

Conducting a Treatment Research Project in a Medical Center-Based Program for Chemically Dependent Pregnant Women

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INTRODUCTION

In many respects a public medical center is an ideal location in which to develop and evaluate the efficacy of a comprehensive drug treatment program for pregnant women. Public hospitals have access to relatively large numbers of women whose medical and obstetrical problems may be a direct or partial result of the use or abuse of alcohol and other drugs. In addition, women residing in the community who are in need of chemical dependence treatment services are frequently identified and referred to a particular hospital by county board of health clinics and community-based health centers. Pregnant women who receive care at public hospitals often lack the financial resources and private medical insurance that are necessary to access drug abuse treatment in the private sector. Their only treatment option may be a program offered by a public hospital. Thus, low-income pregnant women served by a public hospital are a “captive” group for a newly launched, hospital-based addiction research demonstration project that needs to attract many such women over a short time.

In addition to possessing a large, accessible treatment (and therefore subject) population, a public medical center usually offers a broad spectrum of relevant primary through tertiary health care services, including high-risk prenatal care, neonatal intensive care, and specialized pediatric followup care. Often, the medical center is home to a variety of programs and professionals dedicated to clinical research in relevant areas, such as infant and child development, perinatology, psychiatry, and public health. These programs and people, although frequently understaffed and busy, will make themselves available to a treatment program through interdepartmental linkages, allowing for the formation of a comprehensive perinatal addiction treatment service without having to start entirely from scratch and without relying exclusively on external funding support for all program elements.

In spite of possessing this vital mix of ingredients—accessible subjects, skilled health care providers, and a full range of medical services—a medical center-based research demonstration program that serves chemically dependent pregnant women may encounter numerous

difficulties in implementing and running a treatment program and gathering data about the participants and the treatment. Overall, the problems that emerge are related to one of four domains:

1. The traditional structure of health service delivery in hospitals
2. Characteristics of the patient population and the intrinsic nature of addiction-related behaviors
3. Unforeseen difficulties with the research design and with mixing the research and clinical operations
4. Negative perceptions by hospital staff members and administrators of the problem of drug abuse and drug-abusing patients (subjects)

PROBLEMS ASSOCIATED WITH TRADITIONALLY STRUCTURED HOSPITAL SERVICE DELIVERY

Despite recent advances in the development of multidisciplinary care services for specific populations, such as oncology, human immunodeficiency virus (HIV)-positive, and high-risk prenatal patients, services in large hospitals are generally fragmented. Medical and psychosocial services are rarely delivered in a coordinated way. The traditional hospital care system has limited ability to deliver patient-centered care. Fragmentation of care within an institution is commonplace and constitutes a particular problem for an addiction treatment program that aims to provide a “one-stop shopping” service. For example, a common practical problem is the inability of a treatment program to obtain followup on what happens when a patient consults with a provider outside the treatment program. A patient may go to the hospital’s oral surgery, orthopedic, or other subspecialty clinic, but no written or verbal report of the visit may be available for the chemical dependence treatment staff. Ironically, although the visit occurred in the same institution, it may be nearly impossible for the treatment program to obtain documentation of what medication was prescribed, what studies were ordered, and what followup care was arranged.

Hospital care is often fragmented geographically as well. For example, radiology, laboratory, outpatient, and medical records services are usually located far from each other and far from the treatment program. This separation works against the basic goal of comprehensive service delivery, which is to keep the services close to each other to facilitate patient compliance with treatment program elements and minimize patient frustration. The standard hospital and clinic layout requires frequent

waiting in lines, direction and redirection to various parts of the hospital, and a lot of walking. Negotiating the standard configuration of hospitals, especially large ones, is difficult even for able-bodied, motivated patients. In the case of the chemically dependent pregnant or postpartum woman who is new to treatment or in early recovery, the fatigue and frustration engendered by going from department to department for blood tests, ultrasound, appointment scheduling, and so forth may negatively affect her program participation and compliance with medical care, even when the health services appear to be easily accessible. Emphasis on case management and advocacy is needed to enable such a patient to successfully navigate “the system” both physically and mentally, although at times the additional help given her may foster an undesirable sense of dependence or intensify her internal feeling of chaos and nihilism.

