1989

The relationship between methadone dosage and birth weight

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San Jose State University, 1989

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THE RELATIONSHIP BETWEEN METHADONE
DOSAGE AND BIRTH WEIGHT

A Thesis

Presented to

The Faculty of the Department of Nursing
San Jose State University

In Partial Fulfillment
of the Requirements for the Degree
Master of Science

By

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December, 1989

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ABSTRACT

THE RELATIONSHIP BETWEEN METHADONE DOSAGE AND BIRTH WEIGHT

by Efren Manuel Obsuna

This was a study of the relationship between maternal methadone dosage and neonatal birth weight. The records of 41 pregnant addicts who had participated in a methadone maintenance program between January, 1982, and December, 1986, were surveyed. Although all patients were primarily addicted to heroin, addiction to more than one substance was common.

Maternal characteristics, methadone treatment, and neonatal outcomes, especially birth weights, were described for the 41 deliveries. The mean birth weight of all infants was 2,829 grams. All infants were born alive, and 89% of the infants were of normal birth weight.

Based on the data collected from methadone clinic and hospital records, it was found that methadone maintenance dosage had a significant negative correlation with neonatal birth weight ($r = -.31$, $p < .05$). This negative correlation implies that the lower the dosage, the higher the birth weight.

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Chapter 1

INTRODUCTION

Victims of heroin's addictive effects come from all walks of life. Millions of dollars have been spent to combat heroin addiction, which has devastating repercussions in terms of human misery for the addict, his family, and society as well. Women are vulnerable as well as men and constitute a significant portion of the heroin-dependent population. In the United States, approximately one-third of the population using heroin regularly are women (Eldred & Washington, 1975). The great majority of these women are of childbearing age and do not practice contraception (Williams & Bates, 1970). In New York City alone, it was estimated that in the mid-1970s, some 1,300 to 2,500 babies yearly were born to addict mothers (Taleporos, Suffet, & Brotman, 1978). Women who persist in the use of opiates during pregnancy give birth to narcotic dependent offspring.

Opiate addiction can result in a wide variety of physical complications, both for the pregnant mother and the unborn fetus (Shaffer, 1979). Since pregnancy is often not diagnosed at the time of greatest vulnerability of the fetus, all drugs not known to be reasonably safe on the basis of long usage should be avoided by women of childbearing age (Goodman & Gilman, 1970). For the pregnant opiate addict, a synthetic opiate with fewer side effects

needs to be substituted, either to prevent withdrawal symptoms from occurring or to keep her drug-free.

The current drug of choice for the management of opiate addiction is methadone. Methadone, also known as Dolophine, was first synthesized in Germany during World War II (Goodman & Gilman, 1970; Inciardi, 1977) when the usual sources of opium were blocked. For many years, methadone was used as an analgesic and for suppression of withdrawal symptoms in heroin addiction. A single oral dose of methadone can sustain dependence for 24 to 48 hours, whereas morphine or heroin by injection would act in this respect for only 6 to 8 hours (Wilmarth & Goldstein, 1974). Hofmann and Hofmann (1975) reported that 2 mg of methadone can be substituted for 2 mg of heroin or 4 mg of morphine. As a result, methadone became the drug of choice in the management of morphine or heroin detoxification.

Prior to the advent of methadone maintenance as a treatment for heroin addiction and the development of sophisticated neonatal technology, the neonatal morbidity and mortality associated with maternal narcotic dependence was high. By 1979, safe and effective protocols for the medical management of drug dependence during pregnancy and the neonatal period had been developed (Finnegan, 1979). A major weakness of maintenance programs arises in that methadone, being a substitute for heroin, leaves the individual still addicted to opiates and does not insure

that the addict will remain free of illicit drugs. Controversy has evolved regarding what dosage level would yield optimum effects that would suppress supplemental use of illicit drugs. Moreover, genuine concern has been generated from the therapeutic community about methadone's perinatal effects on the offspring of pregnant women maintained on the drug.

Problem

There are various perspectives as to what is directly responsible for low birth weights of infants born to methadone maintained pregnant addicts. Factors posited to cause or contribute to low birth weight include poor maternal health, undernutrition, lack of prenatal care, medically prescribed drugs, and substance abuse. Methadone is therapeutically prescribed for heroin addicts and is being implicated as a factor affecting birth weight. This study explored the relationship between methadone dosage and neonatal birth weight.

Hypothesis

Much controversy exists whether methadone has a direct effect on birth weight. The diverse views of numerous researchers warrant further study in this field. This study aimed to test the proposition that a higher methadone dosage produces a lower neonatal birth weight.

Purpose of the Study

The purpose of this study was to determine if there is

a relationship between prescribed methadone dosage among pregnant addicts and neonatal birth weights. Additionally, it aimed to find out what optimum methadone dose is attributed to higher birth weights.

Definition of Terms

For the purpose of this study, the following definitions applied:

1. An appropriate-for-gestational-age (AGA) infant is one with a birth weight between the 10th to 90th percentile for gestational age.
2. Detoxification is a method of treatment designed to assist in recovery from the addictive properties or toxic effects of a drug.
3. A large-for-gestational-age (LGA) infant is defined as one with a birth weight exceeding the 90th percentile for gestational age.
4. A low-birth-weight (LBW) infant is defined as one weighing 2,500 g or less at birth, regardless of the period of gestation.
5. Maintenance is the therapeutic administration of a legal drug to avoid the debilitating effects of illegal drug usage.
6. Methadone is a synthetic narcotic, which is the drug-of-choice for the detoxification or long-term management of heroin addiction.
7. Neonatal pertains to the first 4 weeks after birth.

8. A premature infant is defined as one born before the completion of 37 weeks of pregnancy, regardless of age. It is dated from the first day of the last normal menstrual period.

9. A small-for-gestational-age (SGA) infant is one with a birth weight below the 10th percentile for gestational age.

Research Design

This was a retrospective study of maternal methadone dosage and neonatal birth weight. Phase I of this research was obtaining the consent of the two institutions where the data needed for this study were available. Also, the Institute for Medical Research (Institutional Review Board of the county hospital) was approached for approval. Approval from the San Jose State University Human Subjects Institutional Review Board was also obtained (Appendix A). Phase II was identifying the subjects using the master list of the three methadone maintenance clinics. All clinic records were surveyed to see which patients delivered between 1982-1986 at the county hospital. Pertinent data about treatment was also acquired. A fill-in clinic chart survey form was used to collect data (Appendix B). A coding system was used to conceal the identities of the subjects, which only the investigator was able to decode.

Phase III of the study entailed reviewing the maternal hospital charts of previously identified pregnant subjects

from the methadone maintenance clinics. The corresponding neonate's chart was also reviewed to procure the data needed to do the correlation of the two variables. A fill-in hospital chart survey questionnaire was used to gather the necessary information (Appendix B). An identification code was entered on the survey forms to conceal the identity of the subjects. Phase IV was analyzing the data using the Pearson product-moment coefficient for determining the relationship between the two variables.

Scope and Limitations

The sample population included all of the pregnant addicts who delivered infants between January, 1982, and December, 1986, at a county hospital. These addicts were previously maintained on methadone at one of the three clinics operated by the county. Mothers who delivered in other hospitals were excluded from this study.

Chapter 2

CONCEPTUAL FRAMEWORK AND RELATED LITERATURE

Conceptual Framework

From the earliest times, narcotics have been used by all classes of people ranging from the very wealthy who indulged in opium as a vice, to the poverty-stricken who need to make life more bearable. The reasons people indulge in drugs at present are not much different from motives in the old days. A complex interplay of heredity, early childhood development, personality, and precipitating factors lead to one's introduction into the drug culture and to drug addiction. Women comprise a significant portion of the drug-dependent population. Unfortunately, for those women who become pregnant, the fetus is likewise exposed to the drugs that they abuse or those that are administered to them. Thus, addiction in the newborn is not uncommon and is seen with a wide array of manifestations. Those newborns getting the attention of the medical community include, but are not limited to, intrauterine growth retardation, low birth weight, and neonatal abstinence syndrome.

Drug Addiction

Although there are numerous ways in which individuals can use drugs, there are four basic patterns of drug use: (a) use of medically prescribed or over-the-counter drugs for therapeutic purposes, (b) occasional use of drugs for

moderate pleasurable effects, (c) occasional use of drugs for intensive psychoactive effects, and (d) compulsive use of drugs for sustained psychoactive effects and/or to avoid withdrawal symptoms. Drug addiction is a pathological process or disease characterized by signs and symptoms of compulsion to use a psychoactive drug, by loss of control over the use of the psychoactive drug, and by continued use despite adverse effects (Smith, 1987). This disease is the result of continuous administration of an addiction-developing drug sufficiently long to develop physical manifestations and body need for the drug (Bishop, 1976).

Origin and Precursors to Drug Addiction

Many cases of developed addiction-disease had their origin in medications prescribed during illness, the condition developing unsuspected by either physician or by patient until its physical manifestations had passed the bounds of control. On the other hand, in illicit drug use or abuse, the initiator is usually a friend (52%) or casual acquaintance (28%), and rarely a stranger (Phoenix House, 1972).

There is a popular belief that before one uses hard drugs, a soft drug is abused first. Abuse of any drug is a symptom of an underlying problem and not a disease in itself. Stimmel (1975) revealed the following findings on precursors to heroin. Of those cases where an immediate precursor to heroin can be identified, the drug most

frequently abused is alcohol, which is reported in up to 90% of instances. However, much attention has been focused upon marijuana as the immediate precursor to heroin. The positive association of marijuana use preceding heroin injection was up to 75%. Stimmel (1975) also notes that the immediate precursor to marijuana smoking is alcohol. Other drugs reported by Stimmel (1975) to be immediate precursors to heroin use are stimulants, cough syrups, and sedatives.

