989-1990 timeperiod (10.4%) due to a higher proportion of infants born at <34 weeks (4.4%) compared to the other three time periods (range 2.1% to 3.1%). This difference was not statistically significant ($p>.05$). (Table 5.1).

The proportion of infants born by cesarean decreased by almost half, from 20.6% in 1988-89 to 11.6% in 1993-94. This decrease was statistically significant ($p<.05$).

Table 5.1: Characteristics of the study population for the four study periods

	Apr 1988 Mar 1989		Oct 1989 Sept 1990		Oct 1990 Sept 1991		Oct 1993 Sept 1994	
	No.	%	No.	%	No.	%	No.	%
MATERNAL AGE								
<20	15	4.7	11	3.4	12	3.8	17	5.2
20-24	53	16.6	59	18.4	49	15.4	44	13.4
25-29*	134	41.9	117	36.6	106	33.2	99	30.2
30-34*	88	27.5	93	29.1	113	35.4	120	36.6
35-39	27	8.4	37	11.6	36	11.3	42	12.8
40+	3	0.9	3	0.9	3	0.9	6	1.8
Total	320	100	320	100	319	100	328	100
no. missing(%)	0		0		1(.3%)		0	
MARITAL STATUS								
single	36	11.4	34	10.6	38	11.9	36	11.0
married*	263	83.2	269	84.1	260	81.3	255	77.7
common-law*	14	4.4	14	4.4	16	5.0	32	9.8
sep/div/wid	3	0.9	3	0.9	6	1.9	5	1.5
Total	316	100	320	100	320	100	328	100
no. missing	4(1.3%)		0		0		0	
PARITY								
primiparous	145	45.3	135	42.3	138	43.3	138	42.1
multiparous	175	54.7	184	57.7	181	56.7	190	57.9
Total	320	100	319	100	319	100	328	100
no. missing (%)	0		1(.3%)		1(.3%)		0	
GESTATION AT BIRTH (completed weeks)								
< 34 weeks	7	2.2	14	4.4	10	3.1	7	2.1
34-36 weeks	20	6.4	19	6.0	15	4.7	18	5.5
37+ weeks	286	91.4	284	89.6	294	92.2	303	92.4
Total	313	100	317	100	319	100	328	100
no. missing(%)	7(2.2%)		3(.9%)		1(.3%)		0	
DELIVERY TYPE								
vaginal	254	79.4	258	80.6	275	85.9	290	88.4
C/S	66	20.6	62	19.4	45	14.1	38	11.6
Total	320	100	320	100	320	100	328	100
no. missing (%)	0		0		0		0	

* significant difference p<.05

Table 5.1: Characteristics of the study population for the four study periods

	Apr 1988 Mar 1989		Oct 1989 Sept 1990		Oct 1990 Sept 1991		Oct 1993 Sept 1994	
	No.	%	No.	%	No.	%	No.	%
GRAVIDITY								
primigravida	112	35	111	34.7	106	33.1	101	30.8
multigravida	208	65	209	65.3	214	66.9	227	69.2
Total	320	100	320	100	320	100	328	100
no. missing (%)	0		0		0		0	
NUMBER of ANTENATAL VISITS								
< 6*	27	10.3	19	7.5	24	9	54	18.5
6 - 11	191	73.2	196	77.5	189	70.5	197	67.5
12+	43	16.5	38	15	55	20.5	41	14.0
Total	261	100	253	100	268	100	292	100
no. missing (%)	59(18.4%)		67(20.9%)		52 (16.3%)		36(11%)	
TRANSFER								
yes	8	2.7	6	1.9	5	1.6	4	1.2
no	283	97.3	314	98.1	315	98.4	324	98.8
Total	291	100	320	320	320	100	328	100
no. missing (%)	29 (9.1%)		0		0		0	

* significant difference p<.05

Approximately one-third of women were pregnant for the first time (Table 5.1). The proportion of primigravidas was not significantly different between the four study years (p>.05).

For the total study population, less than two percent of cases were transferred from another hospital. All transfers were received at the two largest of the five hospitals. There was no significant difference between the four study years in the proportion of women transferred from one hospital to another.

Changes in the number of antenatal visits over time may reflect changes in obstetrical care as more family doctors do not deliver and instead share

antenatal care with obstetricians. In 1993-1994, a larger proportion of women had fewer than six visits compared to the other study years (Table 5.1). There was a significant difference between the four years in the proportion of women having less than 6 visits, the lowest (7.5%) was in 1989 -1990 and the highest rate (18.5%) was in 1993 -1994. The mean number of antenatal visits for the study population was 8.7 with a range from 1-24 visits to the physician.

This variable reflects the number of antenatal visits recorded on the antenatal record and may not be an accurate reflection of the actual number of physician visits that a women had throughout the prenatal period. This is especially true when care is shared. In this case both the family doctor who initiates care, and the obstetrician who follows the woman after 28 weeks, may have antenatal records in their offices. It appears that the record from the obstetrician's office is being sent to the hospital most likely because it is the obstetrician who will deliver the infant. This antenatal record may not give a reliable picture of the actual number of visits that a woman had during the prenatal period as it may include only visits to the obstetrician.

In the study population, woman who were seeing obstetricians were twice as likely to have less than six visits (20.8%) as were woman seeing family doctors (10.3%). This is not because obstetricians see pregnant women less often than family doctors but reflects shared care. Unfortunately it proved difficult using the hospital charts to identify all women receiving shared care. The number of antenatal visits as collected is not a valid indicator of the number

of physician visits that a woman has in the prenatal period. "Number of antenatal visits" was not considered a vital variable in determining risk factors for lack of antenatal HBsAg screening. Therefore this variable was not considered in further analysis.

Information was missing for several variables (occupation, gestational age at first and last visit) on approximately 20% of hospital charts. None of these variables was considered a predictor of HBsAg screening and therefore consideration was not given to using imputed values or to including them in further analysis. Information on the woman's occupation was missing on 353 charts (27.4%). Information on occupation was available on a larger proportion of charts over time. Only 66% of charts had recorded information on occupation in 1988-89 compared to 85% in 1993-94. The following table describes occupation for the total study population.

Table 5.2: Occupation of women in the study

Occupation	Number	Percent (%)
Homemaker	235	25.1
Clerical	209	22.4
Manager	106	11.3
Health	94	10.1
Service	54	5.8
Teaching	53	5.7
Student	40	4.3
Social Sciences	37	4.0
Other	107	11.4
Total	935	100
missing	353	27.4

Information on "gestational age at first visit" was missing from 229 (17.8%) of hospital charts. The mean age at the first visit was 12.8 weeks with a range of one to 40 weeks. Information on "gestational age at last visit" was missing in 17.5% of cases. The mean gestational age at the last visit was 36.3 weeks with a range from 23 to 42 weeks. The mode was 36 weeks as this is about the time that a physician sends in the hospital's copy of the provincial antenatal record. The physician may continue to record visits on the office copy, but the record sent in at 36-37 weeks is the one that is most likely to end up on the woman's hospital chart.

2) Comparability to the Ottawa-Carleton population:

In order to make generalizations using the study results, the sample population should be comparable to the general population of women who gave birth to live infants during the same time periods. Tables 5.3 to 5.6 outline the study population characteristics for which there are comparison data from the Ottawa-Carleton maternal population. The tables give data for each of the four study years and information from the Ottawa-Carleton population of women giving birth to live infants for the most comparable year. The study intervals include more than one year (e.g. October 1, 1989 to September 30, 1990), so Ottawa-Carleton data from the predominant year (e.g. 1990) were used in comparisons. The final study interval (October 1, 1993 to September 30, 1994) contains more data from 1994 than 1993, but Ottawa-Carleton data for 1994

were not available at the time of writing. Therefore the 1993 Ottawa-Carleton maternal population was used as the comparison year.

The two populations had similar age structures for the years compared. There was no significant difference in the proportion of women in the different age groups between the study population and the Ottawa-Carleton maternal population (Tables 5.3-5.6). The study population and the Ottawa-Carleton maternal population show the same trend of a significant increase over time in the proportion of women in the 30-34 age group delivering live births and a decrease in the proportion in the 25-29 age group.

Making comparisons between the marital status of the sample population and the Ottawa-Carleton population was difficult due to problems with the marital status variable on the HELPS database. Common-law relationships were recorded in the study population but there is no "common-law" category in the marital status variable on the HELPS database. This makes it difficult to compare the marital status of the study sample with the Ottawa-Carleton maternal population.

The validity of the marital status variable in the HELPS database is questionable due to the lack of a common-law category. Difficulties with the coding of "common-law" appears to be evident in the increasing proportion of women with "unknown" marital status from 1988 (.01%) to 1993 (18.7%). This increase in the proportion of women with "unknown" marital status coincides with the increase in common-law unions over time. The epidemiologist responsible

for the Livebirth Database at the Ministry of Health confirmed that this problem makes the "single" and "married" categories of "marital status" for the Ottawa-Carleton maternal population unreliable.[59]

The two populations were not similar in the proportion of women who were married or single for the years compared (Tables 5.3 -5.6). This difference was not consistent for every year. The 1988-1989 study sample had a lower proportion married (83.2%) than the 1989 Ottawa-Carleton population (87.5%). In 1989-90 the study population had a lower proportion of single mothers (10.6%) than the 1990 Ottawa-Carleton population (14.7%). The proportion of women who were separated, divorced or widowed was comparable between the two populations over time. The discrepancies are felt to be due to the lack of validity of the Ottawa-Carleton marital status categories for "married" and "single".

There were no differences between the study population and the Ottawa-Carleton population in the proportion of primiparous or multiparous women for the four study years.

There is a significant difference between the two populations in "gestation at birth". .The proportion of women delivering infants at less than 34 weeks was higher (4.4%) in the 1989-90 study population than in the Ottawa-Carleton 1990 population (1.6%). There was a correspondingly lower proportion of deliveries in the 37+ gestation group in the study population (89.6%) compared to the 1990

Ottawa-Carleton population (93.8%). These differences are statistically significant ($p<.05$).

The proportion of women having cesarean sections was lower in the study population than in the Ottawa-Carleton population in 1990-1991 (14.1 versus 16.4) and in 1993-94 (11.6 versus 15.4). These differences are not statistically significant ($p>.05$).

Overall, the study population for the four study years is reasonably comparable to the Ottawa-Carleton population of women who gave birth to live infants during comparable time periods.

