

DEVELOPMENT OF A SIMPLIFIED PERINATAL CLINICAL RECORD¹

Introduction

The bulk of the health work devoted to providing perinatal services in the Americas and around the world consists of primary care. In countries with organized health care systems, the primary care component of that system carries out this function in a generally satisfactory manner. However, in countries lacking health system organization and resources, primary perinatal care is often inappropriate. This deficiency in the primary care services results in part from the fact that many high-risk mothers and children remain at the primary care level (or even outside the health system altogether) and thus do not receive the necessary services—because of failure to recognize their needs, or to make the indicated referral, or to accommodate them at the next higher level of care. Fortunately, this problem is gradually diminishing in the Americas due to various innovations—including the organization of perinatal care services according to their levels of complexity, use of a risk-identification approach, and gradual incorporation of home births into the institutional system.

With the intention of contributing to this trend, and to the goal of “health for all by the year 2000,” the PAHO/WHO Latin American Center for Perinatology and Human Development in Montevideo, Uruguay, has been working on a series of appropriate technological innovations and has developed a form for use in obtaining a simplified perinatal clinical record (SPCR).

This easy-to-use, low-cost record form succeeds in bringing together on one page easily-obtainable data constituting the minimum information needed to provide adequate perinatal care. The SPCR is specifically intended for use in health centers that are unable to complete the more complex and detailed Perinatal Clinical Record (PCR) that is used widely in the Americas and was also created at the perinatology center.² It should be noted that the data codifications used in the PCR and SPCR are similar, and that while the two are generally used in different clinical settings, the PCR and SPCR are compatible for use in the same data bank.

The SPCR, which is designed for use with a risk-identification approach, employs bright yellow “warning” areas to highlight data pointing to increased perinatal risk. The form consists of two attached pages, one to be filled in and the other, below it, to serve as a

¹ By Ricardo Schwarcz, Angel Gonzalo Díaz, Ricardo H. Fescina, José L. Díaz Rossello, Miguel Martell, and Simón M. Tenzer of the PAHO/WHO Latin American Center for Perinatology and Human Development in Montevideo, Uruguay. Also published in Spanish in the *Boletín de la Oficina Sanitaria Panamericana*, 95(2), 1983.

² See J. M. Belizán, A. G. Díaz, H. Giacomini, R. Horcher, M. Martell, P. Quaranta, and R. Schwarcz, *Historia clínica perinatal: Propuesta de un modelo*; Ministerio de Bienestar Social, Secretaría de Estado de Salud Pública de Argentina, Dirección Nacional de Maternidad e Infancia, Centro Latinoamericano de Administración Médica; Buenos Aires, 1976.

copy that can be sent to a processing center for perinatal data—thereby providing a basis for analyzing the collected information.

Aims

In general, the SPCR was designed to do the following:

- 1) provide a basis for planning the care of a pregnant woman and her child, and facilitate provision of basic primary-care perinatal services;
- 2) standardize and unify data collection;
- 3) help health care personnel follow sound guidelines for the care of pregnant women and newborns;
- 4) facilitate supervision of primary maternal and child health care centers;
- 5) help with the training of health care personnel;
- 6) provide relevant perinatal statistics on the population served to authorities planning health programs;
- 7) compile a register of basic perinatal data for research and analysis; and
- 8) compile a register of legally relevant information.

Some SPCR Features

All the information to be collected on the perinatal process has been condensed onto one 8½" × 11" page (27.5 × 21.5 cm). An item-by-item instruction manual is provided for use with the SPCR, and this helps to ensure uniformity in recording data. The two attached sheets that comprise the SPCR are separated only when the perinatal case in question has ended, the lower sheet being an encoded duplicate of the upper.

The First (Upper) Page

Relevant personal information about the patient, obstetric data (on the pregnancy, delivery, and puerperium), and neonatal data are entered on this page in a uniform manner. The page consists of a series of modules with lists of questions, almost all of which can be answered in a multiple-choice fashion, and is laid out so as to encourage systematic gathering of information at the appropriate time (see Annex 1). The above-mentioned instruction manual provides guidelines for uniform recording of data.