Etiology of Addiction

There is a universal human tendency towards addictive behavior. The first signs of incipient addictive behavior can be seen in small children in the form of thumb-sucking, nail-biting, endless daydreaming, and stereotype movement. Every form of addictive behavior stems from anomalous forms of development in conjunction with heredity, early childhood development, a premorbid character structure, and the present life situation which acts as a precipitating factor (Dews, 1973).

General human motives of addictive behavior have their origins in two universal basic human characteristics, first, a tendency to embellish, correct or forget reality, and second, the desire to repeat pleasurable experience and conversely to avoid an unpleasant experience. People seek relief from conflicts, anxiety, intolerable environmental stress, and inner tension. The underlying motives are the gaining of pleasure or the avoidance of unpleasant

experiences and, on the other hand, an attempt to achieve relaxation, narcosis, intoxication, or escape from reality. Addictive behavior arises from a desire to overcome the constraint which reality imposes upon the individual by satisfaction of instinctual urges or by taking drugs. It is generally believed that addiction is produced by a complex of social and psychological factors which can be reduced to personality, drugs, and society.

The heroin addict is overtly unhappy, negative, defiant, unable to tolerate frustration, and not able to verbally express anger. Great difficulty exists in developing interpersonal relationships, thus preventing the development of an identification with a person who can become a healthy role image. This lack of identification results in a delinquent pattern of behavior manifested by physical acting out, rebellion, defiance against society, and a propensity to try anything once, including experiments with illicit narcotics (Moriarty, :976).

Heroin may initially provide relief from anxiety as well as peaceful euphoria. Once the euphoria has subsided, attention becomes focused on finding enough funds to purchase more of this euphoria, and the cycle starts again. The difficulty of obtaining money to purchase the drug serves another goal. Ego drives normally used for both intrapsychic and interpersonal integration are displaced to activities solely concerned with acquiring the drug. This

behavior evolves into a drug-oriented rather than reality-oriented behavior which ultimately becomes an established life pattern. It also serves as a positive reinforcement for continued use. At this point, the use of heroin ceases to be experimental and becomes regular. The drug becomes a support, a means of escape. As achievement and reality goals disappear, the heroin serves an additional function--that of relieving the user of any responsibility for his/her actions. The drug becomes responsible for all subsequent acts.

Heredity

It is possible to discern certain hereditary character traits and stress factors due to frustration in early childhood which may lead to the development of an inclination to addictive behavior. Studies on heredity in both drug addicts and individuals with developmental anomalies and misdirected instincts have revealed that 60% of such cases come from families in which mood-labile, sensitive, and seclusive personalities occur with increased frequency (Dews, 1973). Certain common features can be found among heroin users with respect to the family constellation (Blum, 1972). Often, the heroin user is one of many children of a family having four to five offspring. In most cases, this person is the youngest child, and his/her role in the family is a dependent one. Most of these youths can be seen to have impoverished family ties

marked by separation of parents, often with the absence of a strong father figure. This results in inadequate identification with the male role and a possible undue dependence developing upon the mother. In most instances, the mother is the remaining parent given the responsibility of raising the family. When dependence upon the mother is combined with maternal overprotection, severe maladjustment to society and its values may occur with increasing susceptibility toward deviant behavior.

Early Childhood Development

In early childhood, overly solicitous or rejecting maternal attitudes tend to inundate the child with hostile and aggressive feelings while at the same time preventing him/her from actively relating to the outside world. The marked ambivalence felt toward the parental figure is internalized. Anger is no longer expressed outwardly but turned within. When a situation arises that generates anxiety or anger, the problem is avoided rather than confronted. Withdrawal from reality becomes a way of life. In its place, unrealistic goals may be substituted which are impossible to attain. With recognition of inability to cope, failure then facilitates this process by eliminating the anxiety that might be experienced.

Premorbid Personality

Over the years, many attempts have been undertaken to identify personalities which are particularly predisposed to

addiction. Wikler (1980) conducted a study on detoxified opioid addicts and found evidence of character disorder (psychopathy or sociopathy) in 42%, emotional disorder in 29%, thinking disorder in 22%, and absence of symptoms in 7%. It is possible to discern certain hereditary character traits and stress factors due to frustration in early childhood which may lead to the development of a predisposition to addictive behavior.

Regarding the character structure, the most predominant feelings which tend to produce a feeling of inadequacy are anxiety, seclusiveness, sensitivity, and infantility. A discrepancy may often be noted between aspirations and capabilities, which leads to continuous tension, anxiety, and feelings of inferiority. Occasionally, infantile traits associated with increased dependence, excessive expectations of others and of the environment, as well as marked suicidal impulses have been observed. However, individuals with no striking premorbid personality features can rapidly develop a disposition to addictive behavior under heavy social stresses occurring at times of biological crisis (Dews, 1973).

In addition to basic genetically determined character, environmental influences are of great importance in predisposing to addictive behavior. It is not surprising that as many as 83% of addicts come from broken homes. They suffered under the separation, divorce, or marital

disharmony of their parents, a tense family atmosphere, alcoholism, drug dependence of one or both parents, and/or loss of father or mother. They grew up outside the family, were pushed to and fro between grandparents and mother, were completely rejected by one parent who saw them as the reason for an unhappy forced marriage. They lacked care, love, security, real human contact, a sense of belonging, roots, and a clear model to form themselves on in later life. In childhood, the lack of security and someone to serve as a model can give rise to a lack of confidence, oversensitivity, feelings of inadequacy, shyness, and inhibition. There is a tendency to fail when faced with a stressful situation (Kielholz, 1973).

Precipitating Factors

Addictive behavior is frequently the result of a defective development which manifests itself as anxiety, insecurity, hypersensitivity, and impaired sociability. It is triggered by additional emotional stresses and conflicts. Adolescence is a period of strife and rebellion initially expressed against the family and then extended to society's rules and regulations. That which is illicit becomes desirable simply because it is proscribed. The inaccuracy of parental statements concerning some drugs, such as marijuana, and the inconsistency of parental admonitions against some mood-altering substances, while the parents themselves freely indulge in alcohol and tranquilizers,

makes it easy to ignore warning against drug use (Stimmel, 1975).

After engaging in the initial forbidden act, which is usually the consumption of alcohol or marijuana, the adolescent realizes that much of what he/she has been told concerning these substances is untrue. This leads to skepticism regarding information about other drugs, such as heroin. Thus, educational material disseminated for drug abuse often has the opposite effect. The linking of marijuana and heroin with regard to damage done to the body makes the adolescent--who has usually had contact with the former--disbelieve the detrimental effects of the latter. Only after the immersion in the reality of heroin dependency does the true picture emerge. By this time, dependency has been established and continued use a way of life.

Characteristics of Drug Addiction

The career of the addict involves socialization in a new occupation--drug use, beginning with initiation and followed by apprenticeship. It later involves full immersion in the world of heroin, including participation in illegal work (e.g., hustling), purchasing, and administering drugs. Inherent in these activities are arrests, incarceration, labeling, and psychological identification with the addict world. The addict career, like other careers, involves building a social as well as a psychological identity.

A frequent and prominent feature of addictive behavior is excessive anticipation associated with increased urge. Satisfaction of the urge by taking drugs discharges the tension and hence relieves anxiety. The particular act which was associated with relaxation has a conditioning effect in similar situations involving alleviation of anxiety and tension. The interplay of conditioning and motivation gradually gives rise to automatism. Increasing automatism and conditioning to the anxiety-relief or tension-relief overrides the innate priority of human needs and interests (Kielholz, 1973).

The outstanding and distinctive characteristic of drug addiction is that the major elements--psychic and physical dependence, as well as tolerance--can be initiated by the repeated administration of small doses and increase in intensity is directly related to an increase in dosage. This characteristic implies that dependence on drugs may be created within the dosage range generally used for therapeutic purposes, and that its mechanism may be set in motion by the first dose administered (Eddy, Halbach, Isbell, & Seevers, 1970).

Psychic dependence is a feature of all types of drug dependence and addictive behavior patterns. These patterns of behavior are characterized by an insatiable drive or compulsion to continue taking the drug or obtain it by any means, to avoid discomfort or to derive pleasure. However,

the aim is never fully attained and the desire to re-experience the pleasure grows, so that the addictive craving becomes even more intense. The individual withdraws further from reality, departs from the reality principle, and becomes abandoned to the pleasure principle. The addict is compelled to take the drug because of the relation of the drug-taking to a schedule of reinforcement in which the drug itself functions as a positive reinforcer because it postpones adverse withdrawal symptoms. Psychoactive drugs may have both positive as well as negative reinforcement value. The net effect is a compulsive and dysfunctional user.

Another landmark feature of drug dependence is the early development of physical dependence which increases in intensity paralleling increase in dosage. This requires a continuation of administration of the same drug, or an allied one, to maintain a semblance of homeostasis and to prevent the appearance of symptoms and signs of withdrawal. Withdrawal of the drug or the administration of a specific antagonist precipitates a definite characteristic and self-limited abstinence syndrome. The development of dependence and subsequent withdrawal perpetuate the cycle of narcotic use. It is important to note that once one has become dependent on a narcotic, obtaining this drug takes precedence over all other forms of behavior (Stimmel, 1975). Regularity of administration well within the

duration of action of the drug hastens the development of physical dependence. The time from the beginning of administration to the appearance of demonstrable physical dependence varies with the agent. Development of tolerance is another element that requires an increase in dosage to obtain the initial pharmacodynamic effects.