Exacerbating this problem of scattered services is the fact that neither private nor public institutions are likely to assign conveniently located or adequate space to a new chemical dependence program. Given that most hospitals and clinics generally do not have much unused space to begin with and that chemical dependence treatment may be a low priority in a tertiary care hospital, a new treatment program may be located far from the main hospital and clinics, in space that especially mitigates against the integration of program and hospital services. Reallocation and renovation of the space for a treatment program is an extremely time-consuming process that may require extensive negotiations with hospital administrators, hospital labor union representatives, and municipal building inspectors. The process of locating and renovating space must be done with caution and tact. Serious animosity against the new program can arise if established providers of hospital services or other preexisting programs are displaced or inconvenienced by the new program.

Hospital departments and their service providers may be territorial about job descriptions and space. Institutional “turf” issues may arise when a chemical dependence treatment program appears to be encroaching on another department’s area of expertise. Allied health service disciplines in the hospital, such as health education, occupational therapy, or social services, may refuse to allow treatment program staff members to be cross-trained or credentialed in functions that the other disciplines consider their domain. Moreover, these other disciplines may not be willing to accommodate the unique needs of a chemical dependence program. For example, HIV counseling generally is given prior to HIV serologic testing. In some institutions, this counseling may be available only through a specialized health education service. Despite the fact that each pregnant woman enrolled in chemical dependence treatment needs one or more HIV serologic screens during her pregnancy, scheduling these tests and obtaining the test results, along with the mandated pretest and posttest

counseling, from designated hospital personnel may be discouragingly labor intensive. At the same time, treatment program staff members, although already trained in this counseling, may not be allowed to deliver it.

Departmental directors may object to using personnel in ways that are new or innovative. For example, the use of certified nurse midwives in the addiction program's prenatal clinic may violate a nursing protocol that states that these midlevel providers are to care only for "low-risk" prenatal patients. Changing a nursing protocol, with the goal of providing superior services, may prove to be an almost insurmountable task, requiring many hours of negotiation.

An unwieldy hospital bureaucracy may negatively affect program implementation and functioning. Timely hiring of specialized clinical and research personnel, such as case managers and research associates, is difficult if the hospital personnel department is not flexible about position classification and job descriptions. Purchasing the materials needed for treatment or research purposes may prove to be a time-consuming and frustrating problem. If the items needed are not standard hospital supplies and if they cannot be acquired directly by the program but must be ordered through standard hospital purchasing procedures, the research timeline may be seriously delayed.

Confidentiality

Maintaining confidentiality in a medical center-based research demonstration program can be difficult. Federal law and ethical standards demand that patients in chemical dependence treatment not be openly labeled as chemically dependent. However, in the process of publicizing the program throughout the medical center to facilitate referrals and increase access to treatment for potential program participants, it becomes likely, from the time of the first patient contact, that the women entering the program will be labeled and will have their status known by the hospital and clinic staff members who work with or refer patients to treatment program providers. Further compromise of patient confidentiality occurs when the program refers its patients to other hospital services by using requisitions bearing the program name. Such requisitions are necessary for medical records purposes and for the program to retrieve test and consultation results through the hospital's internal communications system. For example, when a patient in a hospital-based addiction treatment program presents her stamped laboratory requisition to a registration clerk at the laboratory, the clerk who sees the program name may subsequently call out to the phlebotomist or laboratory technician that a drug abuse patient is waiting for service or behave in some

derogatory fashion prompted by negative feelings about drug use or drug addiction treatment.

Loss of confidentiality in terms of patient status in drug abuse treatment is especially common when inpatient hospital admission occurs. For pregnant women in treatment programs, confidentiality is frequently compromised when the patient is admitted for delivery. During the postpartum period, both treatment and research personnel need access to the patient and the neonate. These contacts are difficult to arrange without openly acknowledging the patient's status to medical and nursing staff members.

Hospital Accreditation Standards and Quality Assurance

The complex task of initiating and operating an innovative, comprehensive treatment program with an extensive research component is made more difficult by the need to ensure that the clinical program and the research activities, even as they are in the process of being developed, comply with all internal and external hospital standards. In hospital-based programs, patient assessments, clinician documentation, and staff credentialing and evaluation all must meet the standards for chemical dependence programs of the Joint Commission on Accreditation of Health Care Organizations (JCAHO). These standards are not formulated with allowances for "experimental" or new programming formats. Although JCAHO standards are designed to ensure comprehensive, state-of-the-art treatment service delivery, they are often rigid and inflexibly applied when the JCAHO evaluates drug abuse treatment programs. It is difficult to break new ground in the area of drug abuse treatment and not run afoul of a JCAHO standard.