At the top of the page are spaces for recording the patient's name, address, age, marital status, literacy, and years of education. These are followed by a section requesting basic personal, family, and obstetric information about the patient—information that can be of great importance in reaching a sound prognosis of the current pregnancy.

The next section, on the current pregnancy, contains spaces for entering basic data (the patient's height, weight, blood group, date of last menstrual period, smoking status, immunization with tetanus toxoid, hospitalization, and referral) together with the results of V.D.R.L., clinical, dental, cervical, and breast examinations. In addition, the section requests laboratory and other data that need to be recorded (in spaces provided) at each prenatal visit. By performing the indicated examinations and completely filling out the section over the course of the patient's visits, the attending health worker will help to ensure that the basic minimum of perinatal services needed are provided.

The "labor or abortion" section, which relates to the period of labor and delivery, calls for the basic information needed for controlling the period of dilatation and for providing the mother and newborn with good postpartum care. Some of the information is to be recorded periodically as labor progresses.

The following section, on the newborn, records key data obtained from initial examination of the baby; these data help to determine the type and level of care that the newborn needs. Postpartum (or postabortion) procedures are recorded in a separate "puerperium" section at the bottom right-hand side of the page. This latter section is also designed to include data on the mother's condition at discharge and information about contraceptive counseling.

In addition, the area on the page above the "puerperium" section contains a checkoff list of problems occurring during the perinatal period and a small space ("Notes and Lab. Exam. Results") for recording comments and observations that are considered pertinent and that are not made elsewhere on the page.

The Warning System

On the actual form, many of the page one boxes are colored bright yellow (they are shaded grey in page one of Annex 1). These boxes highlight important conditions that often indicate increased perinatal risk. When one or more of these conditions exist, the

corresponding yellow box or boxes are checked off; that helps alert personnel responsible for maternal and child primary care to the danger, and also facilitates the making of decisions about higher-risk cases according to established local standards.

The Encoded Second Page

The first (upper) page of the SPCR is made of especially treated paper; and, as information is recorded on it, a duplicate "carbon copy" record is made on the second page below. This saves time and avoids the occasional human error made when records are recopied by hand.

This duplicate sheet, which is not identical to the first page (see Annex 1), accommodates and encodes 83 items. Because of the way the sheet is laid out, codification of the data is automatic for 76 of these items. The remaining seven items are directly and easily codified using information recorded on that same duplicate sheet (such as the total number of prenatal visits and the place of the delivery or abortion). A basic instruction manual for codification and transcription of the data is included with the forms.

The whole codification process has been designed for easy transcription onto magnetic media. Accordingly, the data can be transcribed onto most transcriber or computer disks, diskettes, cassettes, and magnetic tapes.³

In this vein, it should be mentioned that the Latin American Center for Perinatology and Human Development has designed a computer program to process SPCR data. This program includes all stages of processing (from analyzing the data for consistency to printing the analytical results) and permits assessment of the perinatal care situation at the institution providing the data. It also provides the basis for creating or maintaining a perinatal data bank that can be utilized for future analysis and investigations.

Acknowledgments

We wish to acknowledge the technical assistance provided by Dr. Kenneth Antrobus, Family Health Advisor, PAHO/WHO, in translating the SPCR form from the original Spanish and adapting it to conditions and health standards prevailing in the Eastern Caribbean. We also wish to thank Miss Paula Lozano and Judy Molina for their assistance with the translation of this text.

³ A machine operating with magnetic registers of 128 positions in EBCDIC or ASCH of eight positions is required. Most transcription machines and computers meet this requirement.

(3) [] [] [] [] [] [] [] [] (9)

Inside the rectangular boxes write only one digit (0 1 2 ... 9) per box. Mark 'X' the square box corresponding to the selected answer. The other boxes of the same item are left blank. There must be only one 'X' mark per item, except for positions (45) (57) to (76) and (116) to (120). These positions may have more than one mark. UNKNOWN (missing data): if all boxes corresponding to one item are left blank it is assumed to be unknown. Numbers within brackets are the recording positions on magnetic media. Numbers at the sides of the square boxes (without brackets) are the codes to be recorded for each box containing an 'X' mark.