Physical and Bodily Reactions During Drug Dependence

Observations show that the length of time over which an addiction sufferer is free from the withdrawal syndrome is in proportion to the amount of drug recently taken. For example, if under given conditions, 1 grain of morphine will keep an addict free from withdrawal for 4 hours, 2 grains will do this for nearly 8 hours (Isbell & Vogel, 1978).

Each addict shows a definite and measurable daily minimum need for the drug of addiction. If the person is suffering from deprivation of the drug, he/she will require a certain dose measurable by its effects upon the symptoms before becoming physically comfortable and efficient again.

The narcotic drug administered to an addict suffering withdrawal will relieve those manifestations exactly in proportion to the amount of drug administered. Each addict has a constant sequence of symptoms attending the so-called "dying out" of the drug (Eddy et al., 1970). These symptoms are relieved in a reverse sequence by the administration of the drug, and in exact proportion to the amount of drug injected. A small amount of opiate will relieve the last

symptoms appearing, another insufficient amount will relieve another portion of the withdrawal signs and so on, until the opiate drug administered balances in amount to the extent of the addict's deprivation or physical need.

The chain of physical manifestations inevitably following the non-administration of the drug of addiction begins with a vague uneasiness, restlessness, and a sense of depression. These symptoms are followed by yawning, sneezing, excessive mucous secretion, sweating, nausea, uncontrolled vomiting and purging, twitching and jerking, intense cramps and pains, and abdominal distress. Later symptoms are marked circulatory and cardiac insufficiency and irregularity, pulse going from extremes of slowness to extremes of rapidity with loss of tone, facies drawn and haggard, pallor deepening to grayness, exhaustion, collapse, and, in some cases, death.

Finally, with drug dependence, harm to the individual arises from preoccupation with drug-taking. Personal neglect, malnutrition, and infection are frequent consequences. For society also, the resultant harm is chiefly related to the preoccupation of the individual with drug-taking. Disruption of interpersonal relationships, economic loss, and crimes against property occur with increased frequency (Blachly, 1970).

Stages of Addiction Development

Every case of well-developed addiction has followed a

course through several stages, marked by clinical signs and reaction phenomena. The stages of addiction include: (a) normal reaction, (b) increased tolerance, (c) beginning addiction, and (d) established addiction. The obvious manifestations of the normal reaction stage are the narcotic and analgesic effect with therapeutic doses. There are the euphoric and inhibitory actions of doses in excess of the therapeutic dose. Also, the toxic action is manifested by slowed pulse, respiration, and generally arrested metabolism and function.

The second stage is characterized by increased tolerance. Following continuous and consecutive administration of opiates is the failure to secure the effect which followed initial administration. Larger doses are needed for the relief of pain, or the original doses give relief for a shorter time. What was previously a toxic dose does not produce toxic manifestations. The person requires what was formerly a toxic dose to secure the former therapeutic effect. The person has acquired a beginning immunity to its toxic action, but does not suffer appreciable hardship from drug deprivation. Discontinuance of the drug causes little or none of the symptoms described as withdrawal signs.

After the stage of increased tolerance comes a stage where discontinuance or lack of administration of the drug gives withdrawal signs due to some beginning physical demand

for the drug which is completely relievable only by its administration. These signs are limited to a peculiar nervousness, restlessness, weakness, depression, etc. They persist for a few days only if the drug is denied and are endurable.

In the established addiction stage, the withdrawal signs and symptoms become more evident as a result of opiate deprivation. The addict proceeds through the mild discomfort and nervousness of the previous stage to the unmistakable withdrawal phenomena. There can be no question of desire for the drug for any other purpose than to escape physical suffering. The person is fundamentally a sick person with a physical disease and gets no pleasure from narcotic administration, but simply gets relief from suffering. The opiate drug has become the only means of securing and maintaining a physical efficiency, a semblance of normality (Bishop, 1976). The person can take tremendous doses with little toxic effects. In this stage, if the drug is denied or withdrawn without competent handling, the addict's suffering and incompetency may persist for weeks or months after no narcotic has been administered.

Characteristics of Drug Dependent Women

Conceptually, it is assumed that chemically dependent individuals are basically deficient as persons. Researchers have sought to identify negatively viewed personality characteristics that are assumed to precipitate and sustain

socially nonsanctioned behaviors. High incidence of childhood personal trauma has been reported among opiate-dependent women (Aron, 1975).

According to Schuckit and Morrissey (1976), there are many theories which emphasize the role of childhood events and family life in the genesis and persistence of substance abuse. They state that family illness, family disruption by parental death or separation, marital disharmony, modeling of parental nonconformity, alcohol and drug abuse, and high rates of physical and sexual assault are features of the early family history of women who abuse drugs. One study found that families of addicted women could be characterized by different kinds of family distress and family incompatibility (Waldorf, 1973). The heroin addict is often a product of battering. She is initially battered in the home and then groomed for failure in her own family (Escamilla-Mondanaro, 1976).

Motivating Factors for Drug Abuse in Women

The reasons women turn to drugs vary. Each is brought to her drug dependence by a unique combination of life experiences, needs, and expectations. Some become dependent on drugs because they are looking for immediate gratification and have poor tolerance for frustration. Others are curious about what it feels like to be "high." Many are bored by their lack-lustre or meaningless existence, and they start to take illicit drugs for the

excitement of it. There are those who become dependent on drugs because of peer or boyfriend pressure and a need to belong. Some turn to drugs following the example of parents or siblings who are drug abusers. Some start taking narcotics to relieve physical pain or emotional pain of anxiety, depression, rage, disillusionment, loneliness, or estrangement. The easy availability of narcotics is a prime factor in establishing drug dependence in most of the women.

Pregnant Addiction

Unique to females is the ability to reproduce. Pregnancy can occur either before or after the introduction into the drug culture. Whatever the case may be, pregnancy is viewed as an added stress in the life of any woman even when she has situational support. Pregnant addiction is an emotionally loaded label that frequently brings to mind many negative images of the women so labeled. They are seen as irresponsible, hedonistic, selfish, psychopathic, unfeminine, unproductive, and parasitic (Moriarty, 1976). Instead of being given the needed emotional support, they are judged before they can present their case and are often sentenced to suffer for bearing a child. Other features attendant to addiction, especially during pregnancy, are mood-swings, doubts, fears, identity problems, and difficulties with body image and desirability. Consequently, reactions to pregnancy vary with individual women. Some have positive while others have negative

reactions, and the latter makes them more inclined to use drugs as a coping mechanism. Negative feelings include fears that their baby will be addicted, have withdrawal symptoms, and/or be physically or mentally abnormal. They also have resentment about the restriction of their freedom during pregnancy and their inability to act out their anxiety through activity to the extent that they were accustomed when they were not tied down. Ambivalence or emotional rejection is also present in women who have broken up or were alienated from the fathers of their babies-to-be. For most, pregnancy is only one of the many stresses in their lives associated with their expected social roles. Their coping mechanisms are marshalled to counteract such pressures (Kandel, Davies, & Raveis, 1981). Socialization experiences, views of women in society, and limited career options lead to feelings of dependency, lack of control, and social isolation. Moreover, poverty, lack of stable relationships, and discrimination due to sex or race have to be dealt with while they are pregnant. To simultaneously contend with all these stresses is a tremendous strain on psychological coping ability. These women are in great need of emotional support, guidance, and relief from environmental pressures to help them adjust successfully to pregnancy.

Pregnancy is a difficult time for women who do not have the emotional support of their parents, particularly their

mother. Coping with pregnancy is also made more difficult for methadone patients, because their daily intake of methadone is lowered as pregnancy advances. As their dosage is reduced, the reasons for first taking narcotics frequently re-emerge. Feelings of depression, anxiety, hostility, and boredom ensue. Relapse is not uncommon during pregnancy when their situational support and coping abilities are exhausted. Drug use is seen as an alternative and potential coping mechanism to counteract the pressures that arise and may, in turn, become another source of stress. When they are condemned and rejected for their behavior, their anxiety is intensified. To overcome these feelings, they revert back to drugs for anxiety-relief or tension-relief.

Once they develop physical dependence and tolerance, they need to take the drug to feel normal, to feel like they were before taking the drugs. Unfortunately, the fetus is almost always an unintended recipient of drugs taken by its mother. The type and severity of adverse effects of a given drug on a fetus depends on a multitude of factors, including amount and frequency of dose, the route of administration, and a myriad of other factors--including concomitant exposure to other drugs.

Transplacental Passage of Drugs to Fetus

It is a commonly held misconception that the placenta protects the fetus from maternally ingested drugs by

preventing their transport to the fetus. Some anatomical differences in the fetal cardiopulmonary circulation exist during the prenatal phase. The fetal cardiopulmonary circulation acts like two parallel pumping systems instead of the sequential system found postnatally. This prenatal system requires 30 minutes or more for a drug to distribute equally throughout the fetus and to come into equilibrium with the mother. Any drug which has psychopharmacologic effects diffuses into the brain which has high permeability requirements. It would follow, then, that this drug also crosses the placenta which has lower permeability requirements than the brain. Furthermore, once across the placenta, these psychoactive drugs distribute into the fetus and the fetal brain. Actually, any drug which can cross the gastrointestinal barrier after oral ingestion can also cross the placenta at least to some extent, because the cellular barrier in both locations has similar permeability characteristics (Finnegan, 1978).