Table 5.3: Comparison of the study population 1988 to 1989 and the Ottawa-Carleton population 1988

	Study population 1988-1989		Ottawa-Carleton 1988	
	No.	%	No.	%
MATERNAL AGE				
<20	15	4.7	294	3.4
20-24	53	16.6	1358	15.8
25-29	134	41.9	3329	38.8
30-34	88	27.5	2608	30.4
35-39	27	8.4	881	10.3
40+	3	.9	118	1.4
Total	320	100	8592	100
	missing = 0		missing = 2 (0.2%)	
MARITAL STATUS†				
single	36	11.4	1031	12
married	263	83.2	7513	87.5
common-law	14	4.4	----	----
sep/div/wid	3	0.9	47	0.5
Total	316	100	8591	100
	missing = 4(1.3%)		missing = 1(.01%)	
PARITY				
primiparous	145	45.3	4075	47.4
multiparous	175	54.7	4515	52.6
Total	320	100	8590	100
	missing = 0		Missing = 2 (.02%)	
GESTATION AT BIRTH (completed weeks)				
< 34 weeks	7	2.2	121	1.4
34-36 weeks	20	6.4	417	4.9
37+ weeks	286	91.4	8051	93.7
Total	313	100	8589	100
	missing = 7 (2.2%)		missing = 3 (.03)	
DELIVERY TYPE				
vaginal	254	79.4	NA	NA
C/S	66	20.6	NA	NA
Total	320	100	NA	NA
	missing = 0			

† Ottawa-Carleton variable has validity problems, see text
* significant difference from Ottawa-Carleton data at p<.05
NA = not available

Table 5.4: Comparison of the study population 1989 to 1990 and the Ottawa-Carleton population 1990

	Study population 1989-1990		Ottawa-Carleton 1990	
	No.	%	No.	%
MATERNAL AGE				
<20	11	3.4	354	3.7
20-24	59	18.4	1439	15.0
25-29	117	36.6	3592	37.5
30-34	93	29.1	2990	31.3
35-39	37	11.6	1055	11.0
40+	3	0.9	137	1.4
Total	320	100	9567	100
	missing = 0		missing = 3 (0.3%)	
MARITAL STATUS†				
single	34	10.6	1410	14.7
married	269	84.1	8112	84.8
common-law	14	4.4	---	---
sep/div/wid	3	.9	44	0.5
Total	320	100	9566	100
	missing = 0		missing = 4 (.04%)	
PARITY				
primiparous	135	42.3	4577	47.8
multiparous	184	57.7	4990	52.2
Total	319	100	9567	100
	missing = 1 (0.3%)		missing = 3 (.03)	
GESTATION AT BIRTH (completed weeks)*				
< 34 weeks	14	4.4	156	1.6
34-36 weeks	19	6.0	436	4.6
37+ weeks	284	89.6	8972	93.8
Total	317	100	9564	100
	missing = 3 (.9)		missing = 6 (0.1%)	
DELIVERY TYPE				
vaginal	258	80.6	9960	81.1
C/S	62	19.4	2322	18.9
Total	320	100	12282	100
	missing = 0		missing = 0	

† Ottawa-Carleton variable has validity problems, see text

* significant difference from Ottawa-Carleton data at $p<.05$

Table 5.5: Comparison of the study population 1990-1991 and the Ottawa-Carleton population 1991

	Study population 1990-1991		Ottawa-Carleton 1991	
	No.	%	No.	%
MATERNAL AGE				
<20	12	3.8	361	3.7
20-24	49	15.4	1329	13.7
25-29	106	33.2	3515	36.3
30-34	113	35.4	3193	32.9
35-39	36	11.3	1145	11.8
40+	3	0.9	153	1.6
Total	319	100	9696	100
	missing = 1 (0.3%)		missing = 2 (0.2%)	
MARITAL STATUS†				
single	38	11.9	1644	18.2
married	260	81.3	7314	81.1
common-law	16	5.0	---	---
sep/div/wid	6	1.9	65	.7
Total	320	100	9023	100
	missing = 0		missing = 675 (7%)	
PARITY				
primiparous	138	43.3	4447	45.9
multiparous	181	56.7	5249	54.1
Total	319	100	9696	
	missing = 1 (0.3%)		missing = 2 (.02)	
GESTATION AT BIRTH (completed weeks)				
< 34 weeks	10	3.1	179	1.8
34-36 weeks	15	4.7	557	5.8
37+ weeks	294	92.2	8949	92.4
Total	319	100	9685	100
	missing = 1 (0.3%)		missing = 13(0.1%)	
DELIVERY TYPE				
vaginal	275	85.9	10411	83.6
C/S	45	14.1	2036	16.4
Total	320	100	12447	100
	missing = 0		missing = 0	

† Ottawa-Carleton variable has validity problems, see text

* significant difference from Ottawa-Carleton data at p<.05

Table 5.6: Comparison of the study population 1993-1994 and the Ottawa-Carleton population 1993

	Study population 1993-1994		Ottawa-Carleton 1993	
	No.	%	No.	%
MATERNAL AGE				
<20	17	5.2	413	4.2
20-24	44	13.4	1308	13.4
25-29	99	30.2	3152	32.3
30-34	120	36.6	3464	35.5
35-39	42	12.8	1262	12.9
40+	6	1.8	166	1.7
Total	328	320	9766	100
	missing = 0		missing = 6 (0.1%)	
MARITAL STATUS†				
single	36	11.0	1323	16.7
married	255	77.7	6559	82.6
common-law	32	9.8	---	---
sep/div/wid	5	1.5	59	0.7
Total	328	100	7941	100
	missing = 0		missing = 1831(18.7%)	
PARITY				
primiparous	138	42.1	4374	44.8
multiparous	190	57.9	5390	55.2
Total	328	100	9764	100
	missing = 0		missing = 8 (.08)	
GESTATION AT BIRTH (completed weeks)				
< 34 weeks	7	2.1	190	1.9
34-36 weeks	18	5.5	614	6.3
37+ weeks	303	92.4	8956	91.8
Total	328	100	9748	100
	missing = 0		missing = 12 (.1%)	
DELIVERY TYPE				
vaginal	290	88.4	10478	84.6
C/S	38	11.6	1904	15.4
Total	328	100	12382	100
	missing = 0		missing = 0	

† Ottawa-Carleton variable has validity problems, see text

* significant difference from Ottawa-Carleton data at p<.05

3) Hepatitis B status:

Of the 1288 women studied, 643 (50%) were known to have been screened for HBsAg prior to delivery of their infant. The remaining 645 women did not have HBsAg results available. Although 643 women were screened, final HBsAg results were available for 642 women. One of the seven women who had a HBsAg test ordered in hospital did not have the final results on her chart. The majority of women, 627 (97.7%) were HBsAg negative. Seven women were reported as immune (1.1%) and eight were HBsAg positive (1.2%). None of these HBsAg positive reports were repeat reports on the same woman during another pregnancy. One carrier was identified of the six women who had HBsAg screening results available from in-hospital testing (16.7%). Only seven women were tested in hospital so the 95% confidence intervals for the prevalence of HBsAg carriers in this group are wide (0.8-59%). The prevalence of HBsAg carriers in the women screened for hepatitis B antenatally was much lower at 1.1% (95% CI, 0.48-2.2%).

A woman could have HBsAg results available on her hospital chart through one of three mechanisms;

a) she could be screened during a prenatal visit and the result recorded on the antenatal record. A copy of this record would then be sent to the hospital prior to the woman's delivery or brought by the woman herself.

b) she could be asked about her HBsAg results or her physician's office could be contacted if the information was not available on the antenatal record but the antenatal screen had been done.

c) she could have a HBsAg test in hospital if the antenatal result was unavailable or was not performed.

Of the 643 women screened, 627 (97.5%) had the HBsAg information available on the antenatal form, indicating they had antenatal screening. Another nine women (1.4%) had results recorded elsewhere in their hospital chart (i.e. delivery record, history and physical record) indicating that either the antenatal care physician's office was contacted for the result or the woman herself was asked about her HBsAg status. Only seven of the 643 women screened (1.1%) had a HBsAg test ordered in hospital (Table 5.7).

Table 5.7: Availability of HBsAg screening results

	No.	%
HBsAg available on antenatal form	627	97.5
HBsAg status from MD's office	9	1.4
HBsAg test ordered in hospital*	7	1.1
Total	643	100

* one case with no antenatal screening but in-hospital screening unknown

B. Impact of Guidelines on Screening for Hepatitis B:

In looking at the impact of the guidelines on physician antenatal screening practices, the outcome variable was the availability of a woman's HBsAg results

on the provincial antenatal record in the hospital chart. In-hospital testing was not included.

For the entire study period 627 women (48.7%) had antenatal HBsAg screening results available on their antenatal record. Prior to the guidelines, only five percent of women had antenatal HBsAg results available confirming that selective screening was occurring. There was a dramatic eight fold increase in HBsAg availability the year following the guidelines when approximately 43% of women had antenatal HBsAg results available. By 1993-1994, more than five years after the guidelines were released, 81% of women had the results of their antenatal testing available on their antenatal record. (Table 5.8).

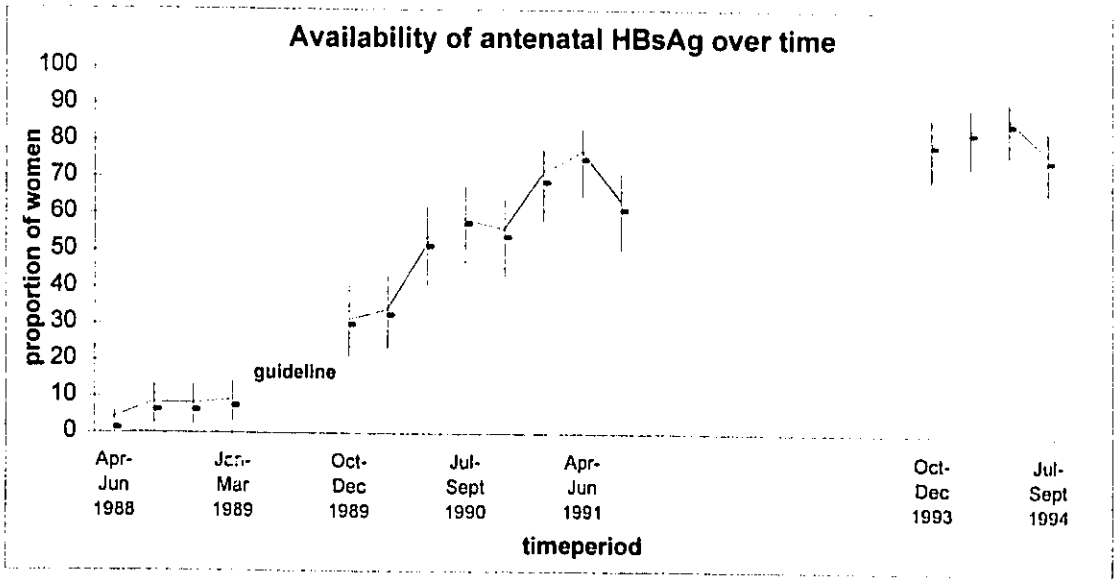
Table 5.8: Percentage of women with antenatal HBsAg screening results available over time

Time Period	Women with antenatal HBsAg results available		Total
	No.	%	
Apr 1988- Mar 1989	17	5.3	320
Guidelines introduced			
Oct 1989-Sept 1990	137	42.8	320
Oct 1990-Sept 1991	208	65.0	320
Oct 1993-Sept 1994	265	80.8	328

The proportion of women with antenatal HBsAg screening results available on the antenatal record was calculated for each of the 16 three-month time periods (Graph 5.1). Chi square test for trend was used to examine the significance of the change in the proportion of HBsAg results available over time.