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Write first and last dates

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1st (48)	DAY	MONTH				
LAST (52)						

0 = None
9 = 9 or more

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Only for data transcription
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10 → 9

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Only for data transcription
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INSTRUCTIONS FOR COMPLETING THE SPCR

General Remarks

The SPCR consists of one single page that includes all items of information needed for providing adequate primary care to a pregnant mother and her child. Three types of data are requested, these being quantitative, qualitative, and descriptive information.

The quantitative information asked for (e.g., the patient's age or height) is expressed in terms of numbers entered directly into the rectangular spaces or boxes provided on the form. When filling in the boxes, put only one number (0 to 9) in each box. If there are more boxes than numbers to be entered, fill in the left-hand spaces with zeros. For example:

- for a pregnant woman, 27 years old, AGE is registered
- when a pregnant woman had two previous deliveries, DELIVERIES are registered

All the numbers entered should be legible. Be especially careful to distinguish clearly between 0 and 6, 1 and 7, and 3 and 8.

Requests for qualitative data can generally be answered "yes" or "no." For example, when a pregnant woman is illiterate:

	YES	NO
Literate	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Please note that "x" marks (rather than checks or plus signs) should be used and that they should not go beyond the boundaries of the box.

Descriptive information (comments included in the "Notes and Lab. Exam. Results" section) should be entered concisely in clear handwriting, and should be confined to the specific space provided.

Special Cases

In the event of a multiple pregnancy, every delivery is recorded on a separate SPCR, even in the case of a fetal death. All data common to all fetuses are repeated on all the SPCRs.

In the case of an abortion, all items from "Institution" to "Gestational Age" (in the "Labor or Abortion" Section) should be filled out. Then fill in the time of the abortion (in the

"Method of Delivery" item) and the "Maternal Discharge" and "Contraception Advice" items. All other items should be left blank.

In the case of fetal death, only the items "Sex," "Alive," "Apgar Score," and "Birthweight" should be filled out in the "Newborn" section. The Apgar score at the first and fifth minutes should be 0-0.

Step-by-Step Instructions

Use of the SPCR is only begun after the patient's pregnancy is confirmed during a visit to the health center. The following are instructions for completing the form section by section.

Section 1: Patient Identification

After "Institution" enter the two-digit code number assigned to the institution attending the patient.

Under "File No." enter the medical record number assigned by the institution to the patient.

After "Surname" enter the pregnant woman's surname and then (after "Other Names") her first name and middle name or initial.

Beside "Address" enter the street name and number where the patient lives.

After "Country" enter the name of the country where the patient lives.

After "Age (Years)" enter the mother's age (in years completed) in the white boxes. For patients under 16 or over 35 years old, place an "x" in the yellow box provided.

Under "Literate" mark the appropriate box to indicate whether or not the mother can read and write.

Under "Educational Level" place an "x" in the appropriate box, and under "Years Completed" enter the number of years of school the patient has completed.

Under "Civil Status" place an "x" in the appropriate box. If the patient is neither married nor a common-law wife nor single, mark the "Other" box and describe the patient's civil status in the "Notes and Lab. Exam. Results" section.

Section 2: History

In the area marked "Family," only consider "first-degree" relatives of the pregnant woman and her husband (grandparents, parents, brothers, sisters, children, and first cousins).

In the area marked "Personal," only place an "x" in the yellow box for an indicated illness if the pregnant woman experienced that illness before her present pregnancy and if the illness was diagnosed by a physician.

In the "Obstetrical" portion, fill out the rectangular boxes provided for every item. If the mother had no previous delivery or more than three, place an "x" within the square yellow box below "Deliveries."

If the mother ever previously delivered a newborn weighing less than 2,500 g, place an "x" in the corresponding yellow box at the far right. Also, enter the month and year in which the mother's last pregnancy ended (even if the pregnancy ended in abortion) after the words "Date of Termination of Last Pregnancy."

Section 3: Pregnancy

This section was designed so that all essential information that should be recalled during each prenatal visit is available. The action of filling out the section, therefore, encourages compliance with acceptable standards of prenatal care. Entries are made during the first prenatal control visit and all later visits.

In the "Pre-preg-weight" and "Height (cm)" boxes, enter the woman's normal weight in kilograms in the three months preceding the current pregnancy and her height (measure her height in stocking feet).