Methadone is widely distributed throughout the body after oral ingestion (Inturrisi & Blinick, 1973; Kreek, 1979). Like other drugs, it is metabolized primarily by the liver and excreted both as unchanged methadone and a variety of metabolites in urine and feces (Kreek, Gutjahr, Bowen, & Field, 1977). There is extensive nonspecific tissue binding of methadone, which creates reservoirs that can release unchanged methadone into the blood thus contributing to its

long duration of action (Dole & Kreek, 1973).

Amniotic fluid and cord levels of methadone have been studied at the time of amniocentesis in mid-pregnancy or at the time of delivery (Blinick, Wallach, Jerez, & Ackerman, 1976; Kreek, Schecter, & Gutjahr, 1974). The presence of two major metabolites of methadone (pyrroline and pyrrolidine) were identified in amniotic fluid along with unchanged methadone (Kreek et al., 1977).

Narcotic dependence during pregnancy leads to narcotic dependency in the newborn which in turn causes obstetrical as well as neonatal complications. Congenital birth defects are inducible primarily during the first trimester of pregnancy (Wilson, 1973). This is true whether or not the drug is abused or medically prescribed. After the completion of organ and skeletal development, the fetus is no longer susceptible to gross anatomical defects. The fetus, however, remains vulnerable to growth retardation and a variety of functional and behavioral abnormalities. For example, addiction to heroin carries a high risk (approximately 30%) of a baby which is small for gestational age as does smoking (Hardy & Mellits, 1972). Therefore, one must consider the maternal to fetal transport both before and after the placental unit becomes functional.

Maternal narcotic withdrawal has been associated with increased muscular activity, thereby increasing the metabolic rate and oxygen consumption in the pregnant

woman. During maternal withdrawal, fetal activity also increases and the oxygen needs of the fetus can be assumed to increase. When this demand is not met, the fetus is exposed in an environment of insufficient oxygen which is a major factor in growth retardation. Naeye et al. (1973) suggest the possibility that periodic episodes of withdrawal during pregnancy might restrict fetal growth by reducing uterine or placental blood flow during contractions. The high incidence of meconium-staining in opiate-exposed infants suggests that they experienced episodes of hypoxia or some other form of distress during fetal life, perhaps related to episodes of narcotic withdrawal (Finnegan, 1978). Particular attention has been focused on the neonatal abstinence syndrome--the withdrawal symptoms experienced by newborns of opiate-addicted and methadone-maintained mothers. The symptoms include tremors, hyperirritability, hyperactivity, tachypnea, diarrhea, vomiting, high-pitched cry, fist sucking, poor feeding, and fever. Sneezing, yawning, myoclonic jerks, convulsions, abnormal sleep cycles, nasal stuffiness, apnea, flushing alternating rapidly with pallor, and lacrimation are less common (Behrman & Vaughan, 1987).

There is no question that healthy women are far more likely to produce healthy babies and that inadequately managed maternal disease, including drug addiction, is associated with an increased risk of obstetrical and

neonatal complications. Therefore, it should be realized that repeated drug abuse by a pregnant woman will result in accumulation of the drug in the fetus.

Related Literature

Methadone maintenance is currently one of the most widely employed techniques in the management of narcotic addiction. With the advent of this legally sanctioned treatment program, an addict might be using any combination of prescribed methadone, heroin, and "street methadone." Treatment involves stabilizing the patient on a regular daily oral dose of methadone. By substituting methadone for morphine or heroin, then gradually withdrawing the methadone, a tolerable (though more prolonged) withdrawal syndrome could be produced (Isbell & Vogel, 1978).

From a pharmacologic standpoint, four properties of methadone are obviously relevant to its use in a maintenance program, and provide what may be a sufficient rationale for its use. First, methadone's effectiveness by mouth and 24 to 48 hour duration of action mean that a patient can drink the drug once daily--a practical kind of regimen. Second, the ability of methadone to maintain physical dependence has two advantages for treatment. Most important, the ambulatory addict is enabled to give up heroin without suffering much discomfort. New patients can be assured in a matter-of-fact way that they can taper their heroin use and soon stop entirely without feeling withdrawal symptoms if

* properly managed. In addition, in methadone dependence, the patient, whose feeling is often ambivalent at the start, is forced to attend a clinic daily in order to ward-off withdrawal symptoms, and thus at the same time is brought into regular contact with the rehabilitative process.

Third, the ability of methadone to produce cross-tolerance to heroin means that a patient receiving methadone regularly will experience a partial or total attenuation of the pharmacologic effects of heroin, if heroin is used. A fourth pharmacologic action of methadone may also play a role. In the early days of administration of the drug to a new patient, there is a considerable feeling of "being loaded" (i.e., experiencing a narcotic euphoric effect) and even drowsiness as well as a variety of other typical narcotic symptoms (Blake & Dictasio, 1973). Thus, a mild euphorogenic effect of methadone when taken daily by mouth in a maintenance program could very well play a major role in retaining patients and facilitating their rehabilitation.

During the early phase of management with methadone, blockade doses of 80 to 120 mg per day are prescribed, but lower doses in the range of 40 mg per day have become the norm (Finnegan, Reeser, & Ting, 1977; Stryker, Wardell, & Markin, 1976). Dosage adjustments are made in response to client symptomatology. The maintenance level must be that which does not give a "high" but does prevent withdrawal symptoms.

Although methadone therapy has demonstrated gratifying individual gains, it does not free the addict from side effects that are a consequence of its use. Of particular importance is the effect it has on the fetus due to the drug's ability to cross the placental barrier which leads to dependency in varying degrees. Narcotic dependency in the newborn is now widely documented. Carr (1975) estimated that in New York alone there were 93,000 children whose mothers were addicted to illegal opiates, and 22,000 were children of mothers in methadone maintenance treatment (p. 412). In 1977, the National Institute on Drug Abuse estimated that 4,742 infants were born to narcotic-addicted mothers. The majority of the offspring of opiate-addicted mothers suffer from various complications. Both prematurity and low birth weight are frequent consequences of addicted pregnancies, regardless of whether use of heroin (Stone, Salermo, Green, & Zelson, 1971; Fricker & Segla, 1978) or methadone predominated (Finnegan et al., 1977). The low birth weight phenomenon has typically been considered an effect of heroin or high levels of methadone ingestion. These results appear to be supported by the evidence that demonstrates higher birth weights of infants born to mothers maintained on lower doses of methadone (Blinick, Jerez, & Wallach, 1973; Finnegan, 1975).

Among low birth weight babies, 35.6% are truly premature (less than 36 weeks of gestation), and 64.4% are

small for gestational age (over 36 weeks of gestation). The contributing causes are maternal pathology and maternal drug habits, both of which influence neonatal growth. The pregnant drug addict is at high risk due to a multitude of pathological conditions. Malnutrition and anemia head the list at 65%, while 38.5% have local and/or systemic infections. Pre-eclampsia, hypertension, premature separation of the placenta, and placenta praevia account for another 20%. Some patients will have two or more conditions, such as cellulitis, malnutrition, and anemia, thus accounting for the 123.5%. Even if a baby's mother does not have a major pathology, a long history of maternal drug use with a high dollar-per-day habit is a causative factor of low birth weight babies. Reports on methadone-maintained pregnancies reveal a decreased incidence of prematurity and low birth weight infants, fewer medical and obstetrical complications, as well as significantly improved retention rates (Davis & Chappel, 1973; Statzer & Wardell, 1972; Davis, Chappel, Mejia-Zelaya, & Madden, 1975; Blinick et al., 1973).

The incidences of prematurity and low birth weight are probably consequences of the combined effects of drugs ingested during pregnancy as well as undernutrition before and during the intrauterine period. Prematurity and intrauterine growth retardation are the primary causes of low birth weight. A certain number of agents have been

identified for which intrauterine growth deficiency is the sole manifestation. With respect to cigarette smoking, Jones and Chernoff (1978) reported the results of the following studies. Younoszai (1968) indicates a decreased birth weight of from 170 to 250 g in the offspring of women who smoke during pregnancy. The influence of smoking seems to be greatest during the last 4 months of pregnancy (Lowe, 1959). Russell et al. (1966) have shown a significantly decreased birth weight in the offspring of women who regularly smoke five or more cigarettes per day throughout pregnancy. Frazier et al. (1961) showed the following correlation between cigarettes smoked by mothers and the birth weights of their offspring: nonsmokers, 3,075 g; less than one half pack per day, 2,952; and one-half to one pack per day, 2,855 (p. 11).

Studies in animals leave no doubt that stunting of growth is the price of prenatal deprivation (Fort, 1971). Soloway and Walters (1976) reported that restriction of the maternal diet during gestation and lactation by 50% has resulted in subnormal size progeny at birth whose body weight does not catch up with normal progeny. Ademowore, Courey, and Kime (1972) state that intrauterine growth retardation is associated with poor placental growth, which in turn is greatly influenced by poor nutrition. However, studies by Naeye, Blanc, and Paul (1973) in humans and by Raye, Dubin, and Blechner (1981) in rabbits indicate that

intrauterine growth deficiency is not secondary to maternal undernutrition.

There is contradictory evidence on whether methadone has a direct relationship with low birth weight. As for possible reasons for low birth weight, Crofford and Smith (1973) have shown impaired growth of neonatal mice given extremely large doses of dl-methadone. Field, McNelly, and Sadava (1977) studied pregnant rats addicted to methadone during pregnancy. Offsprings were examined at birth and compared to controls whose mothers did not receive the drug. Pups of addicted mothers at birth had significantly lower weight, brain weight, and brain protein.