The null hypothesis was H_0 : there is no change in the proportion of women with antenatal HBsAg screening with timeperiod with a 5% chance of making a type I error. Chi square for trend was 361.68 ($p< 0.0001$)

Graph 5.1: Proportion of women with antenatal HBsAg screening results available on the antenatal record over time with 95% CI.



The impact of the NACI guidelines released in 1989 were examined by comparing the proportion of women with antenatal HBsAg results available on their antenatal record for the year prior to the guidelines separately with each of the three one year time periods after the guidelines.

The null hypothesis was H_0: there is no difference between the proportion of women with antenatal screening results available before and after the guidelines.

Table 5.9: Difference between proportion screened before/after guidelines

Time Periods Compared	Z value	Result
1988-89 to 1989-90	11.1	reject H_0
1988-89 to 1990-91	15.2	reject H_0
1988-89 to 1993-94	19.5	reject H_0

$\Diamond = 0.05$

In each case there was a significant increase in the proportion of women screened compared to the baseline proportion prior to the guidelines. A significant increase was seen within the first year after the guidelines' release.

C. In-Hospital Screening for Hepatitis B Surface Antigen:

Women who were admitted to the hospital for delivery after 1989 with unknown HBsAg status should have had a HBsAg test done in hospital in accordance with the NACI recommendations. In March 1990, a memo was sent from the Ottawa-Carleton Health Department to all five hospitals to reiterate that a HBsAg test should be performed on all women admitted for delivery who did not have the antenatal results available. Only seven women had in-hospital testing for HBsAg during the study period. The percentage of women with unknown HBsAg status who were tested upon admission to hospital remained low and did not increase significantly over time (Table 5.10). In 1993-1994, six woman were asked about their HBsAg status or their physician's office was

contacted: the remaining 57 with unknown HBsAg status did not have in-hospital testing.

Table 5.10: HBsAg screening of women admitted without information on antenatal HBsAg results.

	Apr 1988-Mar 1989		Oct 1989-Sept 1990		Oct 1990-Sept 1991		Oct 1993-Sept 1994	
	No.	%	No.	%	No.	%	No.	%
No. of women admitted with unknown antenatal HBsAg results	302		183		112		63	
Women asked HBsAg or MD's office called	0	0	0	0	3	2.7	6	9.5
Women tested in hospital	0 [+]	0	6	3.3	1	0.9	0	0

[+] one case missing information on in-hospital testing
% is percent of women with unknown results

D. Risk Factors for Lack of Hepatitis B Screening:

1) Univariate Analysis:

Univariate analysis was performed using the chi-squared test to identify factors associated with lack of HBsAg screening prior to delivery. All women who had HBsAg results available on their hospital chart either on their antenatal record, through in-hospital screening or through a physician's office being called were considered screened for hepatitis B. The database used in analysis included the 968 charts from the time periods after publication of the NACI guidelines recommending universal screening. The 320 cases from the period prior to the guidelines (1988-89) were excluded as selective screening was the

recommendation at that time and these cases therefore do not reflect risk factors for lack of universal HBsAg screening of women prior to giving birth.

a) maternal characteristics:

Both younger (< 25 years old) and older women (>34 years old) had lower screening rates than the 25-34 year olds but the results were not statistically significant ($p>.05$). The 25 -34 year olds had screening rates of approximately 67% while approximately 58% of the younger and older women were screened for HBsAg (Table 5.11).

Although half of the women who were in the separated, divorced or widowed category were not screened, the numbers are small with only 14 women in this category. The proportion of women who were separated, divorced or widowed who were not screened was higher than in the single or married/common-law groups but this difference was not statistically significant in univariate analysis (Table 5.11).

There was little difference in the proportion of primiparous and multiparous women with HBsAg results available prior to their delivery. Maternal parity was not significantly associated with being screened for hepatitis B in the univariate analysis ($p>.05$) as outlined in Table 5.11.

There was little difference in the proportion of women screened for HBsAg who were pregnant for the first time compared to women with previous pregnancies. Maternal gravidity was not significantly associated with the dependent variable in the univariate analysis ($p>.05$) as outlined Table 5.11.

Women who were received in transfer had much lower rates of screening for HBsAg. All transfers were received at the two hospitals with the lowest screening rates suggesting that "hospital" might be a confounder. Stratification by hospital was not possible due to the small numbers involved and problems with empty cells in the crosstabulation of transfer and screened. Transfer was significantly associated with the outcome of lacking HBsAg screening prior to delivery as outlined in table 5.11.

The proportion of women missing HBsAg results was higher in those delivering infants prematurely (<37 completed weeks) than in those delivering at term (62.7% verses 32.8%). Screening rates increased with increasing gestation at delivery. Screening rates were lowest in the group delivering at less than 34 weeks (29%) compared to both the 34-36 week group (42.3%) and the 37+ week group (67.2%). Gestation at birth was significantly associated with screening for HBsAg ($p<.05$) as outlined in Table 5.11.

The proportion of women missing HBsAg was higher in women who had cesarean sections (48%) compared to women who had vaginal deliveries (33.3%). This is probably due to confounding by time. The cesarean section rate was higher early in the study when screening rates were lower leading to a higher number of women with cesarean sections who were not screened for HBsAg. Stratification by time demonstrated that this relationship was not constant over time. Delivery type was significantly associated with HBsAg screening ($p<.05$) as outlined in Table 5.11.

Screening rates for HBsAg increased over time with the largest proportion of women having results available in 1993-1994 (82.6%). Time period was significantly associated with HBsAg screening ($p<.05$) as outlined in Table 5.11 .

Table 5.11: Univariate analysis of study variables

Variable	Screened		Not screened		Total
	No.	%	No.	%	
MATERNAL AGE					
<20	23	57.5	17	42.5	40
20-24	91	59.9	61	40.1	152
25-29	211	65.5	111	34.5	322
30-34	225	69.0	101	31.0	326
35-39	67	58.3	48	41.7	115
40+	7	58.3	5	41.7	12
Total	624	64.5	343	35.5	967
			X^2 = 7.46 df =5		(p=0.19)
MARITAL STATUS					
Single	73	67.6	35	32.4	108
Married/CL	545	64.4	301	35.6	846
Sep/Div/Wid	7	50.0	7	50.0	14
Total	625	64.6	343	35.4	968
			X^2 = 1.69 df =2		(p=0.43)
PARITY					
Primiparous	268	65.2	143	34.8	411
Multiparous	356	64.1	199	35.9	555
Total	624	64.6	342	35.4	966
			X^2 = 0.12 df = 1		(p=0.73)
GRAVIDITY					
Primigravida	208	65.4	110	34.6	318
Multigravida	417	64.2	233	35.8	650
Total	625	64.6	343	35.4	968
			X^2 = 0.15 df = 1		(p=0.70)
TRANSFER					
Yes	2	13.3	13	86.7	15
No	623	65.4	330	34.6	953
Total	625	64.6	343	35.4	968
			X^2 = 17.21 df = 1		(p=.00003)
GESTATION					
< 34 weeks	9	29.0	22	71.0	31
34-36 weeks	22	42.3	30	57.7	52
37 + weeks	592	67.2	289	32.8	881
Total	623	64.6	341	35.4	964
			X^2 = 29.52 df = 2		(p<0.00001)
DELIVERY TYPE					
Cesarean section	76	52.4	69	47.6	145
Vaginal delivery	549	66.7	274	33.3	823
Total	625	64.6	343	35.4	968
			X^2 = 10.66 df = 1		(p=0.001)

Table 5.11: Univariate analysis of study variables

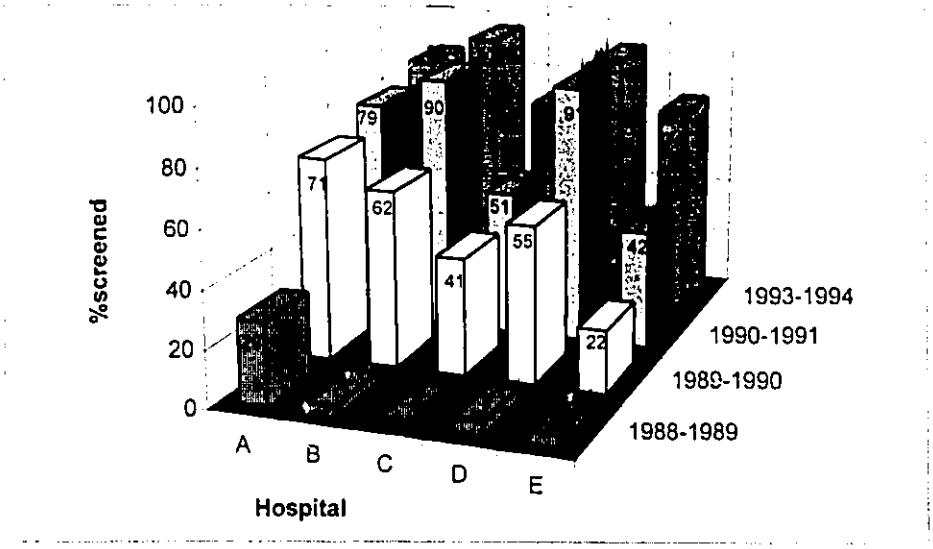
Variable	Screened		Not screened		Total
	No.	%	No.	%	
TIME PERIOD					
1989 - 1990	142	44.4	178	55.6	320
1990 - 1991	212	66.3	108	33.8	320
1993 - 1994	271	82.6	57	17.4	328
Total	625	64.6	343	35.4	968
			X^2 = 106.87 df = 2 (p<.00001)		
HOSPITAL					
A	60	78.9	16	21.1	76
B	159	82.8	33	17.2	192
C	142	54.6	118	45.4	260
D	148	80.4	36	19.6	184
E	116	45.3	140	54.7	256
Total	625	63.7	343	36.3	968
			X^2 = 111.39 df = 4 (p<.00001)		
QUALIFICATION of ATTENDING PHYSICIAN					
Obstetrician	501	63.9	283	36.1	784
Family Practice	122	67.4	59	32.6	181
Total	623	64.6	342	35.4	965
			X^2 = 0.80 df = 1 (p=0.37)		
QUALIFICATION of ANTENATAL CARE PHYSICIAN					
Obstetrician	470	69.1	210	30.9	680
Family Practice	133	67.9	63	32.1	196
Total	603	68.8	273	31.2	876
			X^2 = 0.11 df = 1 (p=.74)		
GRADUATION YEAR of ATTENDING PHYSICIAN					
1945-1954	1	3.6	27	96.4	28
1955-1964	80	67.2	39	32.8	119
1965-1974	128	57.4	95	42.6	223
1975-1984	335	68.0	158	32.0	493
1985-1989	75	79.8	19	20.2	94
Total	619	64.7	338	35.3	957
			X^2 = 62.98 df = 4 (p<.00001)		
GRADUATION YEAR of ANTENATAL CARE PHYSICIAN					
1945-1954	3	11.1	24	88.9	27
1955-1964	76	73.8	27	26.2	103
1965-1974	127	63.5	73	36.5	200
1975-1984	325	71.1	132	28.9	457
1985-1989	69	83.1	14	16.9	83
Total	600	69.0	207	31.0	870
			X^2 = 53.13 DF = 4 (P<.00001)		

b) hospital characteristics:

Screening rates for HBsAg were higher in the smaller community hospitals than in the larger teaching hospitals. During the period after the guidelines approximately 80% of women who gave birth at the community hospitals were screened versus only 50% of women who gave birth at the larger teaching hospitals during the same time period. There was a significant relationship between hospital and HBsAg screening ($p < .05$) as outlined in Table 5.11.