In the "L.M.P." (last menstrual period) boxes, enter the day, month, and year when her last menstrual period started.

In the "E.D.C." (estimated delivery of child) boxes, place the estimated delivery date (day, month, and year). This should be calculated by adding 280 days (40 weeks) to the first day of the woman's last menstrual period.

In the "Doubt" box, mark "No" when the patient has regular cycles, was not taking oral contraceptives prior to this pregnancy, and was sure of the date of her L.M.P. Otherwise mark "Yes."

In the "Tetanus Toxoid" boxes, enter the months of pregnancy in which the mother received her first tetanus toxoid inoculation and her second (booster) inoculation.

In the "Hospitalization" portion of the form, if the patient was admitted during pregnancy mark the "Yes" box and write the number of days of hospitalization (length of stay). Admission to the hospital during labor is not considered as an admission during pregnancy.

To complete the "Referral" portion, mark "Yes" if the patient was referred to another hospital or clinic; otherwise mark the "No" box. If a referral occurred, fill out the date of referral and write the name of the institution where the patient was transferred.

In the "Blood Group" portion, write the patient's blood group in the large box at left, mark the box indicating the patient's Rh type (+ or -), and mark the "Yes" box at right if the pregnant woman has become sensitized or has a history of blood transfusions. (If the "yes" box is checked, more detailed information should be provided in the "Notes and Lab. Exam. Results" section.

In the "V.D.R.L. Result" portion, insert the date and result of the examination.

In the "Smokes" section, indicate whether the patient has been smoking during this pregnancy by checking the appropriate box.

In the "Clinical Exam. (Normal), Dental Exam. (Normal), Cervix Exam. (Normal), and Breast Exam. (Normal)" portions, mark the appropriate boxes to indicate whether the admitting clinical examination, dental examination, cervical examination, and breast examination were normal. Note all positive findings in the "Notes and Lab. Exam. Results" section, and also indicate whether the patient was referred to a dentist.

The next portion down on the left requests basic information to be recorded during each of the patient's prenatal control visits. If there are more control visits than the six provided for on the form, use another form to record the data from these additional visits. After "Date" write the day, month, and year of the control visit. After "Weeks of Amenorrhea" state the number of full weeks elapsed between the first day of the patient's last menstrual period and the date of the control visit. After "Weight (Kg.)" insert the patient's weight to the nearest tenth of a kilogram (e.g., 68.5 kg, 71.2 kg, etc.). (The patient should be weighed while lightly clothed and in stocking feet.) After "Blood Pressure" record the patient's systolic and diastolic pressures in millimeters of mercury (these should be taken with the patient in a sitting position). After "Uterine Height," insert the distance (in centimeters) from the upper edge of the pubic symphysis to the fundus, as indicated by an accurate tape-measure. After "Fetal Heart Rate" record that rate taken for 30 seconds between contractions. After "Presentation" indicate whether the presentation is vertex, breech, or transverse. If the information is not known, leave the appropriate space blank.

The portion to the right ("Problems of Pregnancy/Delivery/Puerperium") is to be marked if the patient has any of the indicated pathologies (if she has none, mark "none"). Any additional problems should be indicated by marking "other" and specifying the problems in the "Notes and Lab. Exam. Results" portion.

Section 4: Labor or Abortion

This section contains data recorded during labor and delivery. In the "Gest. Age" (gestational age) item, insert the number of weeks elapsed since the start of the patient's last menstrual period until her admission to the hospital in labor into the boxes above. If this period is less than 37 weeks or more than 42 weeks, mark the yellow box below. To complete the "Fetal Size Corresponds to G.A." (gestational age)

portion, determine whether fetal size (clinically evaluated by palpation, uterine height, etc.) agrees with the time of amenorrhea and mark the appropriate box. In the "Onset" portion, mark the appropriate box to indicate whether labor was spontaneous or induced. To complete the "Fetal Membranes" portion, mark the appropriate box indicating whether the membranes were intact or ruptured upon examination of the patient. (Anamnesis data should be confirmed by physical examination.) If the membranes were ruptured, insert the hour, day, and month of the rupture in the boxes to the right. In the "Vertex, Breech, Transv." (transverse) portion, mark the box indicating the position of the fetus at the onset of labor.