Freeman (1980) studied four groups of rats injected with 0, 4, or 16 mg/kg methadone and found that body weights were low at birth among the high methadone offspring. The effect of chronic maternal methadone exposure on perinatal development was studied by Zagon and McLaughlin (1977). Perinatal exposure to methadone and effects on body growth and brain development were studied in the rat. Body weights were reduced in drug-treated mothers during gestation and the first 2 weeks of lactation. No differences in gestation time, litter size, or infant mortality were recorded. However, methadone-treated offspring grew more slowly than controls. From birth to day 21, brain weight and length, cerebral width, and cerebellar weight and width were generally smaller in methadone-exposed rats. It seemed from

these results that maternal methadone treatment retards the growth of young rats and affects brain development.

Studies by Smith, Hui, and Crofford (1974) in salamanders have shown that methadone prevents regeneration of the limb and can cause taste bud degeneration. Taeusch, Carson, Wang, and Avery (1973) have shown decreased cell number in fetal rabbits exposed to heroin.

Average weights of infants for different ethnic groups receiving methadone was done by Zelson, Jales, and Casalino (1974) and revealed that the pattern is the same as in the general population: white babies had the highest mean weight (2,926 g); black babies, the lowest (2,635 g); and Puerto Rican babies were intermediate (2,746 g).

In Freedman Hospital, mean birth weight for full term black males and females were 3,340 g and 3,193 g, respectively (Rahbar, 1975). Those born to heroin-addicted mothers had a mean birth weight of 2,646 g, while those born to methadone infants were about 300 g higher than for heroin infants.

In 1976, Stimmel studied the impact of methadone on birth weight. He found that although rates of neonatal complications were lower in supervised than nonsupervised patients, outcomes were not better in terms of the percentage of low birth weight infants.

Strauss, Andresko, and Stryker (1974) found that infants born to drug-addicted mothers were, in general, of

normal birth weight for gestational age. The infants born to mothers on a methadone clinic program had higher birth weights compared to those whose mothers were not. However, in a 1976 report by Strauss et al., their findings have suggested that "in high dose blockade programs . . . the incidence of low birth weight infants is similar to that in untreated addicts" (p. 341).

Davis et al. (1975) reported on 49 infants born to mothers on methadone maintenance. The methadone group was divided into a low-dose group ($\underline{n}$ = 31) in which the mothers received 50 mg or less of methadone and a high-dose group ($\underline{n}$ = 18) containing mothers on 60 mg or more of methadone per day. The general condition and withdrawal signs in babies were dose related. Those babies whose mothers were on high dosage had poorer outcomes and more severe narcotic abstinence syndrome.

Thirty-seven pregnant women on methadone maintenance were studied by Harper, Solish, Purow, Sang, and Panepinto, (1974) in New York. Fifty-six percent of the women were between the ages of 21 and 25 years old. All had a history of heroin use. Nineteen of the women joined the program 9 to 20 weeks prior to delivery. At delivery, 26 women were maintained on 60 mg or less of methadone per day. Six of these women had been detoxified and were drug-free. Eleven women were maintained between 60-120 mg of methadone daily. Thirty-seven infants were delivered, of which 28 were female

and 9 were male. Fifteen weighed less than 2,500 g and were considered premature.

In 1976, Finnegan, Reeser, Connaughton, and Schut found that the incidence of low birth weight infants in three drug dependent groups was twice that of controls (30.9% versus 15.2%). Finnegan (1978) found that for pregnancies managed with a lower dosage of methadone, birth weight was favorably affected by the number of prenatal visits. The incidence of death in low birth weight infants was highest for methadone-dependent women with little prenatal care. Thus, she concluded that, "this suggests that uncontrolled methadone use in pregnant women may be more harmful than illicit heroin" (p. 693). Another study by Finnegan (1981) indicated that infants born to methadone-maintained mothers had birth weights higher than heroin-addicted mothers and lower than non-drug using comparisons.

Hutchings, Hunt, Towey, Rosen, and Gorinson (1976) administered methadone orally to four groups of pregnant rats on days 8 through 22 of gestation. Methadone, particularly at higher dose levels, reduced maternal weight gain during pregnancy and increased both maternal mortality and neonatal mortality among the young. Birth weight covaried with dose level and litter size, the 5, 10, and 15 mg per kilogram dosage yielded litter sizes comparable to, or somewhat smaller than controls, but with lower birth weights. The 20 mg dosage yielded the smallest litter sizes

but with birth weights greater than any other treated or control group. Blood levels were dose-related and corresponded to those found in human subjects receiving daily maintenance doses of approximately 30, 60, and 100 mg, respectively.

Hutchings, Towey, Gorinson, and Hunt (1979) further studied pregnant rats who were given methadone by gastric intubation. Beginning on day 8 of gestation, a drug group received 5 mg/kg/day; the daily maintenance dose was increased to 10 mg/kg after 4 days with the final dose given on day 22. An intubation control group received sterile water alone on the same gestation days, and a nontreated control group was left undisturbed. All experimental and control litters were compared at birth to untreated mothers. Body weights were low at birth among the methadone offspring but were similar to controls by the time of weaning.

Studies on the offspring of heroin-addicted mothers have demonstrated a high incidence of low birth weight. According to these studies, approximately 50-60% of babies born to heroin addicts weigh less than 2,500 g (Finnegan, 1975; Reddy, Harper, & Stern, 1971). Both true intrauterine growth deficiency and prematurity have been documented. Stone et al. (1971) studied 384 babies born to heroin-addicted mothers. Of the almost one-half who weighed less than 2,500 g, 60% were appropriate and 40% were small for gestational age. Similar results have been published by

Harper et al. (1974) and Wilson, Desmond, and Verniaud (1973). One study of 665 infants born to drug-addicted mothers found that 318 (48%) were under 2,500 g at birth; of these, 140 (44%) were low-weight-for-date infants (Zelson & Green, 1977, p. 446).

Zelson, Rubio, and Wasserman (1971) studied 34 infants born to mothers who had used methadone alone or in combination with heroin and 24 mothers who used heroin only. A comparison of the two groups showed the following: (a) the incidences of low birth weight infants were similar; (b) among infants born to mothers on methadone, weight and gestational age were more frequently concordant than for infants born to heroin-addicted mothers; and (c) methadone infants had higher birth weights (p. 180). Further studies by Zelson et al. (1974) reported an average birth weight of 2,625 g, with almost 50% less than 2,500 g on babies whose mothers had been receiving methadone during pregnancy. Zelson (1973) studied offspring of 45 heroin-addicted mothers and 46 children born to women on methadone. The incidence of intrauterine growth deficiency was greater among the offspring of women exposed to heroin, 35% versus 22%. The researchers also concluded that the longer the time the mother was taking methadone, the higher the birth weight. Although the mechanism whereby methadone functions in this regard is unclear, it may well correct the reduction in organ cell number, as documented by Naeye, Blanc,

Leblanc, and Khatamee (1973) in the offspring of heroin-addicted mothers.

In a 2 year study by Ramer and Lodge (1975), the average birth weight for all single births was 3,015 g. However, when the infants were divided into two groups, those whose mothers were heroin addicts at the time of conception and later entered the methadone maintenance pregnant addict program, versus those infants whose mothers were enrolled and stabilized on methadone maintenance when conceived, a significant weight difference was demonstrated. The average birth weight of infants conceived while mothers were using heroin was 2,775 g, while the average birth weight of infants conceived while mothers were taking methadone was 3,240 g, a difference of 465 g. In addition, the mother of the largest infant of the heroin-conceived group (3,320 g) entered the methadone program in her first trimester and received methadone for 8 months of her pregnancy.

Blinick et al. (1973) reported on 39 births by mothers on methadone maintenance. Twenty-four mothers conceived while on heroin and were maintained through part of pregnancy on methadone. Fifteen conceived while on 60-120 mg doses of methadone. Results of the study showed that one-third of the babies weighed less than 2,500 g and were considered premature. These findings are almost identical to those reported by Newman, Bashkow, and

Calko (1975) on 313 infants delivered by methadone-maintained mothers; the average birth weight (recorded on the birth certificates) was 2,738 g. Thirty-five percent weighed less than 2,500 g.

Davis et al. (1975) reported on 156 births, of which 127 of the mothers were on methadone maintenance, 15 were on heroin, and 14 were abstinent. They had an average age of 27.2 years and were addicted to heroin an average of 6 years. Birth weight is correlated with psychological and social support services. The mothers with no support services had the highest percentage of babies of birth weight less than 2,500 g.

Chasnoff, Burns, and Scholl (1984) compared (a) the offspring of nonnarcotic-abusing women, (b) infants born to mothers on low-dose methadone maintenance, and (c) a group of infants delivered to drug-free women. Nonnarcotic-exposed infants were of normal birth weight and length and had a normal head circumference. On the other hand, opiate-exposed neonates were of low birth weight and length and had a small head circumference.

Chasnoff, Hatcher, and Burns (1982) also compared (a) infants born to mothers on well-controlled low-dose methadone maintenance, (b) infants born to polydrug-abusing mothers, and (c) infants born to control mothers who had no history or evidence of drug use. All three groups were matched for maternal factors that might affect neonatal

outcome. Infants of low-dose methadone-maintained mothers were significantly smaller than control infants for all growth measurements and had a significantly smaller head circumference than infants of polydrug-abusing mothers. The effects of nonnarcotic drugs on intrauterine growth appear to place the polydrug-addicted newborn in an intermediate zone of deficit between normal and opiate-addicted mothers. Birth weight, length, and head circumference were all lower in a methadone group than in a polydrug or control group.