Availability of the HBsAg screening increased at all hospitals over time. One community hospital had a preguideline screening rate of almost 30% while the others had screening rates between two and five percent. In 1993-1994, rates ranged from 73% to 96% at the different hospitals (Graph 5.2). Availability of a woman's HBsAg results increased at all hospitals over time. The hospitals starting with the lowest screening rates also showed an increase over time but continued to have lower screening rates than the other hospitals for each year and in the final study year, 1993-1994.

Graph 5.2: Proportion of women with HBsAg results available at the time of delivery by hospital over time



c) physician characteristics:

Overall, screening rates were highest (80%) in the physicians who graduated during the five years before the guidelines (1984-1989). Rates were lowest in the smaller group of physicians who graduated between 1945 and 1954 (3.6%). Physicians graduating between 1955 and 1984 had screening rates ranging from 57% to 68%. The graduation year of the attending physician was significantly associated with HBsAg screening as outlined in Table 5.11.

There was a similar relationship between the year graduated and HBsAg screening for the antenatal care physician as for the attending physician. This is not surprising, as the antenatal care physician is usually also the attending or admitting physician. The screening rates were highest in the most recent

antenatal care physician graduates (83.1%) and lowest in those who graduated between 1945 and 1954 (11.1%). The graduation year of the physician responsible for antenatal care was significantly associated with HBsAg screening as outlined in Table 5.11 ($p<.00001$).

Women who were admitted to hospital by family doctors had similar rates of screening (32.6%) to women who were admitted by obstetricians (36.1%), ($p>.05$). Hepatitis B surface antigen screening rates were also comparable between women who saw an obstetrician for prenatal care and women who saw a family doctor for prenatal care ($p>.05$) (Table 5.11).

2) Multivariate analysis:

The dependent variable was lack of HBsAg screening results prior to birth of a live infant. All variables were categorical except for timeperiod which was continuous. The sixteen three-month time periods were coded from one to 26 as they were not contiguous. Table 5.12 outlines the variables that were included in obtaining the main effects logistic regression model.

Table 5.12: Variables with p<.25 in the univariate analysis

Variable	Abbreviation	p-value
Time period	timeperiod	.00000
Age	age	.19
Transfer	transfer	.00004
Hospital	hospital	.00000
Delivery type	deltype	.00100
Gestation at birth	gestation	.00000
Graduation year of antenatal M.D.	GradMD	.00000

The main effects subset of variables were selected by using a stepwise approach with forward selection with a test for backward elimination. Table 5.13 describes the main effects model resulting from stepwise logistic regression analysis.

Table 5.13: Results of stepwise logistic regression containing variables identified in the univariate analysis

Variable	Estimated coefficient	Estimated SE	Coeff. / SE	$e^{coeff.}$	95% CI Lower	95% CI Upper
Timeperiod	-.1300	.0153	-8.4967			
Hospital						
smallest	referent					
community A	-.3230	.3934	-.8210	.7240	.5644	.928?
teaching A	.6226	.3729	1.6696	1.8638	1.1824	2.9376
community B	-.0725	.3954	-.1834	.9301	0.8793	0.9538
teaching B	1.8309	.3653	5.0120	6.2394	1.682	23.146
Gestation						
37+ weeks	referent					
34-36	1.0408	.3545	2.9360	2.8314	1.3738	5.8357
< 34 weeks	.6853	.5140	1.3333	1.9843	1.3757	3.9578
Graduation year of physician						
1985-1989	referent					
1975-1984	-.2912	.3710	-.7849	.7474	.6484	0.9236
1965-1974	.2819	.3906	.7217	1.3257	1.0683	1.6449
1955-1964	.1521	.4362	.3487	1.1643	1.0223	1.3260
1945-1954	2.8449	.7535	3.7756	17.1996	0.2575	1148.7
Constant	1.8538	.3411	5.4348			

Interaction was considered between "GradMD" and "Timeperiod" and "GradMD" and "Hospital". In the two logistic regressions involving the two variables and their two-way interaction only "GradMD * Timeperiod" had a goodness-of fit p-value of less than 0.10. Graphing the year of graduation against time showed that although all physicians gradually increased their screening rates over time, older physicians were generally slower to adopt HBsAg screening.

The final model was obtained using forward stepwise logistic regression including main effects variables and the interaction term "GradMD*Timeperiod".

There was a meaningful change in the coefficients when comparing the model with and without "GradMD*timeperiod". The variable timeperiod squared was examined but did not improve the model and was not included in the final model. The final model correctly classified approximately 78% of women.

Table 5.14: Results of stepwise logistic regression with main effects variables and interaction

Variable	Estimated coefficient	Estimated SE	coeff. / SE	$e^{coeff.}$	95% CI Lower	95% CI Upper
Timeperiod	-.1508	.0294	-5.1293			
Hospital						
smallest	referent					
community A	-.3874	.4011	-.9658	0.7	0.5	0.9
teaching A	.6027	.3789	1.5907	1.8	1.2	2.9
community B	-.1001	.4014	-.2494	0.9	0.8	1
teaching B	1.8546	.3710	4.9989	6.4	1.7	24.6
Gestation						
37+ weeks	referent					
34-36	1.0406	.3577	2.9091	2.8	1.4	5.9
< 34 weeks	.6378	.5107	1.2489	1.9	1	3.6
Graduation year of physician						
1985-1989	referent					
1975-1984	1.3695	1.0752	1.2737			
1965-1974	2.5391	1.1407	2.2259			
1955-1964	3.6053	1.4054	2.5653			
1945-1954	5.1167	2.1593	2.3696			
*GRADMD*Timeperiod*						
Int 1	-.0850	.0541	-1.5712			
Int 2	-.1326	.0620	-2.1387			
Int 3	-.2434	.0996	-2.4438			
Int 4	-.1222	.1116	-1.095			
Constant	1.9486	.5284	3.6877			

Women who delivered at the two larger hospitals were more likely to lack HBsAg screening than women who delivered at the smaller community hospital (OR, 1.8; 95% CI, 1.2-2.9) and (OR, 6.4; 95% CI, 1.7-24.6). Women who delivered at 34-36 weeks gestation were almost three times as likely to lack HBsAg screening results when compared to women delivering at term (Table 5.14). Women delivering prematurely at less than 34 weeks gestation also had a higher risk of missing HBsAg results, but this difference was not statistically significant (OR, 1.9; 95% CI 1-3.6). There was interaction between the graduation year of a physician and time. Older physicians increased their rate of HBsAg screening at a slower rate than recent graduates.

E. Hospital Policies on Hepatitis B Screening in Pregnancy:

The head nurse on the labor and delivery ward of each hospital was contacted in early 1996 and again in August 1996 and asked about their hospital's policy regarding screening of pregnant women for HBsAg. Questions were specifically asked about the hospital's policy on women who arrived for delivery without HBsAg results.

1) Hospitals with no policy:

One of the five hospitals did not have a policy on HBsAg screening in pregnant women. The head nurse felt that the screening was being done in the doctor's office. This hospital requested that physicians send in the first part of the antenatal record at around 20 weeks and the second sheet which contains the HBsAg result, at around 32 weeks.

This hospital reported that if a woman arrived at the hospital without HBsAg results it would be recorded as "unknown". Screening might be done if the woman was in a high risk group. The nurse reported that they followed a policy of "universal precautions" suggesting that she misinterpreted the purpose of HBsAg screening in pregnancy. A universal precautions policy is implemented to protect staff from infection with hepatitis B through contact with infectious body fluids. The main purpose of universal screening in pregnancy is to provide protection against hepatitis B to the newborn infant via timely passive and active immunization. This hospital (hospital E) had a screening rate of 74% (95% CI, 63-83%) in 1993-1994.

2) Hospitals with a non-written policy:

Three hospitals reported a verbal or "understood" policy, one teaching and two community hospitals. This non-written policy involves checking the antenatal form when it is submitted by the physician at 34-36 weeks. If HBsAg results are not available on the form then the physician's office is contacted.

At the teaching hospital, if the office was closed at night they would question the woman regarding her exposure history and might order HBsAg if she was in a high risk group. Otherwise they would wait until the doctor's office was open the next morning to obtain the result. If the result could still not be obtained then the physician would be requested to order a HBsAg test. A HBsAg test would not be ordered stat as it increases costs and a routine HBsAg test is usually available within 72 hours through the hospital lab. The nurse reported that the neonatologist felt it was O.K. to give immunoglobulin within 90 hours of delivery, so receiving the test results 72 hours or later was not seen as a problem. In 1993-1994, only 73% (95% CI, 62-82%) of women delivering at this hospital (hospital C) had HBsAg results available.

One community hospital originally reported no policy but subsequently reported that the Society of Gynecologists and Obstetricians of Canada (SOGC) guidelines were followed. Most HBsAg screening is done in the physician's office. A physician's office would be contacted if the result was not available. The approach to a woman admitted for delivery without HBsAg test results would be to record it as "unknown" and to "observe the baby". There was no policy on

stat testing. This hospital (hospital A) had the lowest screening rate of the community hospitals at 86% (95% CI, 67-97%) in 1993-1994.

Another community hospital with a nonwritten policy reported that if antenatal HBsAg test could not be obtained from a physician's office, then the doctor would be expected to order a HBsAg test. There is no policy on doing this test on a stat basis. Approximately 92% (95% CI, 82-97%) of women giving birth at this hospital (hospital D) in 1993-94 had their HBsAg results available prior to the delivery of an infant.

3) Hospitals with a written policy:

Only one hospital has a written policy on HBsAg screening of pregnant women. This policy was instituted after the Health Department memo in March 1990 and was incorporated into the infection control policy manual. The policy stated that all women admitted to the hospital for delivery were to have HBsAg screening. There is approximately 96% physician compliance with sending in the Ontario antenatal record.[60] If a woman is admitted without HBsAg results then a physician would be notified and asked to order a stat HBsAg test. The head nurse also reported some concern in getting stat HBsAg results back promptly in order to provide immmunoprophylaxis to the infant in a timely manner. In this community hospital (hospital B) 96% of women had HBsAg status available in 1993-1994 (95% CI 88-99%).