The next portion down on the left requests data obtainable by observation or palpation about the progress of labor during each of various control periods. The material is organized so that the examiner can systematically document all examinations and orders made during the evolution of labor in order to obtain a good clinical followup. Only those items observed during the particular control period being recorded should be noted; it is not necessary to fill out all items during every control period; and in the event there are more than six control periods during labor, data from the additional ones should be entered on another form.

Proceeding item by item, after "Time" record the hour of the control period (0 to 24 hours or 0 to 12 a.m. or p.m.). After "Maternal Heart Rate" record the mother's number of heartbeats in 60 seconds. After "Blood Pressure" record the maximum and minimum pressures measured between contractions (in millimeters of mercury).

After "Contract." (uterine contractions), "Freq. in 10 Min." record the number of contractions occurring in 10 minutes. If the observation period exceeded 10 minutes, record the average number of contractions occurring in 10 minutes. After "Contract.; Duration (Sec.);" record the duration of a contraction as determined by abdominal palpation. After "Fetal Heart Rate" insert the basal fetal cardiac frequency between contractions in beats per minute. In the event of bradycardia associated with contractions, take the fetal heart rate during and after a contraction. Note if there is or is not a transitory lessening of the basal fetal cardiac frequency initiated in the relaxation phase of the uterine contraction. (This refers to the presence of Dips, type II, or late decelerations.) For example, the notation 160/II indicates that 160 beats per minute is the basal fetal heart rate, with the II showing the presence of a type II Dip or late decelerations. After "Dilation Cx. (in cm), Meconium," insert the dilation of the internal orifice of the cervix, estimating it to the closest centimeter. If meconium is present, mark the yellow triangle.

To complete the "Method of Delivery" portion, mark the appropriate box indicating whether the delivery was spontaneous or involved a Cesarean section, use of forceps, or other special procedure or manipulation. Also enter the time (hour, day, month, and year) of the delivery.

In the "Level of Care" portion, referring to the place where the delivery occurred, mark the box indicating the level of care provided, where the delivery took place (or "Home" if the delivery happened there). If "Other" is marked, specify the place involved in the "Notes and Lab. Exam. Results" section.

In the "Episiotomy," "Lacerations," "Expulsion of Placenta," and "Complete Placenta" sections, complete merely by marking the appropriate boxes.

Regarding the "Fetal Death" portion, it should be stressed that fetal death is defined as "death prior to complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of pregnancy; the death is indicated by the fact that after such separation the fetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles."⁴ Indicate whether fetal death occurred; if it did, specify whether it happened before labor began (by marking "Preg."), or during labor (by marking "In Labor"), or at an uncertain time that could have been either during labor or before it (by marking "Not Sure When").

In the portion dealing with attendance ("Attended by"), mark the appropriate box indicating the status of the most senior health worker (1) present during delivery and (2) attending the newborn after delivery.

Section 5: The Newborn

In the portion on "Sex," check the "M" or "F" box indicating the birth product's sex whether it was born alive or dead.

In the "Alive" section, mark the box indicating whether or not the birth product was alive, noting that a live birth is defined as "the complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of the pregnancy, which, after such separation, breathes or shows any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached; each product of such a birth is considered live born."⁵

In the "Apgar Score" portion, enter the Apgar evaluation made at the first and the fifth minutes. If the Apgar score is 0 to 6 at the first minute, mark the yellow box.

In the "Birthweight" portion, enter the nude infant's weight in grams. (Weigh the birth product even if it was stillborn.) If the birthweight is less than 2,500 grams, mark the yellow box provided.

⁴ World Health Organization, *International Classification of Diseases, Ninth Revision*, Geneva, 1978.

⁵ World Health Organization, *International Classification of Diseases, Ninth Revision*, Geneva, 1978.

In the "Gest. Age" (gestational age) portion, enter the gestational age of the newborn as estimated on the basis of physical examination. If this gestational age is less than 37 weeks, mark the yellow box to the right of the dotted line.

In the "Weight/Gest. Age" (weight for gestational age) portion, use a standard fetal growth curve to determine whether the ratio of weight to gestational age is appropriate, small, or large, and mark the indicated box.