Kandall et al. (1976) observed that intrauterine growth deficiency in the offspring of addicts and ex-addicts indicates that heroin abuse in the past, despite abstinence in the current pregnancy, may still contribute to fetal growth retardation. The increased incidence of intrauterine growth deficiency in the offspring of heroin-addicted mothers can be at least partially offset by the use of methadone during pregnancy.

More pertinent findings by Kandall et al. (1977) on human neonates show a direct relationship between maternal dosage of methadone and birth weight. An analysis of birth weights of 338 neonates in relation to the history of maternal narcotic usage showed that infants born to women who have used methadone have somewhat higher birth weights than infants born to women using heroin. Mean birth weights of infants born to mothers abusing heroin during pregnancy was 2,490 g, an effect primarily of intrauterine growth

retardation. Low mean birth weight (2,615 g) was also seen in infants born to mothers who had abused heroin only prior to their pregnancy and mothers who had used both heroin and methadone during the pregnancy (2,535 g). Infants born to mothers on methadone maintenance during the pregnancy had significantly higher mean birth weights (2,961 g), but they were lower than the control group (3,176 g). A notable relationship was observed between maternal methadone usage in the first trimester and birth weight; for example, the higher the dosage, the larger the infant. In contrast to the fact that heroin has been found to cause fetal growth retardation that may persist beyond the period of addiction, this study indicated that methadone may promote fetal growth after maternal use of heroin. It suggests that heroin may retard fetal growth and that methadone may promote fetal growth after maternal heroin use, particularly during the first trimester of pregnancy. Moreover, in the study by Newman et al. (1975) on 313 live births, no significant association was found between maternal dosage of methadone in the last trimester of pregnancy and length of gestation or birth weight.

Kandall et al. (1976) found a positive correlation between methadone dosage and birth weight (i.e., higher doses early in pregnancy were correlated with higher birth weights). The causes for differential birth weights remain unknown. The authors speculate that methadone may either

(a) correct the heroin effect of reducing organ cell numbers (e.g., reduced brain size in infants) (Naeye, Blanc, & Leblanc, 1973), (b) affect maternal hormones which influence fetal growth, or (c) have a less variable effect on fetal carbohydrate metabolism.

In summary, the extensive body of literature presented here pertains to the condition of the addict mother's newborn child. Low birth weight has been commonly attributed to heroin and/or higher levels of methadone ingested during pregnancy. However, extrapharmacologic factors have also been considered to play a significant role in the incidence of low birth weight. These include malnutrition, anemia, smoking, and prenatal care.

Chapter 3

METHOD

Research Design

This was a retrospective review of quantitative data on pregnant women who received methadone treatment between January, 1982, and December, 1986. These women subsequently delivered their babies in a county medical center.

Methodology

Phase I of this research was obtaining the consent of the two institutions involved. These included a county medical center and a drug abuse services agency. Likewise, the medical center's Institutional Review Board was approached for approval of the study. Approval was also obtained from the Institutional Review Board of San Jose State University (Appendix A).

Phase II involved identification of the subjects at the three methadone clinics. Approximately 450 female records were reviewed to see which patients delivered in the 5 year period at the county medical center. Ninety-seven (22%) either entered the treatment while pregnant or conceived while being treated. Pertinent data about their treatment was concurrently acquired. Forty-one (42%) of these patients delivered at the county medical center, while the rest delivered at other hospitals and were excluded from this study. A structured, fill-in clinic record survey form

was used (Appendix B). A coding system was used to mask the identities of the subjects.

Phase III entailed reviewing the corresponding hospital maternal records of the 41 pregnant addicts and 42 newborn records, including a set of twins born between the inclusive dates. A hospital record survey form was used to gather the information (Appendix B). An identification code was also used to protect subjects.

Phase IV included analysis of the data using Pearson product-moment coefficient for determining the relationship between birth weight and maternal variables, particularly maternal methadone dosage. This analysis was done with the aid of the Statistical Package for Social Sciences (SPSS).

Chapter 4

ANALYSIS AND INTERPRETATION OF DATA

Maternal Characteristics

The ages of patients at the time of delivery ranged from 20 to 41 years, with an average of 29. Of the mothers, 24 (59%) were 26 to 30 years old. The mothers were predominantly of Spanish origin (49%).

Nature of Drug Problem

Of the 41 patients in treatment, five (12%) were on methadone only, while 30 (73%) were using multiple drugs. Information regarding supplemental drug abuse was not available for the remaining 15% of the patients because of missing biweekly urinalysis results. Thirty (73%) of the mothers consumed one-half to one pack of cigarettes daily; three (7%) were non-smokers.

Ten (24%) of the patients reported drinking alcohol. Only two, however, indicated that they moderately drank. The rest were minimal or occasional drinkers.

Methadone Treatment

Four (10%) of the patients conceived while on methadone maintenance. The rest were admitted at different stages of gestation. Only four (10%) of the patients were treated for longer than 30 weeks.

For the most part, daily dosages of methadone ranged from 9 to 60 mg; 33 mg per day was the average. Twenty-six (63%) received 21 to 40 mg.

Tables 1 and 2 summarize the characteristics of the 41 subjects in this study. The tables include demographic data and methadone treatment information.

Neonatal Outcomes

Sixty percent of the infants were male. Eleven (26%) were premature, whereas 31 (74%) were delivered after more than 37 weeks of gestation. Four (10%) infants were small-for-gestational-age (SGA), 36 (86%) were appropriate-for-gestational-age (AGA), and 2 (4%) of them were large-for-gestational-age (LGA). Birth size was determined with the use of Lubchenco's intrauterine growth chart (Figure 1). Three (7%) of the infants were delivered by Cesarean section, while the rest were born vaginally. All 42 (100%) were liveborn.

Two (5%) neonates were in moderate distress (Apgar score 4 to 6), and 2 (5%) were in severe distress (Apgar 1 to 3) initially. However, all infants had final Apgar scores between 7 to 10. The 2 infants who were in severe distress at the first minute extra-utero belonged to mothers on polydrug use, both with a history of heroin use.

Birth Weight

The highest birth weight was 3,740 g, and the lowest was 1,430 g. The mean weight was 2,829 g. Eleven (26%)

Table 1

Characteristics of 41 Pregnant Addicts on Methadone Maintenance
By Age, Race, Drug Group, and Cigarette Consumption

Characteristics	Number	%
Total number of mothers:	41	100
Maternal age (years):		
<20	1	2
21-25	6	15
26-30	24	59
>31	10	24
Race:		
Hispanic	20	49
White	18	44
Black	3	7
Drug Group:		
Methadone	5	12
Methadone-Heroin	9	22
Polydrug	21	51
Unclassified	6	15
Cigarette consumption (packs per day):		
Non-smoker	3	7
One half	12	29
One	18	44
One and one-half	4	10
Two	4	10

Note. Categories are not mutually exclusive.

Table 2

Characteristics of 41 Pregnant Addicts on Methadone Maintenance
By Gestation, Length of Treatment, and Methadone Dosage

Variables	Number	%
Total number of mothers:	41	100
Gestation on admission (trimester):		
First	15	37
Second	12	29
Third	14	34
Length of treatment (weeks):		
1-15	16	39
16-30	21	51
30-45	4	10
Methadone dosage (mg.):		
<20	7	17
21-40	26	63
41-60	8	20

Note. Categories are not mutually exclusive.

Figure 1. Classification of Newborns Based on Intrauterine Growth.

of the infants weighed less than 2,500 g, while 31 (74%) weighed more than 2,500 g. The females weighed 118 g more than the males, collectively. White babies had the highest mean birth weight among the three ethnic groups. The group of infants whose mothers were on methadone with no supplemental use of illicit drugs had the highest mean weight.

There were 6 recorded birth abnormalities and 8 delivery complications. The clinical outcomes of the 42 infants are summarized in Table 3. Birth weights are compared by sex, ethnic group, and drug group.

Disposition

Twenty-seven (64%) of the 42 infants were discharged to their mothers, and 5 (12%) were under the custody of relatives either by request or out of necessity. Ten (24%) were referred to Child Protective Services for placement in foster homes.

Analysis and Interpretation

In general, 89% of the infants born to drug-addicted mothers were of normal birth weight. Table 4 summarizes the correlation of birth weight with maternal variables. It seems clear from the findings that methadone dosage ($r = -.31$) and gestational duration on admission into the program ($r = .30$) are the only variables that have a strong correlation with birth weight. However, only dosage had a statistically significant level, $p < .05$. Figure 2 portrays

Table 3

Outcomes of 42 Neonates Born to Mothers on Methadone Therapy

Outcome	Birth weight	No.	%
Total number of neonates:		42	100
Gestational age (weeks):			
29-36		11	26
37-39		21	50
>40		10	24
Sex:			
Male		25	60
Female		17	40
Apgar score at 1 minute:			
1-3		2	5
4-6		2	5
7-9		38	90
Apgar score at 5 minutes:			
4-6		0	0
7-10		42	100
Mean birth weight (gm):	2,829		
Sex			
Male	2,822		
Female	3,019		
Race			
Hispanic	2,718		
White	2,960		
Black	2,493		
Drug group:			
Methadone	3,058		
Methadone-Heroin	2,798		
Polydrug	2,714		
Congenital anomalies:			
Anal fissure		1	2
Cor pulmonale		1	2
Hypospadias		1	2
Neurologic handicap		1	2
Skin tag on digit		1	2
Umbilical hernia		1	2
Complications:			
Meconium-aspiration		3	7
Nuchal cord entanglement		5	12

Note. Categories are not mutually exclusive.