VI. DISCUSSION:

A. Guidelines Impact on Physician Screening Behavior:

The 1989 NACI recommendations had a major impact on physician hepatitis B screening over time. The proportion of women with antenatal HBsAg status available at the time of delivery increased more than eight-fold in the year following release of the NACI recommendations (42.8%) from a low preguideline rate of five percent. Thereafter overall rates increased by approximately 20% during the second year after the guidelines to 65% in 1990-1991 and to 81% in 1993-1994. There was however little change in in-hospital testing for hepatitis B which remained low over time. As a result, the overall rate of hepatitis B screening in either the antenatal or intrapartum period was still only 83% in 1993-94. The HBsAg screening rate in Ottawa-Carleton in 1994 (83%) was similar to the Netherlands rate in 1992 (84%) and an estimate of the U.S. rate in 1993 (84%).[33,37] All these rates are below the rate of 98% achieved in California in 1991.[33]

The percent compliance with the NACI guidelines is higher than in the review undertaken by Lomas where in all but one of the ten cases, compliance was less than two-thirds of potential (67%).[41] The time between the release of these guidelines and their subsequent evaluation was not stated in the Lomas study. In Ottawa-Carleton, approximately 66% of women had HBsAg results available two years after the NACI recommendations. Evaluation at this point would lead to the conclusion that compliance was also less than two-thirds of

potential. However, by 1993-1994, 83% of women had HBsAg results available leading to a conclusion of moderate compliance with the guidelines. Grilli showed there was a trend toward increased compliance with increased time from guideline release to assessment, but this trend was not significant.[42] This current evaluation of recommendations on hepatitis B screening in pregnancy demonstrated a significant trend in the proportion of women with HBsAg results available over time. Time was an important factor in guideline implementation.

Ordering HBsAg is low on complexity and simply involves adding another test to the prenatal blood work already being requested. Grilli showed that studies low on complexity are more likely to be adopted.[42] In addition the ACOG study showed high compliance among physicians ordering blood tests in pregnancy.[46] They also demonstrated lower compliance with new tests or procedures. Screening for HBsAg was not new in 1989 as it had been recommended on a selective basis prior to this. In fact a space for writing HBsAg results was incorporated into the provincial antenatal record as early as 1987.

If a guideline is simple, low in complexity and likely to be adopted then problems in implementation may relate to other factors in the practice environment. These factors need to be considered and addressed in implementation of the guidelines in order to accelerate the process to attain high compliance at an earlier time. The producers of clinical practice guidelines should assess and address the barriers to timely implementation of their

recommendations. Instructions on the implementation of their recommendations should be an integral part of their original guidelines. Some authors argue that successful implementation of guidelines requires that the emphasis should be equally divided between physician knowledge and awareness of the recommendations and barriers in the practice environment. Such attention "may ease the jump from page to practice and perhaps even provide a bridge."[61]

This current study found that maternal factors such as age, marital status, gravidity and parity were not associated with availability of HBsAg screening results. This is similar to results found in the CDC study.[33] Transfer from one hospital to another was not a significant factor in hepatitis B screening when adjusted for other factors.

The gestational age of the newborn was identified as a risk factor for lacking maternal hepatitis B screening results at birth. Women giving birth to infants at 34-36 weeks were more likely to be missing HBsAg results than women giving birth at term. The influence of gestational age at delivery on availability of HBsAg was not examined by other studies. Women giving birth at less than 37 weeks are less likely to have their antenatal record available as it is usually sent to the hospitals by approximately 36-37 weeks. Women who deliver prematurely are also less likely to have been given a copy of their antenatal record to carry with them.

The timing and number of prenatal visits were not identified as risk factors in the CDC study, but women with no evidence of prenatal care were more likely

to be missing HBsAg screening results. This current study on HBsAg screening in Ottawa-Carleton had no method of reliably determining if a woman lacked prenatal care. A valid determination of the number of antenatal visits that a woman had through pregnancy also proved difficult. As a result lack of prenatal care, and number of antenatal visits were not examined as risk factors.

Women cared for by family doctors were just as likely to be screened for HBsAg as women cared for by obstetricians. The Connecticut hospital study found similar results of no association between the qualification of the prenatal care provider and availability of hepatitis B screening results.[33] In contrast, the Kansas physician study showed that women cared for by family doctors were more likely to lack screening than women cared for by obstetricians. The Kansas survey relied on self-reported screening by questionnaire whereas the Connecticut study involved a less biased review of maternal charts.

The study of physician's compliance with ACOG standards showed that older physicians were significantly less likely than younger physicians to adhere to three of the recommendations.[48] Age of physicians was not identified as a risk factor in the Kansas study.[33] In the current study there was interaction between time and year graduated with older physicians tending to increase their rate of HBsAg screening at a slower rate than more recent graduates.

The CDC study also found that women giving birth at rural hospitals were more likely to be lacking HBsAg. This was not examined in the current study as all the five hospitals are located in a region with a population of 700,000. This

does however have implications for other hospitals in the more rural parts of the province where the screening rates may be lower than those found in Ottawa-Carleton. In fact, a study that measured screening rates at a hospital in a small central Ontario city of 50,000 only reached screening rates of 59% in 1990.[62] This was despite extra efforts applied during the study to screen all women to determine the prevalence of HBsAg carriers in the area.

Availability of HBsAg results increased at all five hospitals over time, but was lower at the larger hospitals than at the smaller community hospitals for every year examined. In the year following the guidelines (1989-1990) availability of HBsAg by hospital ranged from approximately 22% at a large teaching hospital to 71% at a small community hospital. The larger teaching hospitals lagged behind the community hospitals for each study year examined. In 1993-1994, the gap narrowed somewhat with both teaching hospitals having HBsAg results available for approximately 74% of pregnant women while the community hospitals had HBsAg results on 86% to 96% of pregnant women.

The difference between the teaching and the community hospitals cannot be explained by a higher rate of in-hospital screening at the community hospitals. Only seven women had in-hospital testing for HBsAg during the entire study period. Most of the increase over time in availability of HBsAg results was due to an increase in antenatal HBsAg screening in the community. There was very little increase in screening done in hospital even after the Health Department memo in March 1990. In 1994, in-hospital screening increased the coverage of

the maternal population by less than two percent (from 80.8% to 82.6%). In the Netherlands study use of in-hospital screening for women without HBsAg results raised the screening rates by ten percent from 87% to 97%.[35] This demonstrates the importance of in-hospital screening in achieving complete screening coverage of the pregnant population. The population without antenatal HBsAg screening had a higher prevalence of hepatitis B carriers in this current study and in other studies.[36,37] This is likely due to a higher prevalence of risk factors for chronic hepatitis B infection in women with no antenatal care. Failure to screen this population with in-hospital HBsAg testing will result in missing infants who require hepatitis B immunoprophylaxis.

B. The Place of Policy:

Myers and Gleicher showed that putting in place a system that encouraged and facilitated change resulted in a decrease in the cesarean section rate in their hospital.[50] With some foresight NACI did acknowledge in 1989 that "an effective system to transmit information regarding the HBsAg status of a mother should be implemented to ensure that a baby of a HBsAg positive mother will receive appropriate prophylaxis as soon as possible after birth."[9] These systems are still not in place at all hospitals in 1996.

Hospital policies appear to influence the presence of HBsAg status at the time of birth.[33] In this current study, the hospital with a written policy on hepatitis B screening in pregnancy had HBsAg results available on 96% of pregnant

women in 1993-1994 while the hospital with no policy had HBsAg results on 74% of women. At the hospital with a written policy a woman admitted to hospital without HBsAg results would have a stat test. Hospitals with a non-written policy were less firm about the procedure in the same situation and might even apply high risk criteria in their decision to do a HBsAg test. None of these hospitals screened on a stat basis. These findings are supported by the CDC study that women giving birth at hospitals with no policy on HBsAg were almost seven times more likely to be lacking HBsAg results than women giving birth at a hospital with a written policy. In addition, women giving birth at hospitals with a nonwritten or verbal policy were still twice as likely to be missing HBsAg results as those giving birth at a hospital with a written policy.

In setting a policy, hospitals highlight the importance of an issue to staff. In planning a policy, the barriers to obtaining the desired outcome are considered. Thus a system can be established to ensure that the final outcomes of both HBsAg availability on all pregnant women and immunoprophylaxis of at-risk infants can be achieved. Establishing a policy that involves calling physicians if HBsAg results are not on the submitted antenatal record reinforces screening behavior. It also provides a way of reaching physicians that are unaware of the screening requirements or slow to adopt them. Such an approach does not leave the physician as solely responsible for implementation of the guidelines but provides a supportive environment that enables and reinforces adoption of the guideline. Hospitals are an ideal place to establish

such a system. Both the pregnant population and the providers that care for them are a captive population that have contact with the hospital system. Setting up a system in the hospital that increased awareness, reinforced screening behavior and screened women without HBsAg results, may have achieved higher rates of HBsAg screening earlier.

All hospitals need to adopt a written policy on hepatitis B screening that outlines the importance of having the HBsAg results available prior to the birth of an infant. Hospitals should be alert to the difficulties in obtaining the antenatal screening results on women who deliver prematurely. This problem can be solved if timely in-hospital screening of women without HBsAg results is adopted. With shorter hospital stays, in-hospital screening will have to be timely if an infant is to be vaccinated prior to discharge. One hospital reported that results from routine HBsAg testing at their laboratory can usually be received in 72 hours. Yet many women are discharged home at 24-36 hours after the birth of an infant. Rapid reporting of HBsAg tests is therefore necessary. Timely screening also allows for the administration of hepatitis B immune globulin at birth, as its efficacy decreases sharply after 48 hours.[12] The Public Health Laboratory runs HBsAg tests several times a day. Stat HBsAg testing can be available on the same day.[63]

Having the maternal HBsAg status available at the time of an infant's birth is only one step in the process of preventing perinatal transmission of HBV. An infant of an identified HBV carrier must receive timely immunoprophylaxis. In the

CDC study of a sample of births from 183 hospitals in the U.S., not all infants received the correct immunoprophylaxis at birth and some received no hepatitis B immune globulin or vaccine. The lack of availability of maternal HBsAg results in the delivery room record has been associated with inadequate immunoprophylaxis of infants born to HBsAg-positive mothers.[64] This current study did not examine the immunoprophylaxis of the eight infants born to hepatitis B carrier mothers.

C. Strengths and Weaknesses of the Study:

This study used a simple interrupted time series design to examine the impact of the guidelines for universal prenatal hepatitis B screening. As these guidelines are national and widely disseminated it was impossible to examine HBsAg screening rates over time in a control population not exposed to the recommendations. This study made use of chart reviews and took measurements both before and after the guidelines as recommended by Lomas when evaluating the impact of guidelines.[65] This study also assessed the availability of HBsAg at the crucial time of giving birth rather than measuring the rates of HBsAg screening in physician's offices. Looking at screening in physician's offices would have reliably measured the rate of antenatal screening in the community but this may have overestimated the proportion of women with HBsAg results available at the hospital at the time of an infant's birth.