In the "Physical Exam." and "Neuro. Exam." (neurological examination) portions, mark the appropriate boxes, giving the details of any observed abnormalities in the "Notes and Lab. Exam. Results" spaces.

In the "Problems" portion, mark the appropriate boxes if the newborn has any of the following problems: "H.M.D." (hyaline membrane disease) when demonstrated by a clinical or radiologic picture of this disease that worsens during the first six to 24 hours of life; "Aspirat. Synd." (aspirative syndrome), the clinical radiologic syndrome of amniomeconial aspiration; "Other RDS" (other respiratory distress syndromes), any respiratory pathology besides the aforementioned ones; "Apnea" (periodic breathing involving frequent respiratory apneic spells with bradycardia or cyanosis); "Bleeding" (external or internal bleeding involving a decreased hematocrit); "Hyperbilirrub." (hyperbilirrubinemia), a condition difficult to assess because bilirrubin values do not mean the same thing for newborns of different birth weights or gestational ages (mark the indicated box when the bilirrubin value determined a therapeutic action such as an exchange transfusion, phototherapy, or administration of drugs such as luminal, etc., because the presence of this condition in the newborn and its cause are not of interest, but rather the fact that the gravity of it merited treatment); "Infection" (a diagnosis that should be based on results of clinical laboratory tests in accordance with the norms of the health services involved); "Neurologic" (neurological pathologies), a box that should be marked when the neurologic examination was not normal; "Congen. Anom." (congenital anomalies) consisting mainly of visible malformations or those that can be diagnosed by manipulation or physical examination, such as esophageal atresia, congenital cardiopathy, etc. The "Other" box should be marked if the infant has a problem other than those listed, and the "None" box should be marked if the infant was born in good condition, needed no special diagnostic examinations (just the routine ones were performed), developed no morbidity, and required no treatment before discharge.

In the "Neonatal Discharge" portion, mark the appropriate box to indicate whether the infant was discharged as healthy or ill, whether it was referred to another health facility, or whether it died before discharge.

In the "Age at Discharge or Referral" portion, enter the infant's postnatal age at discharge in hours and days; or else, if the infant died before discharge, enter its postnatal age at death in the "Age at Death" portion.

In the "Final Diagnosis" portion, state the relevant diagnosis made prior to discharge, referral, or death and mark the box indicating the type of feeding being provided at discharge.

Section 6: The Puerperium

This section provides spaces for entering the results of three postpartum control examinations. After "Time Elapsed Since Delivery or Abortion" enter that time. After "Temperature" enter the infant's temperature taken according to normal practice in three digits (e.g., 36.8°C), adding the letter "R" if the temperature was rectal and "A" if it was axillary. After "Pulse" enter the infant's heart rate as measured over a period of 60 seconds. After "Blood Pressure" enter the infant's systolic and diastolic blood pressures in millimeters of mercury. After "Uterine Retraction" state whether the retraction was good, poor, or absent (measure uterine height by using the pubis as a reference point, leading to results such as "eight cm above the pubis"). And after "Lochia" state the characteristics of the lochial flow.

In the "Maternal Discharge" portion, indicate whether the mother was healthy, ill, or referred elsewhere at discharge, or whether she died before discharge (during pregnancy, during delivery, or during the puerperium).

And finally, in the "Contraceptive Advice" portion, indicate whether or not the mother was given advice about family planning and indicate the method or methods about which advice was provided.

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ELAYED-TYPE HYPERSENSITIVITY IN HUMAN VOLUNTEERS IMMUNIZED WITH A CANDIDATE LEPROSY VACCINE

Introduction

One of the major goals of the IMMLEP (immunology of leprosy) program of the UNDP/World Bank/WHO Special Program for Research and Training in Tropical Diseases is the development of a vaccine against leprosy. A major step towards this goal was made in 1971 when Kirchheimer and Storrs (1) discovered that the nine-banded armadillo was extremely susceptible to infection with *Mycobacterium leprae*. This led to the availability of unprecedented amounts of bacilli and the possibility of developing a vaccine consisting of killed *M. leprae*.

Such a vaccine would have to meet two important requirements. First, it would have to be purified to remove contaminating host tissue by a process that would leave its immunogenicity