Table 4

Correlation of Birth Weight with Maternal Variables

Variable	Pearson r coefficient (r)	Significance value (p)
Maternal age	-.09	.58
Length of treatment	-.16	.33
Gestation on admission	.30	.06
Cigarette consumption	-.03	.84
Methadone dosage	-.31	.05 *
Supplemental drug abuse	-.04	.81

* $p \leq .05$

Figure 2. Correlation Between Birth Weight and Methadone Dosage.

a graphic representation of the maternal methadone dosage and neonatal birth weight.

Infants born to mothers on lower methadone dosage had higher mean birth weights compared to babies whose mothers were on higher dosage. This significant correlation is shown in Table 5. Furthermore, Table 6 suggests that the optimum maintenance dosage for a favorable neonatal outcome, as far as birth weight is concerned, is between 21 to 40 mg. Although it appears that neonates tend to have lower birth weights when born to mothers using many drugs than methadone-maintained mothers, this has no statistical foundation.

Maternal variables that were not found to be significantly correlated with birth weight include maternal age, length of treatment, gestation on admission, cigarette consumption, and supplemental drug use ($p > .05$).

Table 5

Mean Birth Weight by Ethnicity and Methadone Dosage

Ethnicity	Methadone dosage (mg)		
	under 21	21-40	41-60
Hispanic			
Number	4	10	5
Mean wt. (gm)	2,910	2,819	2,510
White			
Number	3	12	3
Mean wt. (gm)	3,315	2,927	2,736
Black			
Number	0	3	0
Mean wt. (gm)	-	2,492	-

Table 6

Relationship Between Birth Weight and Maternal Methadone Dosage

Birth weight (gm)	Methadone dosage (mg)			Total
	under 21	21-40	41-60	
<1,000	-	-	-	0
1,000-1,500	-	1	-	1
1,501-2,000	-	2	1	3
2,001-2,500	1	3	2	6
>2,500	6	19	5	30
Total	7	25	8	40

Chapter 5

CONCLUSIONS AND RECOMMENDATIONS

Conclusions

The question of what methadone dosage is appropriate for maintenance of clients to optimize fetal well-being is one that continues. Although methadone dosage is significantly correlated to birth weight, this does not rule out the possibility that other factors may cause low birth weight. High incidences of low birth weight are probably consequences of the combined effects of drugs ingested during pregnancy, undernutrition before and during the intrauterine period, and lack of prenatal care. Therefore, drawing a conclusion as to whether methadone has a direct effect on birth weight is made difficult by the presence of extrapharmacologic factors which may influence the newborn. Other variables known to affect neonatal outcomes include the mother's use of substances such as alcohol, marijuana, and cocaine. However, this study did not cover the relation between birth weight and the input of such substances. Also, there are insufficient data on alcohol consumption from this study for a correlation with birth weight to be of any value.

The effects of heavy cigarette smoking is a further confounding variable, one that has been shown to be related to such problems as low-birth-weight newborns. On the

contrary, the findings of this study do not show a significant correlation between birth weight and cigarette consumption. As a result, analysis of the effects of methadone, per se, is contaminated by the relationship of these antecedent events to methadone treatment.

Since methadone dosages are adjusted to prevent supplemental drug abuse, it is safe to conclude that methadone better serves the immediate needs of the mother, with less regard for the overall well-being of the unborn fetus. Whatever dosage is decided as optimal or therapeutic, methadone maintenance is, in many ways, deleterious to the fetus.

Recommendations

The variability and conflicting nature of research results in most of the areas reviewed suggests the need for better designed studies. As far as this study is concerned, the findings indicate that mothers should be maintained on a low dosage during pregnancy to benefit from its therapeutic value. Moreover, dosage should be individualized at a level sufficient to suppress or at least minimize the use of supplemental illicit drugs, since they represent a greater risk to the developing fetus than to the mother. For pregnant women seen during the last trimester, manipulation of the dosage should be avoided because of its association with prematurity, low birth weight, and fetal complications.

Since the majority of studies conducted on the effects

of methadone have been of a retrospective type, prospective studies with better control of extrapharmacologic factors should be undertaken to ensure improved reliability. Furthermore, study of the pharmacologic effects of methadone on birth weight should be conducted, as well, in order to really understand the etiology of low birth weight among babies born to opiate addicts. Future studies should investigate newer forms of treatment modalities for drug dependent mothers and monitor the safety of various methadone maintenance dosage regimens.

Government funds should be channeled to rehabilitation programs, so that comprehensive care can be provided to reduce the incidence of low birth weight. Another option would be for the government to underwrite treatment programs for addicts which are of the non-addictive type. An example of this treatment model is the use of antabuse to prevent alcohol intake. Once a small amount of ethanol is absorbed in the body, a variety of physiologic disturbances will ensue. Realistically speaking, however, this is problematic. A drug has yet to be discovered with such pharmacologic properties, and there would likely be low compliance.

In treatment programs, efforts should be directed towards drug abuse abatement. For women seen in the first trimester, the results of the biweekly urinalysis should be monitored to determine the effectiveness of methadone in

preventing heroin and other drug use. Dosage adjustments should then follow this re-evaluation.

Treatment programs should be designed to incorporate ex-drug addicts in the system as counselors since they can serve as role models. They are also able to relate better to patients because of their knowledge of street jargon, which enables them to establish an immediate trusting relationship. This is critical in the initial period for retention of patients. Also, the recovered chemically-dependent person in a counselor role has a broader horizon and is able to act as an intermediary between professional treatment staff and the patients in a way which has a valuable buffering effect. Lastly, this type of counselor can design a recovery plan which appears realistic and attainable, because the patient sees him/her as a person who "has been there."

The time is long overdue for the synchronization of efforts, for if society--health care providers--do not focus on the potential problems that are incidental to substance abuse (e.g., birth defects and neurologic handicaps), then billions of dollars to be generated in the future will have already been spent for setting up custodial facilities to care for this unfortunate subculture.

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APPENDIX A
Letters and Approvals

March 15, 1989

Dr. Anthony Puentes
Medical Director
Methadone Maintenance Program
Santa Clara County

Dear Sir:

I am a nurse currently enrolled at San Jose State University completing a Master of Science Degree in Nursing. A research component including a thesis is a requirement to earn the degree.

The objective of my thesis is to study the correlation between the methadone dosage of pregnant addicts treated at the different methadone maintenance clinics in Santa Clara County and the birth weights of their neonates delivered at Santa Clara Valley Medical Center. The research will entail reviewing and collecting data from patients' records in order to extract information relevant to the study.

Anonymity of the patients will be protected and confidentiality will be maintained. In addition, the proposal will be reviewed by the San Jose State University Committee for the Protection of Human Subjects.

If additional information is needed, I will gladly provide it at your convenience. Thank you!

Efren Obsuna, R.N., M.A.

March 15, 1989

Michelle Bushong, CNM, MS
Program Director
Perinatal Drug Abuse Program
2220 Moorpark Avenue
San Jose, CA 95128

Dear Madam:

I am a nurse currently enrolled at San Jose State University completing a Master of Science Degree in Nursing. A research component including a thesis is a requirement to earn the degree.

The objective of my thesis is to study the correlation between the methadone dosage of pregnant addicts treated at the different methadone maintenance clinics in Santa Clara County and the birth weights of their neonates delivered at Santa Clara Valley Medical Center. The research will entail reviewing and collecting data from patients' records in order to extract information relevant to the study.

Anonymity of the patients will be protected and confidentiality will be maintained. In addition, the proposal will be reviewed by the San Jose State University Committee for the Protection of Human Subjects.

If additional information is needed, I will gladly provide it at your convenience. Thank you!

Efren Obsuna, R.N., M.A.

March 15, 1989

Mr. Robert Garner
Director
Bureau of Drug Abuse Services
Santa Clara County

Dear Sir:

I am a nurse currently enrolled at San Jose State University completing a Master of Science Degree in Nursing. A research component including a thesis is a requirement to earn the degree.

The objective of my thesis is to study the correlation between the methadone dosage of pregnant addicts treated at the different methadone maintenance clinics in Santa Clara County and the birth weights of their neonates delivered at Santa Clara Valley Medical Center. The research will entail reviewing and collecting data from patients' records in order to extract information relevant to the study.

Anonymity of the patients will be protected and confidentiality will be maintained. In addition, the proposal will be reviewed by the San Jose State University Committee for the Protection of Human Subjects.

If additional information is needed, I will gladly provide it at your convenience. Thank you!

Efren Obsuna, R.N., M.A.

March 15, 1989

Kathy Hoare, R.N., D.N.S.
Assistant Director
Education and Research
Santa Clara Valley Medical Center

Dear Madam:

I am a nurse currently enrolled at San Jose State University completing a Master of Science Degree in Nursing. A research component including a thesis is a requirement to earn the degree.

The objective of my thesis is to study the correlation between the methadone dosage of pregnant addicts treated at the different methadone maintenance clinics in Santa Clara County and the birth weights of their neonates delivered at Santa Clara Valley Medical Center. The research will entail reviewing and collecting data from patients' records in order to extract information relevant to the study.

Anonymity of the patients will be protected and confidentiality will be maintained. In addition, the proposal will be reviewed by the San Jose State University Committee for the Protection of Human Subjects.

If additional information is needed, I will gladly provide it at your convenience. Thank you!

Efren Obsuna
Efren Obsuna, R.N., M.A.

March 15, 1989

Carole Guthrie
Administrator of RHSRC
Institute for Medical Research
2260 Clove Drive
San Jose, CA 95128

Dear Madam:

I am a nurse currently enrolled at San Jose State University completing a Master of Science Degree in Nursing. A research component including a thesis is a requirement to earn the degree.

The objective of my thesis is to study the correlation between the methadone dosage of pregnant addicts treated at the different methadone maintenance clinics in Santa Clara County and the birth weights of their neonates delivered at Santa Clara Valley Medical Center. The research will entail reviewing and collecting data from patients' records in order to extract information relevant to the study.

Anonymity of the patients will be protected and confidentiality will be maintained. In addition, the proposal will be reviewed by the San Jose State University Committee for the Protection of Human Subjects.

If additional information is needed, I will gladly provide it at your convenience. Thank you!

Efren Obsuna, R.N., M.A.

County of Santa Clara
Health Department

2220 Moorpark Avenue
San Jose, California 95128

March 23, 1989

Virgil Parsons, DNSC
Department of Nursing
1 Washington Square
San Jose, CA 95192-0057

Dear Mr. Parsons,

Erren Obsuna has requested our permission to use our client records to collect data for his research project. Having reviewed the proposal, I feel assured that Mr. Obsuna will protect the confidentiality of our clients.

He has been granted permission to review our client records in accordance with the protocol in his research proposal. I will inform all the clinical sites regarding this matter. I have asked Mr. Obsuna to share his data results with Michelle Bushong, CNM, our program coordinator.

Sincerely,

Anthony Puentes, M.D.
Anthony Puentes, M.D.
Medical Director
Santa Clara County
Perinatal Substance Abuse Program

Santa Clara Valley Medical Center
751 South Bascom Avenue
San Jose, California 95128
(408) 299-5100

Nursing Administration
Annex Building
751 South Bascom Avenue
San Jose, California 95128
(408) 299-6950

April 19, 1989

TO: David Kerns, M.D.
Chairman, Department of Pediatrics

FROM: Kathy Hoare, R.N. *[Signature]*
ADN, Nursing Quality Assurance,
Education and Research

SUBJECT: Research Proposal

Efren Obsuna, R.N., a member of our nursing staff, has submitted a proposal to do his graduate research project here at SCVMC. He is a graduate student at San Jose State University.

The project titled, "Correlations Between Methadone Dosage and Birth Weight," involves reviewing the medical records of women who delivered at SCVMC between January 1982 and December 1986, and the medical records of their infants. Mr. Obsuna will personally review the medical records.

I have enclosed a copy of the proposal for your perusal. I would appreciate receiving from you a note indicating your support of the project. It would be helpful to have the note by April 26, 1989 so that I can place the proposal on the Human Subjects Committee agenda for review. For your convenience I have attached a pre-typed standard statement used in the Department of Nursing. Thank you for your assistance.

If you have any questions or need additional information, please call me at X8275.

I have reviewed the research proposal titled, "Correlations Between Methadone Dosage and Birth Weight," submitted by Efren Obsuna, R.N. and support the conduct of this research project at SCVMC.

5/10/89 *[Signature]*
Date Signature

rb4199kh3

SCVMC is an EEO/AA Employer

Owned and operated by the County of Santa Clara. Affiliated with Stanford University School of Medicine.

INSTITUTE for MEDICAL RESEARCH

2260 Clove Drive, San Jose, California 95128
Telephone: (408) 998-4554

May 8, 1989

Mr. Efren Obsuna
Santa Clara Valley Medical Center
751 South Bascom Avenue
San Jose, CA 95128

RE: Project entitled "Correlations Between Methadone Dosage and Birth Weight"

Dear Mr. Obsuna:

On April 28, 1989, the Research and Human Subjects Review Committee for Santa Clara Valley Medical Center (an IRB holding Department of Health and Human Services Assurance #M1306) approved your application requesting access to SCVMC medical records.

Please be advised that approval is subject to acceptance by the Santa Clara Valley Medical Center Department of Medical Records. For further consideration of your request, please contact Ms. Joann Taylor at 408/299-6674.

In compliance with Title 45, Sec. 46.117 (c) (1) of the Code of Federal Regulations, the Committee waived consent form requirements with the understanding that information will be recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Approval is granted with the understanding that no changes will be made in the protocol without the knowledge and prior approval of the Committee.

The number assigned to this approval is 4/28/89-06. Approval is for a period of one year. If the study is to continue beyond the expiration date of April 27, 1990, it must be renewed in accordance with the Committee's renewal instructions. As a courtesy reminder, a renewal application will be mailed to you approximately two months prior to the expiration date.

Should you have any questions, please contact the Administrator of the Committee, Carole Guthrie, at 408/998-4554, ext. 15.

Sincerely,

Elisabeth Mailhot, M.D., Chairman
Research and Human Subjects Review Committee

EM/cg

cc: Ms. Joann Taylor

**SAN JOSE STATE UNIVERSITY
GRADUATE STUDIES AND RESEARCH**

**HUMAN SUBJECTS INSTITUTIONAL REVIEW BOARD
PROJECT PROPOSAL REVIEW**

Regular Review ☐ Expedited Review ☐ Deadline Date _____

I, the undersigned member of the San Jose State University Human Subjects Institutional Review Board, have reviewed the following proposal submitted to the Board on 5/23/89 by:

PRINCIPAL INVESTIGATOR: Efren Obsuna
 PROTOCOL #: 7509 DEPT: Nursing
 PROJECT TITLE: METHADONE DOSAGE AND BIRTH WEIGHT

I recommend the following action (indicate one):

1. Approved for clearance as involving minimal risk to Human Subjects. ☒

2. Approved for clearance with risk to Human Subjects. ☐

3. Approval depends upon the satisfactory completion of the following conditions. ☐

4. I have serious concerns about this protocol and it should go before the full committee to review. ☐

Robert J. Latta, MS 5/31/89
 Signature of IRB-HS member Date

5. Not Approved. ☐

Approved. ☒

OFFICIALS SIGNING FOR INSTITUTION

Goni Campbell 6/3/89
 Chair, Human Subjects Institutional Review Board Date

Serena Stanford 6/7/89
 Serena Stanford, Ph.D. Date
 AAVP for Graduate Studies & Research

Please return to: San Jose State University Foundation, One Washington Square, San Jose, CA 95192-0139
 (408) 924-1438

APPENDIX B
Data Collection Forms

CLINIC CHART SURVEY FORM

1. Identification code _____
2. Age _____ yrs
3. Prepregnancy wt. _____ lbs Maternal wt.gain _____ lbs
4. Date of delivery _____ / _____ / _____
 (mo) (day) (year)
5. Treatment modality at admission _____
6. Smoker? ____ Yes ____ No If yes, how much _____
7. Drinker? ____ Yes ____ No If yes, how much _____
8. Primary drug problem _____
9. Frequency of use _____
 _____ 0 (no use in prior month)
 _____ 1 (less than once per week)
 _____ 2 (once per week)
 _____ 3 (several times per week)
 _____ 4 (once daily)
 _____ 5 (more than once daily)
10. Other drugs used _____
11. Positive urine tests for illicit drug use _____ times
12. Type of drug/s _____
13. Age of gestation on admission _____ weeks
14. Age of gestation upon discharge _____ weeks
15. Dose on admission _____ mg
16. Dose upon discharge _____ mg
17. Lowest methadone dose during pregnancy _____ mg
18. Highest methadone dose during pregnancy _____ mg
19. Total dose during entire pregnancy _____ mg

1. ID code/record # _____ Baby's Record # _____
2. Diagnosis _____
3. Race W B H I A O
4. Occupation _____
5. Marital Status M W D S Sep
6. Medical history
Disease/s _____
Medication/s _____
7. Laboratory
Hematocrit _____ %
Toxicology screen _____ Pos _____ Neg
8. Prepregnancy wt. _____ lbs Predelivery wt. _____ lbs
9. Abortion _____ Spontaneous _____ Induced _____ Ectopic
10. Date of delivery _____ / _____ / _____
 (mo) (day) (year)
11. Age of gestation _____ wks
12. Type of delivery _____ vaginal _____ cesarean
13. Nature of labor _____ precipitous (less than 3 hours)
 _____ normal
 _____ prolonged (more than 20 hours)
14. Complication/s
Before childbirth _____
During childbirth _____
15. Medication/s _____
16. Anesthesia _____

NEWBORN HOSPITAL CHART SURVEY FORM

1. ID code/medical record number _____
2. Sex _____ M _____ F
3. Age of gestation at birth _____ weeks
4. Diagnosis _____
5. Type of delivery _____ vaginal _____ cesarian
6. Condition _____ Liveborn _____ Stillborn _____ Neonatal death
7. Apgar score _____ 1 min _____ 5 min
8. Birth size
Weight _____ lbs _____ ozs _____ gms
Length _____ in _____ cms
Head circumference _____ cms
Chest circumference _____ cms
Abdominal circumference _____ cms
9. Toxicology screen _____ Pos _____ Neg
10. Withdrawal signs _____

11. Type of withdrawal _____ mild _____ moderate _____ severe
12. Length of withdrawal _____ days
13. Medication/s given _____
14. Complication/s _____
15. Defects/Abnormalities _____
16. Disposition of newborn _____ mother
_____ relative
_____ foster care