It is difficult using this design to control for other factors unrelated to the guidelines (e.g. continuing medical education) that may have increased the HBsAg screening rate. As time goes on it becomes more difficult to attribute the increase in the rates to the 1988-1989 NACI guidelines release due to intervening factors. For example a hospital's adoption of a policy on prenatal HBsAg screening may impact on the screening rates at that hospital if more pressure is applied to the physicians that admit to that hospital to screen for HBsAg. In this case a physician's increased screening could not be attributed solely to the NACI guidelines.

VII. CONCLUSION:

NACI guidelines did have a major impact on physician's screening for hepatitis B over time. However in 1993-1994, there still remained approximately 17% of the maternal population without HBsAg results available at the time of the birth of their infant. It is unlikely that screening rates have changed much since 1994 as several of the hospitals still have no written policy on screening and in particular no policy on in-hospital screening in 1996. The solution lies in establishing a system that promotes high rates of antenatal screening; makes available the HBsAg results at the time of birth and ensures in-hospital testing of those women admitted without HBsAg results.

VIII. RECOMMENDATIONS

1. Hospitals should hold an in-service on hepatitis B for nursing and medical staff to increase awareness of the risks of perinatal transmission and the importance of timely immunoprophylaxis of the infants of carrier mothers.

2. Hospitals should examine their system for obtaining the Ontario antenatal record and for ensuring that the antenatal HBsAg screening result is on the antenatal record. Women admitted without HBsAg results should be screened with a stat test to ensure that results are available prior to the discharge of the mother and infant.

3. All hospitals should outline in a written policy their system for ensuring HBsAg is available on all women. This policy should define the routine and the personnel responsible for the routine. The written policy should include the procedures and time line for immunoprophylaxis of newborns so that infants are given hepatitis B immune globulin immediately following birth and the vaccine series started as soon as possible.

4. Developers of guidelines should consider barriers in implementation of their recommendations and acknowledge them in their original guideline. Practical suggestions on how to address these barriers and achieve timely compliance with the recommendations should be outlined by the guideline producers.

REFERENCES

1. Chassin MR, Brook RH, Park RE et al. Variations in the use of medical and surgical procedures by the Medicare population. N Engl J Med 1986;314:285-290.

2. National Academy of Sciences, Institute of Medicine: Clinical Practice Guidelines: directions for a new program, Natl Acad Pr, Washington, 1990.

3. Dr. Anne Carter. Canadian Medical Association, personal communication 1996.

4. Field MJ, Lohr KN (eds). Guidelines for clinical practice: from development to use. Committee on Clinical Practice Guidelines, Division of Health Care Services, Institute of Medicine, Natl Acad Pr, Washington, 1992:4.

5. Kosecoff J, Kanouse DE, Rogers WH, McCloskey, Winslow CM, Brook RH. Effects of the National Institute of Health Consensus Development Program on physican practice. JAMA 1987;258:2708-2713.

6. Lomas J, Enkin M, Anderson GM, Hannah WJ, Vatda E, Singer J. Opinion leader vs audit and feedback to implement practice guidelines. JAMA 1991;265:2202-2207.

7. Lomas J, Anderson GM, Domnick-Pierre K, Vayda E, Enkin MW, Hannah WJ. Do practice guidelines guide practice? the effect of a consensus statement on the practice of physicians. New Engl J Med 1989;321:1306-1311.

8. Cohen MC, Roos NP, MacWillian L, Wajda A. Assessing physicians' compliance with guidelines for Papanicolaou testing. Med Care 1992;30:514-528.

9. National Advisory Committee on Immunization. Canadian Immunization Guide Third Edition. Health and Welfare Canada, 1989.

10. Jonas MM, Schiff ER, O'Sullivan MJ, DeMedina M, Reddy KR, Jeffers LJ. Failure of Centers for Disease Control criteria to identify hepatitis B infection in a large municipal obstetrical population. Ann Intern Med 1987;107:335-337.

11. Kumar ML, Dawson NV, McCullough AJ, Radivoyevitch M, King KC, Hertz R et al. Should all pregnant women be screened for hepatitis B? Ann Intern Med 1987;107:273-277.

12. National Advisory Committee on Immunization. Canadian Immunization Guide Fourth Edition. Health Canada 1993.

13. Report of the Hepatitis B Working Group. CCDR 1994;20:105-112.

14. Margolis HS, Coleman PJ, Brown RE, Mast EE, Shangold SH et al. Prevention of hepatitis B virus transmission by immunization. JAMA 1995; 274:1201-1208.

15. Immunization Practices Advisory Committee. Recommendations for protection against viral hepatitis. MMWR 1985;34:313-315.

16. Beasley PR, Trepo C, Stevens CE, Szmuness W. The e antigen and vertical transmission of hepatitis B surface antigen. Am J Epidemiol 1977;105:94-98.

17. Sinatra F, Shah P, Weissman JY, Thomas DW, Merritt RJ, Tong MJ. Perinatal transmitted acute icteric hepatitis B in infants born to hepatitis B surface antigen positive and anti-hepatitis Be-positive carrier mothers. Pediatrics 1982;70:557-559.

18. Beasley RP, Hwang LY. Epidemiology of hepatocellular carcinoma. In: Vyasn GN, Dienstag JL, Hoofnagle JH, eds. Viral hepatitis and liver disease. Orlando, Florida:Grune and Stratton, 1984: 209-224.

19. Carter AD, Walsh P. Hepatitis B in Canada: surveillance summary 1980-1989. CDWR 1991;17:166-72.

20. Alter MJ, Hadler SC, Margolis HS, Alexander JW, Yahu P, Judson FN. The changing epidemiology of hepatitis B in the United States: need for alternate vaccination strategies. JAMA 1990;263:1218-1222.

21. Infectious Diseases and Immunization Committee, Canadian Pediatric Society. Hepatitis B in Canada: the case for universal immunization. Can Med Assoc J 1992;146:25-28.

22. Beasley RP, Hwang LY, Lee GCY, Lan CC, Roan CH, Huang FY. Prevention of perinatally transmitted hepatitis B virus infections with hepatitis B immune globulin and hepatitis B vaccine. Lancet 1983;ii:1099-1102.

23. National Advisory Committee on Immunization. A Guide to Immunization for Canadians, second edition. Health and Welfare Canada, 1984.

24. Okun NB, Bryce Larke RP, Waters JR, Joffres MR. Success of a program of routine prenatal screening for hepatitis B surface antigen: the first 2 years. Can Med Assoc J 1990;143:1317-1321.

25. Sekla LH, Hammond G, Stackiw W, Eibischg G, Fast M. Testing pregnant women for hepatitis B surface antigen:a pilot study in Manitoba. CDWR 1988;14:137-140.

26. National Advisory Committee on Immunization. Statement on immunizing agents for the prevention of viral hepatitis. CDWR 1987;13:99-107.

27. Arevalo JS, Washington AE. Cost-effectiveness of prenatal screening and immunization for hepatitis B vaccine. JAMA 1988;259:365-369.

28. Prevention of perinatal transmission of hepatitis B virus: prenatal screening of all pregnant women for hepatitis B surface antigen. MMWR 1988;37:341-346,351.

29. Chernesky MA, Blajchman MA, Castriciano S, Basbaum J, Spiak C, Mahony JB. Analysis of a pregnancy-screening and neonatal immunization program for hepatitis B in Hamilton, Ontario, Canada, 1977-1988. J Med Vir 1991;35:50-54.

30. Universal prenatal screening for hepatitis B, Alberta 1985-1988. CDWR 1989;15:29-32.

31. Immunization Practices Advisory Committee. Prevention of perinatal transmission of hepatitis B virus: prenatal screening of all pregnant women for hepatitis B surface antigen. MMWR 1988;37:341-346.

32. Guidelines for hepatitis B virus screening and vaccination during pregnancy. ACOG committee opinion no 78, January 1990.

33. CDC. Maternal hepatitis B screening practices - California, Connecticut, Kansas, and United States, 1992-1993. MMWR 1994;43:311,317-320.

34. Eng Tr, Borges ML, Harlin VK, Kobayashi JM. Screening for hepatitis B during pregnancy: awareness of current recommendations among Washington hospitals. West J Med 1991;155:613-615.

35. Grosheide PM, Klokman-Houweling JM, Conyn-van Spaendonck MAE, and the National Hepatitis B Steering Committee. Programme for preventing perinatal hepatitis B infection through screening of pregnant women and immunisation of infants of infected mothers in the Netherlands, 1989-92. BMJ 1995;311:1200-1202.

36. Silverman NS, Darby MJ, Ronkin SL, Wapner RJ. Hepatitis B prevalence in an unregistered prenatal population. JAMA 1991;266;2852-2855.

37. Grosheide PM, Wladimiroff JW, Heijtink RA, Mazel JA, Christiaens GCML, Nuijten ASM et al. Proposal for routine antenatal screening at 14 weeks for hepatitis B surface antigen. BMJ 1995; 311:1197-1199.

38. Rogers E. The diffusion of innovation. New York: The Free Press 1983.

39. Chen DS, Hsu NH, Sung JL. A mass vaccination program in Taiwan against hepatitis B virus infection in infants of hepatitis B surface antigen-carrier mothers. JAMA 1987; 257:2597.

40. Stroffolini T, Pasquini P, Mele A, and Collaborating Group for Vaccination against Hepatitis B in Italy. A nationwide vaccination programme in Italy against hepatitis B virus infection in infants of hepatitis B surface antigen carrier mothers. Vaccine 1989;7:152-154.

41. Lomas J. Words without action? The production, dissemination, and impact of consensus recommendations. Annu Rev Publ Health 1991;12:41-65.

42. Grilli R, Lomas J. Evaluating the message: the relationship between compliance rate and the subject of a practice guideline. Med Care 1994;32:202-213.

43. Lomas J. Teaching old (and not so old) Docs new tricks: effective ways to implement research findings. In: Dunn EV, Norton PG, Stewart M, Tudiver F, Bass MJ, eds. Disseminating Research/Changing Practice. Thousand Oaks, California: sage publications, 1994 p.9.

44. Dietrich AJ. External support can change primary care practice patterns. In: Dunn EV, Norton PG, Stewart M, Tudiver F, Bass MJ, eds. Disseminating Research/Changing Practice. Thousand Oaks, California: sage publications, 1994 p.177.

45. Standards for obstetric-gynecologic services. 1st ed. Chicago: American College of Obstetricians and Gynecologists, 1959.

46. Gibbs RS, McGregor JA, Mead PB, Eschenbach DA, Hager WD, Sweet RL. A survey of practices in infectious diseases by obstetrician - gynecologists. Obstet. Gynecol 1994;83:631-6.

47. Jafari HS, Schuchat A, Hilsdon R, Whitney CG, Toomey KE, Wenger JD. Barriers to prevention of perinatal group B streptococcal disease. Pediatr Infect Dis J 1995;14:662-667.