Similarly, it is difficult for a new research demonstration project serving and studying a chemically dependent population to integrate successfully with internal hospital utilization review (UR) operations and quality assurance (QA) activities. In the early stages of program startup, this may be because the project treatment, research, and clinical staff members are focused on simply getting the program "off the ground." The intense effort involved in setting up a new program may leave treatment staff members and program leaders with little time or energy to devise and carry out routine QA activities. At the same time, designated hospital UR and QA personnel may be unfamiliar with the nature of the services offered in a drug abuse treatment program and therefore may have difficulty accomplishing the necessary independent reviews of treatment program activities. Evaluation of program performance may be impossible for QA staff members unless they obtain special training in the field of addiction services. When institution administrators are ambivalent about

starting chemical dependence services, the special UR and QA needs of the addiction treatment program may be yet more evidence to those institution administrators of the “troublesome” aspect of these types of programs.

PROBLEMS ASSOCIATED WITH THE PATIENT/SUBJECT POPULATION

The social and economic problems associated with poverty and drug use have been described in numerous publications. The overwhelming needs of chemically dependent women greatly affect routine treatment activities and data collection. Patients often lack basic resources such as food, clothing, or transportation.

Housing

Many patients in a research demonstration drug abuse treatment program may be homeless sporadically or continuously. Treatment staff members may spend an inordinate amount of time attempting to arrange temporary or permanent housing. Research associates, primarily master’s-level members of the research team, often have difficulty locating patients for time-limited research measures. Patients may live in dangerous places where staff safety during outreach and data collection activities is problematic.

Transportation

Given patient needs and program requirements, assistance with transportation is a necessary component of a drug abuse treatment program for pregnant women. Achievement of regular program attendance is a problem when a woman in treatment must make long, tiring trips, often with small children in tow, using public transportation. When public transportation is the only available option, most women require a financial subsidy, especially if daily program attendance is expected. Hospital administrators may have an expressed or unspoken perception that providing a pickup and dropoff service or financial subsidy for chemical dependence treatment program patients is equivalent to “coddling.” In part, this is because the women, even when pregnant, are seen as relatively able-bodied compared with other patient groups served by the institution. Hospital administrators may reason that if “sicker,” that is, frailer, patients with physical disabilities do not receive transportation assistance, it is unfair for this group to receive it. There is also frequently a perception that the women and children coming to the addiction treatment program increase the need for insurance coverage carried by the hospital on its minivan transportation system.

Child Care

Child care is another essential service element in a program that cares for pregnant or parenting women with small children. Regular patient attendance cannot be expected unless child care is available to the women enrolled. Child care services may range from simple babysitting for a few hours each day to a specialized, daylong therapeutic nursery. Creation of child care services on hospital premises may prove surprisingly challenging, and many hospital administrators may be inexpert or unmotivated in handling issues that arise. Hospital facilities often will need substantial renovation to comply with the stringent codes that apply to areas where children are cared for. A day care license may have to be obtained. Quality-assured recordkeeping systems, daily screening for communicable diseases, proof-of-vaccination status, and an emergency pediatric care referral system need to be in place even for a “simple” onsite babysitting service. Although the mother is in treatment on the premises, many requirements and specific guidelines must be followed. An additional problem arises during the summer when the demand for child care services becomes heavier because school-age children enter day care. During summer vacation, the program may have to cope with large numbers of children, many of them teenagers, within the confines of hospital premises that are ill suited to accommodate adolescents.

Security Concerns

Even when a treatment program has a limited number of treatment slots or a low census, the regular presence on the hospital premises of a population of low-income, homeless, chemically dependent women and children, together with their significant others, relatives, and acquaintances, may be viewed as a security problem by hospital administrators. Thefts or other untoward incidents that occur within the medical center often may be attributed to the drug abuse treatment program, even when no substantiating evidence is available. Addressing both the legitimate and exaggerated security concerns associated with a drug abuse treatment program operating onsite in a medical center may prove challenging.

PROBLEMS ASSOCIATED WITH INTEGRATION OF RESEARCH REQUIREMENTS AND CLINICAL OPERATIONS

Whereas multidisciplinary programs function best when program staff members are flexible in assuming each other’s roles and responsibilities, a potentially negative aspect involves the research staff taking on clinical duties. The research staff members are key figures in recruiting and introducing patients into a program, and they are responsible for following

the patients' progress in treatment. Because research staff members are so active in subject recruitment, the general hospital staff members are often more familiar with them than with the treatment staff members. As a result, the research team personnel often are inappropriately contacted by nonprogram hospital service providers when there is a problem or a concern with one of the program patients.

Limited space for program activities affects data collection. Physical proximity of the research and treatment staffs may make it impossible to maintain blinding with regard to patient assignment to the treatment or control condition. In addition, a research staff member who works next to a treatment staff member may be unwittingly kept abreast of patients' successes or failures in treatment. This knowledge has the potential to influence or bias the data gathered by the research staff from patients assigned to the treatment condition.

Case management often occurs in the course of patient-research staff contacts. As noted above, low-income chemically dependent women have extensive human service and emotional needs. The services the research staff members deliver to the patients, as well as the relationships that form between them as a result of the service delivery and frequent, nonjudgmental contacts for performance of research measures, are likely to alter outcomes and affect data collection. It is difficult to create and maintain a program with sufficient physical and organizational distance among the research team, the clinical team, and the patient cohort, particularly in a hospital setting where geographic separation may be impossible and where other hospital systems exert a "blending" pressure on the research and treatment teams.

PROBLEMS ASSOCIATED WITH INSTITUTIONAL PREJUDICE

Despite widespread public knowledge of the existence of the problem of maternal drug abuse and a stated societal commitment to addressing it effectively and humanely, deep-seated dislike, distrust, and distaste for chemically dependent pregnant women persist within medical centers. Some of this prejudice is the result of a belief that chemical dependence is not a medical condition like some others, that is, one that is worthy of medical treatment or in need of hospital-based services. Another important factor may be the uniquely negative, condemnatory feelings that a pregnant, drug-abusing woman often evokes. It is difficult for many people to acknowledge how powerfully they are affected by the concept of an "innocent baby" being "abused" in utero by an "unfeeling" or "monstrous" mother. These negative and frequently unconscious

feelings exist at every level of hospital personnel, from administrative personnel, to the clinical staff, to support personnel, to the janitorial and housekeeping staff. The prejudice is manifested in different ways, from the trivial to the serious: in prolonged timeframes for setting up program services caused by exacerbation of usual bureaucratic delays and as vague opposition by nurses or resident physicians to program needs and goals. Hospital administrators may require program patients to be sequestered physically as much as possible from other hospital patients. Janitorial and housekeeping service personnel may clean the program space less frequently. This issue is exceedingly difficult to deal with because it is rarely openly acknowledged by those who are responsible for it.

Negative feelings about chemically dependent pregnant and parenting women are exacerbated when the women in question are indigent or of low-income status. Many hospital personnel perceive these patients as dangerous, manipulative, and criminal. A woman's lack of education and inability to support herself and her family are seen by some hospital personnel as a result of her addiction rather than as a contributing factor. Fear and distrust of program patients may be openly or subtly conveyed to them by the hospital staff members they encounter and can be expected to have a negative effect on the patients' self-esteem and progress in treatment.

CONCLUSIONS

In spite of all the problems enumerated above, medical centers are desirable locations in which to conduct research in the area of maternal addiction. The following recommendations and suggestions for overcoming barriers to program implementation and service delivery may be useful for prospective investigators and funders.

- Substantial increases need to be made in the amount of time allowed for program startup. Additional time should be allocated for piloting the treatment program with a patient group whose data will be excluded from the final analysis.
- Extensive involvement of all branches of medical center administration and all hospital departments is mandatory in the planning of a proposal for treatment and study of chemically dependent women. Early, coordinated planning may help ameliorate or remove existing prejudices and promote institutional investment in the clinical research project's success. The planning should involve hospital QA and risk management personnel and relevant outside accreditation bodies. Space commitments and space renovation plans should be made as far in advance as possible.

- Widespread and ongoing education about drugs and addiction is needed for all hospital personnel. Inservice training provided by program staff members, as well as collaborative presentations by the mental health department and employee assistance program personnel, should be held throughout the medical center so that the treatment research project will become an accepted and vital part of medical center activities.

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