48. Baldwin LM, Raine T, Jenkins LD, Hart LG, Rosenblatt R. Do providers adhere to ACOG standards? The case of prenatal care. Obstet Gynecol 1994;84:549-556.

49. Eskeland B, Malterud K. Iron supplementation in pregnancy. General practitioners compliance with official recommendations. Scand J Primary Health Care 1993;11:263-266.

50. Myers SA, Gleicher NA. A successful program to lower Cesarean-section rates. N Engl J Med 1988; 319:1511-1516.

51. Coleman JS, Katz E, Menzel H. Medical Innovation: a diffusion study. Indianapolis: Bobbs-Merrill, 1966.

52. National Advisory Committee on Immunization. Canadian Immunization Guide. CDWR 1989;15:85-87.

53. National Advisory Committee on Immunization. Canadian Immunization Guide. Can Med Assoc J;141:227-228.

54. Statistics Canada. Standard Occupational Classification 1980. Minister of Supply and Services 1981, p.11.

55. Lwanga S.K., Lemeshow S. Sample size determination in health studies: a practical manual. Geneva, World Health Organization, 1991.

56. Dr. Margaret Fearon. Ontario Ministry of Health, personal communication 1994.

57. Hosmer DW, Lemeshow. Applied Logistic Regression, New York, John Wiley and Sons,1989,p. 86.

58. Statistics Canada. Canadian families: diversity and change. The Daily June 19, 1996.

59. Chee Wong. Ontario Ministry of Health, personal communication, 1996.

60. R. Benwell. personal communication, 1996.

61. Dietrich AJ. External support can change primary care practice patterns. In: Dunn EV, Norton PG, Stewart M, Tudiver F, Bass MJ, eds. Disseminating Research/Changing Practice. Thousand Oaks, California: sage publications, 1994 p.183.

62. Morris BAP, Sabetti L. Prenatal screening for hepatitis B surface antigen: is universal screening necessary? Can Fam Physician 1993;39:61-64.

63. Dr. Kasatiya. Ottawa Public Health Laboratory. personal communication, 1996.

64. Birnbaum JM, Bromberg K. Evaluation of prophylaxis against hepatitis B in a large municipal hospital. Am J Infect Control 1992;20:172-176.

65. Lomas J, Words without action? The production, dissemination and impact of consensus recommendations. Annu. Rev. Publ. Health 1991;12:41-65.

Appendix A: Data Collection Form

Chart number _____

Time period _____

Hospital _____

Discharge date (d/m/y) _____

Transferred Yes _____ No _____

Physician

Attending _____

Family _____

Antenatal care _____

Age or birthdate _____

Marital status
M _____
D _____
S _____
CL _____
Sep _____
NA _____

Postal code _____

Occupation _____

Employed _____

G____ P____ A____

LNMP (d/m/y) _____

Antenatal visits _____

First visit (d/m/y) _____ Gest. age (weeks) _____

Last visit (d/m/y) _____ Gest. age (weeks) _____

Hepatitis B status (HBsAg):

Antenatal record: Yes ____ No _____ Not Available _____

Chart (stat): Yes ____ No _____ Not Applicable _____

Result HBsAG: Pos ____ Neg _____ Not Available _____ Immune ____

Gestation at birth (weeks) _____

Delivery type _____

Appendix B: Data Abstractor Instructions

HOSPITAL A INSTRUCTION SHEET

Take the information from the chart starting with number 1. If it is not available go to option number 2, etc. If you have questions put the charts aside and call me at work at 724-4122 ext 3531 or home 798-1861.

write "?" if this is what is indicated on the record.
write "0" if the data is not available.
write "-" if this is what is on the record.

Chart number - take this from the master list and pull the chart

Time period - take this from the master list

Hospital - hospital where baby is delivered

Discharge date (d/m/y) -1. summary sheet - **check this agrees with the time period**
2. discharge summary-if written date of discharge.
3. admission date plus length of stay.

Transferred - on demographic sheet/pink medical file sheet

Physician

Attending - 1. on demographic sheet/pink medical file sheet
2. on addressogram

Family - 1. demographic sheet/medical file sheet
2. Antenatal Record

Obs care - 1. Antenatal Record (check page 1 and 2)
2. Obstetric Record/protocol- Family Pract/Obstetrician (indicate if taken off Obstetric Record)

Age or birthdate - 1. demographic sheet/medical file sheet (if age not indicated record birthdate).
2. obstetrical admission sheet
3. addressogram
4. discharge summary

Marital status - 1. demographic sheet/pink medical file sheet
2. addressogram
3. Antenatal Record

Postal code - 1. demographic sheet/pink medical file sheet
2. addressogram

Occupation - 1. Antenatal Record
2. demographic sheet/pink medical file sheet

Employed - 1. Antenatal Record
2. demographic sheet/pink medical file sheet (employer)

G (total number of pregnancies including this one)
P (number of deliveries)
A (number of abortions)

1. Antenatal Record
2. Obstetric Protocol
3. Obstetrical Admission
4. Discharge summary

HOSPITAL B INSTRUCTION SHEET

Take the information from the chart starting with number 1. If it is not available go to option number 2, etc. If you have questions put the charts aside and call me at work at 724-4122 ext 3531 or home 798-1861.

write **"?"** if this is what is indicated on the record.
write **"0"** if the data is not available.
write **"-"** if this is what is on the record.

Chart number - take this from the master list and pull the chart

Time period - take this from the master list

Hospital - hospital where baby is delivered

Discharge date (d/m/y) - 1. on the first page of chart- **check this agrees with the time period**
2. discharge summary- if written date of discharge
3. admission date plus length of stay

Transferred - on cover sheet-arrived from /by

Physician

Attending - 1. on cover sheet or
2. on addressogram

Family - 1. cover sheet or
2. Antenatal Record

Obs care - 1. Antenatal Record (check page 1 and 2)
2. Obstetrical record- (indicate if taken off Obsterical Record (OR))

Age or birthdate - 1. cover sheet (if age not indicated record birthdate)
2. Obstetrical Record
3. addressogram
4. discharge summary

Marital status - 1. cover sheet
2. addressogram
3. Antenatal Record

Postal code - 1. cover sheet or
2. addressogram

Occupation - 1. Antenatal Record or
2. Nurses Obstetric history

Employed - 1. Antenatal Record
2. Nurses Obstetric history

G (total number pregnancies including this one)
P (number of deliveries)
A (number of abortions)

1. Antenatal Record or
2. Obstetrical/labor record
3. Discharge summary

LNMP (d/m/y) - 1. Antenatal Record or
2. Obstetric/Labor Record

 # Antenatal visits - Antenatal Record

First/last visit (d/m/y) - check first visit on bottom of page one

Gest. age (weeks) - (in 1988 G-age is right after date of visit)

Hepatitis B status (HBsAg)

Antenatal record: check all over page 2

Chart (stat): - if not on above check both Physicians orders **and** lab tests

Result HBsAG: - from either of above

Gestation at birth (weeks) - 1. Obstetrical Record/Labor Record or
2. Discharge summary
3. Prenatal Record-clinical presentation

Delivery type - 1. Labor Record - delivery data or
2. Discharge Summary or
3. cover sheet summary

HOSPITAL C INSTRUCTION SHEET

Take the information from the chart starting with number 1. If it is not available go to option number 2, etc. If you have questions put the charts aside and call me at work at 724-4122 ext 3531 or home 798-1861.

write **"?"** if this is what is indicated on the record.
write **"0"** if the data is not available.
write "-" if this is what is on the record.

Chart number - take this from the master list and pull the chart

Time period - take this from the master list

Hospital - hospital where baby is delivered

Discharge date (d/m/y) - 1. from the Hospital Admission Report- **check this agrees with the time period**
2. discharge summary -if written date of discharge
3. admission date plus length of stay

Transferred - on Hospital Admission Report sheet

Physician

Attending - 1. on Hospital Admission Report sheet
2. on addressogram

Family - 1. Hospital Admission Report or if not available
2. Antenatal Record

Obs care - 1. Antenatal Record (check page 1 and 2)
2. Obstetric Record- Family Pract/Obstetrician (indicate if taken off Obstetric Record)

Age or birthdate - 1. Hospital Admission Report
2. Obstetric record
3. addressogram
4. discharge summary

Marital status - 1. Hospital Admission Record or
2. addressogram
3. Antenatal Record

Postal code - 1. Hospital Admission Record
2. addressogram

Occupation - 1. Antenatal Record or
2. Obstetric Record

Employed - 1. Antenatal Record
2. Obstetric Record

G (total number of pregnancies including this one)
P (number of deliveries)
A (number of abortions)

1. Antenatal Record or
2. Obstetric Record or
3. Labor and Delivery or
4. discharge summary

LNMP (d/m/y) - 1. Antenatal Record or
2. Obstetric Record

 # Antenatal visits - Antenatal Record

First/last visit (d/m/y) - check first visit on bottom of page one

Gest. age (weeks) - (in 1988 G-age is right after date of visit)

Hepatitis B status

Antenatal record: check all over page 2

Chart (stat): - if not on above check both Physicians orders and lab tests

Result HBsAG: - from either of above

Gestation at birth (weeks) - 1. Obstetric Record or
2. Discharge summary
3. Hospital Admission Record

Delivery type - 1. Labor and Delivery Summary or
2. Discharge summary or
3. Hospital Admission Record summary

HOSPITAL D INSTRUCTION SHEET

Take the information from the chart starting with number 1. If it is not available go to option number 2, etc. If you have questions put the charts aside and call me at work at 724-4122 ext 3531 or home 798-1861.

write "?" if this is what is indicated on the record.
write "0" if the data is not available.
write "-" if this is what is on the record.

Chart number - take this from the master list and pull the chart

Time period - take this from the master list

Hospital - hospital where baby is delivered

Discharge date (d/m/y) - 1. on the first page of chart- **check this agrees with the time period**
2. discharge summary -if written date of discharge
3. admission date plus length of stay

Transferred - on Health Record sheet

Physician

Attending - 1. on Health Record sheet
2. on addressogram

Family - 1. Health Record sheet
2. Antenatal Record

Obs care - 1. Antenatal Record (check page 1 and 2)
2. Obstetrical Record- Family Pract/Obstetrician
(indicate if taken off Obstetric Record)

Age or birthdate - 1. Health Record sheet
2. Obstetrical record
3. addressogram
4. discharge summary

Marital status - 1. Health Record sheet or
2. addressogram
3. Antenatal Record

Postal code - 1. Health Record sheet
2. addressogram

Occupation - 1. Antenatal Record or
2. Nurses History (occupation)
3. Health Record sheet

Employed - 1. Antenatal Record
2. Health Record sheet (record employer)

G (total number of pregnancies including this one)
P (number of deliveries)
A (number of abortions)

1. Antenatal Record or
2. Obstetrical Record or
3. Nurse's history or
4. discharge summary

LNMP (d/m/y) - 1. Antenatal Record or
2. Obstetric Record

 # Antenatal visits - Antenatal Record

First/last visit (d/m/y) - check first visit on bottom of page one

Gest. age (weeks) - (in 1988 G-age is right after date of visit)

Hepatitis B status

Antenatal record: check all over page 2

Chart (stat): - if not on above check both Physicians orders **and** lab tests

Result HBsAG: - from either of above
check obstetrical record

Gestation at birth (weeks) - 1. Obstetrical Record or
2. Discharge summary (first page summary)
3. Nurses history

Delivery type - 1. Obstetrical record
2. Discharge summary (first page summary)

HOSPITAL E INSTRUCTION SHEET

Take the information from the chart starting with number 1. If it is not available go to option number 2, etc. If you have questions put the charts aside and call me at work at 724-4122 ext 3531 or home 798-1861.

write **"?"** if this is what is indicated on the record.
write **"0"** if the data is not available.
write **"-"** if this is what is on the record.

Chart number - take this from the master list and pull the chart

Time period - take this from the master list

Hospital - hospital where baby is delivered

Discharge date (d/m/y) - 1. from the front sheet (Control Record) - **check this agrees with the time period**
2. Summary sheet
3. discharge summary -if written date of discharge
4. admission date plus length of stay

Transferred - on Delivery Record "transferring hospital"

Physician

Attending - 1. on Summary sheet
2. on addressogram

Family - 1. Hospital Admission Report
2. Antenatal Record

Obs care - 1. Antenatal Record (check page 1 and 2)
2. Delivery Record "antepartum physician"
3. Gynecology Observation Record (front of chart-orange stripe)

Age or birthdate - 1. Summary sheet
2. Labor to Recovery flowsheet
3. addressogram
4. discharge summary

Marital status - 1. Summary sheet
2. Labor to Recovery flowsheet
3. Antenatal Record

Postal code - 1. Summary sheet
2. addressogram

Occupation - 1. Antenatal Record
2. Labor to Recovery flowsheet
3. Clinical History and Physical exam

Employed - 1. Antenatal Record
2. Labor to Recovery flowsheet
3. Clinical History and Physical exam

G (total number of pregnancies including this one)
P (number of deliveries)
A (number of abortions)

1. Antenatal Record or
2. Labor to Recovery flowsheet
3. Delivery record,
4. discharge summary

LNMP (d/m/y) - 1. Antenatal Record or
2. Delivery Record

 # Antenatal visits - Antenatal Record
ALSO LOOK GYN OBSERVATION RECORD

First/last visit (d/m/y) - check first visit on bottom of page one

Gest. age (weeks) - (in 1988 G-age is right after date of visit)

Hepatitis B status

Antenatal record: check all over page 2

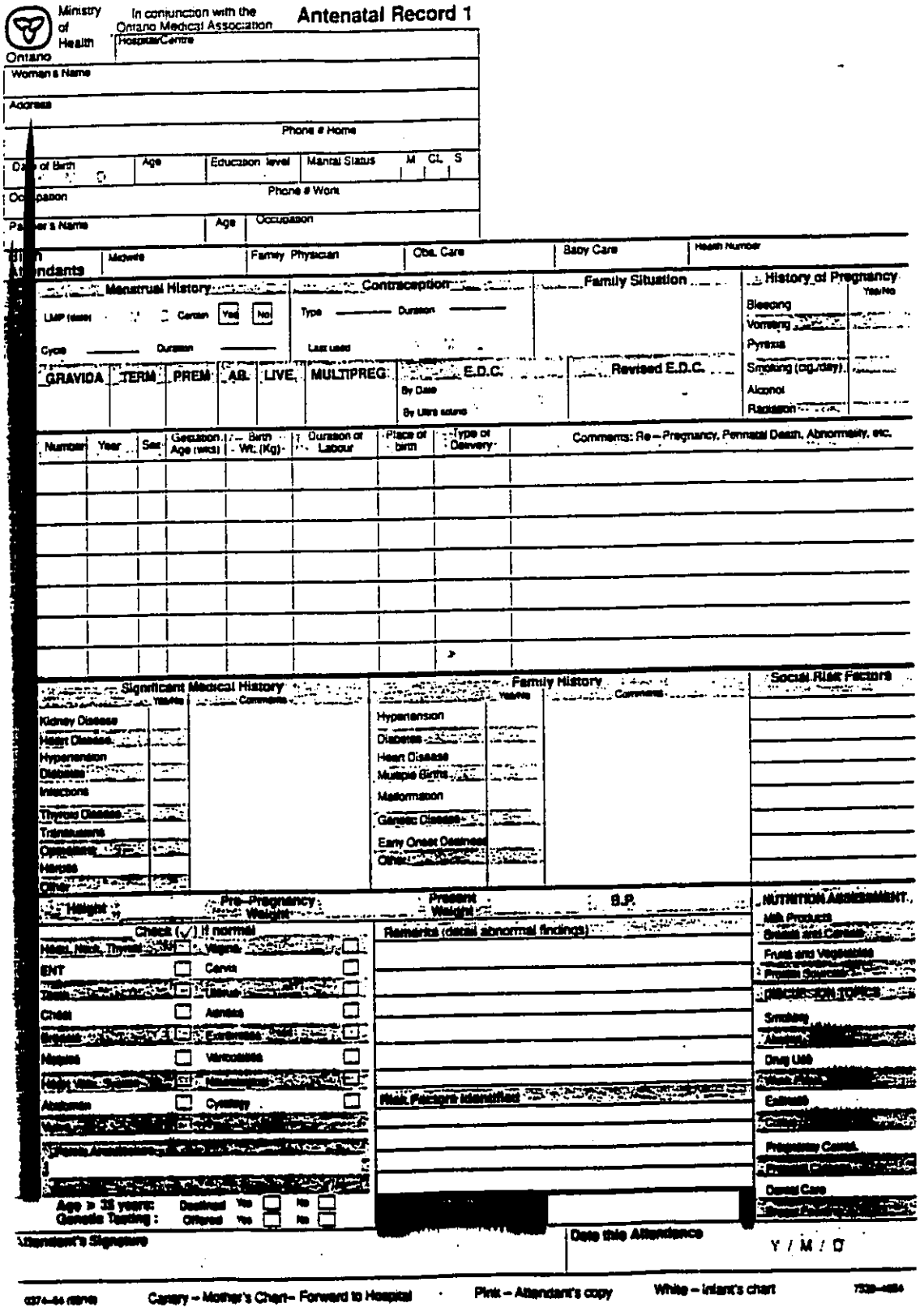
Chart (stat): - if not on above check both Physicians orders **and** lab tests

Result HBsAG: - from either of above
also check clinical History and Physical Exam

Gestation at birth (weeks) - 1. Delivery Record
2. Discharge summary or summary sheet
3. Clinical History and Physical Exam

Delivery type - 1. Delivery Record
2. Discharge summary or summary sheet

Appendix C: Antenatal Record



Ministry of Health Ontario

In conjunction with the Ontario Medical Association

Antenatal Record 1

Hospital/Centre

Woman's Name

Address

Phone # Home

Date of Birth | Age | Education level | Marital Status M CL S

Occupation | Phone # Work

Partner's Name | Age | Occupation

Birth Attendants: Midwife | Family Physician | Obs. Care | Baby Care | Health Number

Menstrual History

LMP (date) Certain Yes No

Cycle Duration

Contraception

Type Duration

Last used

Family Situation

History of Pregnancy

	Yes/No
Bleeding	
Vomiting	
Pyrexia	
Smoking (cig./day)	
Alcohol	
Radiation	

GRAVIDA	TERM	PREM	AB.	LIVE	MULTIPREG

E.D.C. By Date By Ultrasound

Revised E.D.C.

Number	Year	Sex	Gestation Age (wks)	Birth Wt. (Kg)	Duration of Labour	Place of birth	Type of Delivery	Comments: Re – Pregnancy, Perinatal Death, Abnormality, etc.

Significant Medical History

	Yes/No	Comments
Kidney Disease		
Heart Disease		
Hypertension		
Diabetes		
Infections		
Thyroid Disease		
Transfusions		
Operations		
Hernias		
Other		

Family History

	Yes/No	Comments
Hypertension		
Diabetes		
Heart Disease		
Multiple Births		
Malformation		
Genetic Disease		
Early Onset Deafness		
Other		

Social Risk Factors

Height | Pre-Pregnancy Weight | Present Weight | B.P.

NUTRITION ASSESSMENT

Milk Products

Breads and Cereals

Fruits and Vegetables

Protein Sources

PRESCRIPTION TOPICS

Smoking

Alcohol

Drug Use

Work Place

Exercise

Coitus

Pregnancy Course

Prenatal Classes

Dental Care

Check (✓) if normal

Head, Neck, Thyroid		Vagina	
ENT		Cervix	
Teeth		Uterus	
Chest		Adnexa	
Breasts		Extremities	
Nipples		Varicosities	
Heart, Vein, Spleen		Neurological	
Abdomen		Cystocy	
Pelvis			
Pelvic Measurements			

Age ≥ 35 years: Declined Yes No

Genetic Testing: Offered Yes No

Remarks (detail abnormal findings)

Risk Factors Identified

Attendant's Signature

Date this Attendance Y / M / D

Canary – Mother's Chart– Forward to Hospital · Pink – Attendant's copy White – Infant's chart

Ministry of Health
Ontario

In conjunction with the Ontario Medical Association

Antenatal Record 2

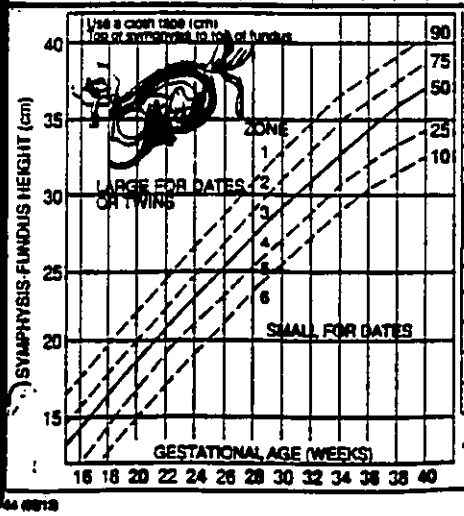
Woman's Name

Address

Birth Attendants

RISK FACTORS, ALLERGIES, MEDICATIONS - specified at Initial Visit

Date	WT. (lb./K).	G-Age Wt.	S–F HT.	Presn Posn.	FH	Urine Pr	Urine Gl	B.P.	Risk Ass.	Comments: (other lab. medications etc.)



Ultrasound and Abnormal Laboratory Results

Additional Comments:

REFERRAL PLAN	DISCUSSION TOPICS
Public Health Nurse	Nutrition
	Diet
Dietitian	Rest
	Travel
Social Worker	Presn. Labour
	Breast Care
	Fetal Movement Counts
	V.B.A.C.
	Birth Plan
	Pain Relief
	Type of Delivery
	Labour Support
	Breast Feeding
	Room-in
	Circumcision
	Baby Belongings
	R.P.S.P.
	Car Safety

Measure symphysis-fundus height at each antenatal visit., and record on graph opposite

Attendant's Signature: