SUPPLEMENT

Perspectives on the Control of Viral Hepatitis, Type B

A joint statement by the Committee on Viral Hepatitis, Division of Medical Sciences, National Academy of Sciences-National Research Council, and the Public Health Service Advisory Committee on Immunization Practices
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PREAMBLE

In 1972 the Committee on Viral Hepatitis of the Division of Medical Sciences, National Academy of Sciences-National Research Council, published a statement on the public health implications of hepatitis B surface antigen in human serum.1 The statement was revised and updated in 1974.2 These commentaries dealt with the significance of hepatitis B surface antigen and suggested ways to manage hepatitis B patients and other persons found to have this antigen in their blood.

Recent data on the diagnosis, epidemiology, and management of hepatitis B have helped clarify its complex natural history. Important questions remain to be answered, but there is sufficient new information to warrant thorough review of the subject and interpretation of its health significance.

Traditional prevention and control of hepatitis A involve good hygienic practices and passive prophylaxis (immune serum globulin, human—ISG) for close personal contacts of hepatitis patients. For control of hepatitis B, in view of its only partially understood natural history and epidemiology, we rely on establishing personal and environmental barriers to transmission. At present, ISG appears to be of limited value as a preventive of hepatitis B; therefore, considerable effort is being directed toward the development of biologics for both active and passive immunization.

In order fully to consider the current implications of hepatitis B, both in clinical and public health practices, the Committee on Viral Hepatitis is joined in the following statement by the Public Health Service Advisory Committee on Immunization Practices. Since 1968, this latter group has considered the control of viral hepatitis in its recommendations on use of ISG and has become increasingly cognizant of the need for hepatitis B control in addressing the community management of viral hepatitis.

The following perspectives and recommendations are based on facts known about hepatitis B, sound general principles of containment of infectious diseases, and judgments on the interpretation and significance of antigenemia in hepatitis patients and other persons.

EXTENT OF THE PROBLEM

Viral hepatitis, type B, is of major public health importance in the United States. The number of cases reported have been increasing steadily since 1966, the first year hepatitis B was differentiated from hepatitis A in reports to the Center for Disease Control (CDC). In 1975 approximately 55,000 cases of viral hepatitis were reported, more than 20% of them diagnosed by report-
used in most blood banks and many health department and hospital laboratories.

HBsAg appears during the incubation period, preceding clinical or biochemical evidence of infection by several weeks. It persists during early symptomatic illness and usually disappears before liver function returns to normal. Antibody to HBsAg (anti-HBs) is first detectable late in convalescence and indicates complete or partial immunity to subsequent hepatitis B infection.

Five to ten percent of hepatitis B patients have HBsAg in their blood for many months, even years. Some of them progress to chronic active hepatitis and cirrhosis. Patients who are asymptomatic or have mild disease are more likely to have persisting antigenemia than those with icterus. Persistent antigenemia is also seen in persons with impaired or immature cellular or humoral immune systems. These include hemodialysis patients, children with Down's syndrome in institutions for the mentally retarded, patients on immunosuppression, and infants whose mothers had hepatitis B during pregnancy.

**EPIDEMIOLOGY**

Hepatitis B used to be called "serum hepatitis" and was thought to be transmitted only by parenteral routes such as inoculation or transfusion of blood or blood products. Recent evidence indicates that HBV is spread in other ways as well: Experimental studies have established that oral administration of serum containing HBV can cause hepatitis; observations in non-experimental settings have shown that this can also occur naturally. Although HBsAg has been detected in many human biologic fluids during acute infection, transmission of disease by saliva or other body fluids containing antigen has not yet been convincingly demonstrated. Evidence for person-to-person spread of hepatitis B includes the spread of infection among mentally retarded persons in institutions and transmission of disease to household or other intimate contacts of patients with hepatitis B or persons with persistent antigenemia.

Although adult volunteer blood donors are not representative of the United States population, 1-5 per 1,000 of them have HBsAg and thereby are considered potentially infectious. This and other observations on the prevalence of antigenemia in selected groups indicates that there is only a very small risk of hepatitis B for most people. However, HBV infection is more likely for those whose occupation (e.g., hospital, laboratory, and other health care personnel) or household exposure results in close and continued contact with HBsAg-positive persons. For example, a high risk of acquiring hepatitis B has been reported for patients and staff in hemodialysis units, hematology-oncology units, surgery units, and for workers in clinical pathology laboratories and plasma fractionation facilities.

Transmission of HBV is either direct—when an infectious individual is in physical contact with a susceptible person—or indirect—when the infectious and susceptible persons are separated and HBV is transferred by contaminated substance or object such as blood or needle.

Direct transmission is the principal mechanism of infection for household contacts of patients with acute hepatitis B (primarily spouses) and for workers in certain occupations. HBV can enter the body orally, through mucous membranes, or percutaneously. Blood or serum is most often responsible for infection. (Since HBsAg has also been demonstrated in saliva and other body substances, these might also transmit the agent.)

Indirect transmission is the principal mechanism of infection for persons exposed to HBV by blood transfusion, sharing contaminated needles in self-injection of drugs, and other such parenteral means. Tattooing, ear piercing, using multiple dose syringes, and handling blood-stained towels have been implicated. Oral exposures such as mouth pipetting infective substances have also caused hepatitis B. Airborne and vector-borne mechanisms of spread of HBV have been postulated but never proven.

**CONTROL AND PREVENTION**

Widespread application of serologic tests for HBsAg have underscored the significance of hepatitis B as a clinical and public health problem. HBsAg in the blood of a patient or of an apparently healthy person raises questions not only of the presence of liver disease but also of the risk of transmitting infection to others. Only limited data are presently available to assess the extent of this risk, but it is clear that not all HBsAg-positive persons spread infection. The likelihood of transmitting HBV to susceptible contacts is related to many factors including personal hygiene, aseptic technique, protective clothing, state of mind, etc.

Recommendations for limiting the spread of hepatitis B have emphasized minimizing exposure to sources of infection. They have focused on improving personal and environmental hygiene, disease surveillance, public education, and the safety of blood transfusion. These have been partially successful.

Several prospective studies of transfused patients show that the incidence of transfusion-associated hepatitis B has been significantly reduced by the required testing of every unit of blood for HBsAg by a method of third generation sensitivity (either RIA or RPHA). Nevertheless, there remain a small number of cases presumably due to transfusion of blood contaminated with HBV but with insufficient HBsAg for detection with the most sensitive tests currently available.

An additional benefit of the advent of HBsAg testing of blood donors has been definitive identification of a 3-10 times greater prevalence of HBsAg contamination of blood collected from paid donors than in blood from volunteer donors. The term "paid donor" is used here to describe a donor whose economic status or life-style greatly increases the likelihood that his blood is infectious. It does not include donors who are paid for regularly contributing low-risk blood for special pur-
poses. Most cases of transfusion-associated hepatitis appear to be caused by an agent, or agents, other than HAV or HBV. They are reasonably called non-A, non-B hepatitis cases. The risk of non-A, non-B hepatitis is also much greater from paid donor blood than from volunteer donor blood. Therefore, currently the most effective means of further reducing the risk of transfusion-associated hepatitis is elimination, to the extent feasible, of blood from paid donors.

Eliminating commercialism in acquiring blood for transfusion is one of the key objectives of the National Blood Policy. (This policy was announced by HEW in 1973 and is supported by the American Blood Commission, formed in 1975.) In order to provide information regarding relative safety to physicians prescribing and patients receiving blood transfusions, the Food and Drug Administration published a proposal in the Federal Register in November 1975. This proposal would require that all units of blood be labeled to identify the donors as paid or volunteer. Labels would also state that blood from paid donors is associated with a higher risk of hepatitis than blood from volunteer donors. Such labeling requirements are already in effect in California and Illinois. In Illinois there has been a dramatic reduction in the use of blood from paid donors and, based on one study, an equally dramatic reduction in the incidence of transfusion-associated hepatitis.

Definitive control or prevention of hepatitis B awaits development of biologics for active and passive immunization or other specific measures. In the meantime, we must continue to rely on general measures to reduce the chances of exposure and on sound practices for containing infection when the risk of hepatitis B is great.

General Recommendations

The following recommendations offer guidance to those living or working where there is a risk of hepatitis B infection; they can be applied to all settings or environments. (Recommendations tailored to specific settings will be presented later.)

Personal Hygiene: Good personal hygiene is the keystone of protection against hepatitis B infection. The single most important practice is careful handwashing. This combined with the common-sense avoidance of likely sources of infection are fundamental in hepatitis B control.

Disinfection and Sterilization: Most data on inactivation of HBV are from studies conducted prior to the discovery of the HBsAg in 1965. And many of these studies are deficient in that they involved too few volunteers. In recent years there have been limited opportunities to study the effects of physical and chemical treatments on HBV infectivity. This is because animals that can serve as models for HBV studies are in short supply and HBV has never been adapted to a tissue culture system.

HBV in blood plasma or serum appears to be quite stable and is capable of withstanding wide ranges of temperature and humidity and a variety of chemical agents. Its infectivity persisted for 15 years at -20°C, 6 months at room temperature, and 4 hours at 60°C. In a 1:10 dilution of serum, infectivity was destroyed by boiling for one minute although antigenicity was not altered.

The following methods for disinfection or sterilization are recommended either because of proven effectiveness in volunteer studies, demonstrated destruction of immunological reactivity of HBsAg, or, on an empirical basis, because of known biocidal activity of the particular treatment.

Heat sterilization is the treatment of choice for instruments and other objects that can conveniently be handled this way. The importance of thoroughly cleansing instruments, containers, or surfaces, etc. to remove adherent material before treatment cannot be overemphasized. HBV has been shown or is expected to be inactivated by heat under each of the following conditions: 1) boiling in water (100°C) for 10 minutes, 2) steam under pressure (autoclaving) at 121°C and 15 pounds per square inch pressure for 15 minutes, or 3) dry heat (160°C) for 2 hours.

Alternatives to heat, presumed to be effective, include some chemical disinfectants: 1) solutions of sodium hypochlorite, 0.5% to 1.0% (5,000-10,000 ppm available chlorine) for 30 minutes, 2) 40% aqueous formalin (16% aqueous formaldehyde) for 12 hours; formalin, 20% in 70% alcohol, 18 hours, 3) 2% aqueous alkalinized glutaraldehyde for 10 hours, and 4) gas sterilization with ethylene oxide (check manufacturer’s recommendations).

Immune Serum Globulin: There have been conflicting results from the many well-designed studies evaluating the efficacy of ISG in hepatitis B prophylaxis. Most commercial lots available before 1972 appeared to be ineffective in preventing or modifying parenterally acquired hepatitis B. The lack of effect of these ISG preparations was presumed to be due to the absence or low levels of anti-HBs. By contrast, more than 90% of samples of ISG manufactured after 1972 were found to have some anti-HBs. Although there was considerable variation in the titers of anti-HBs among lots tested, titers were generally greater than in pre-1972 lots.

ISG with detectable but low levels of anti-HBs has been shown to reduce the clinical severity and complications of HBV infection when the virus inoculum was small and the exposure either percutaneous or oral. Therefore, ISG with anti-HBs could be of value in hepatitis B prophylaxis under some conditions of exposure.

ISG with high anti-HBs titers (1:200,000-1:500,000 passive hemagglutination—PHA), hepatitis B immune globulin (HBIG), has been evaluated in a few investigational trials in settings with various kinds of exposure and found to provide significantly greater protection against hepatitis B than ISG with intermediate or low anti-HBs titers (≤ 1:5,000 PHA). It is expected that
HBIG will be licensed for specified uses; guidelines for use are under development.

As has been stated, standard ISG appears to provide only limited protection against hepatitis B under some conditions of exposure. It is therefore recommended that ISG manufactured after 1972 be offered to individuals who clearly have had an oral or percutaneous exposure to known HBsAg-positive blood or fluids (e.g., accidental ingestion or accidental needle punctures). The best available data on dosage suggest that, for an adult, a single 5 ml intramuscular injection may be of benefit.

Reporting and Education: Every case of hepatitis should be tested for HBsAg and reported promptly to the local or state health department. Reporting of confirmed cases permits more accurate hepatitis surveillance, identification of changes in epidemiologic trends, and community-wide prevention and control measures.

HBsAg-positive persons and their close contacts should be fully informed about HBV and how to limit its spread. This education is especially important for health care professionals since they often have continual exposure to sources of possible infection (patients, blood, body fluids, etc.).

Recommendations for Minimizing Transmission in Specific Settings

The risk of acquiring hepatitis B is greatest for persons who frequently encounter hepatitis patients or specimens containing HBsAg. Generally speaking, the highest risk involves a few specific household and hospital settings. Before considering them in detail, and to avoid redundancy, some general comments can be made.

Regardless of the setting, patients and human biological specimens should be managed carefully because some will present an unrecognized hepatitis risk. To protect susceptible patients and staff, blood and other specimens from hepatitis patients and HBsAg-positive persons should be labeled as such and optimally be enclosed in impermeable bags. Charts of these patients should be flagged (e.g. “Hepatitis B,” “blood and instrument precautions,” etc.). All persons involved, patients and staff, should practice careful handwashing and personal hygiene.

Specific recommendations should be tailored to the particular setting and reflect the unique aspects of each environment:

Household: Within the household, spouses and other intimate contacts of patients with acute hepatitis B or of asymptomatic HBsAg-positive persons appear to have the greatest risk of infection. It is important that all household contacts know how hepatitis B is transmitted and that blood and possibly other body fluids, if HBsAg-positive, might spread HBV infection. In addition to practicing good personal hygiene (especially handwashing), they also need to handle and dispose of blood-contaminated articles carefully and avoid practices which might increase the opportunity for infection such as sharing razors, toothbrushes, towels, washcloths, or other personal items.

Hospitals: General Patient Care Area: Hepatitis B has spread from patients to staff in intensive care units, transplant units, hematology-oncology wards, and general medical-pediatric and surgical wards. Nevertheless, patients with acute hepatitis or HBsAg-positive persons in these environments generally need not be placed in isolation; they can be cared for in semi-private or ward accommodations providing blood and instruments are handled with the precautions discussed earlier. When handling blood or blood-contaminated objects from HBsAg-positive patients, staff should wear gloves and possibly other protective clothing as well. During procedures which could result in splattering or splashing infective material, a surgical-type mask or facial covering to protect eyes, nose, and mouth has value. Disposable needles and syringes, proper sterile technique, and adequate sterilization and chemical disinfection procedures are important to control percutaneous spread.

Laboratories: Clinical biochemistry and hematology-serology laboratories, hepatitis research laboratories, and autopsy laboratories are recognized to be settings where hepatitis B transmission occurs. Common exposures are accidentally pricking the skin with instruments contaminated with HBV, pipetting infective fluids, contaminating cuts or scratches with infective blood or splashing it in eyes or mouth. Contamination may result from shaking specimens, homogenizing, opening screw-cap bottles, blowing the last drop of fluid from a pipette, pouring fluids, and centrifuging. Mouth pipetting, smoking, and eating in the laboratory are dangerous practices and should be forbidden. Protective clothing, including gloves and facial coverings (if there is danger of splashing), may be appropriate. This is especially important when performing autopsies on HBsAg-positive persons. Gloves and other protective clothing must be properly used (changed frequently, especially when contaminated or torn) and should not be considered a substitute for careful technique and good personal practices. Work areas should be thoroughly cleaned and disinfected daily. All laboratory accidents resulting in HBsAg exposure must be promptly reviewed with regard to need for environmental decontamination and personal prophylaxis.

Laboratories should specify that potentially infective specimens be properly packaged and labeled. It may be useful for them to have a designated safety officer who keeps records of laboratory accidents, educates personnel in methods of control and prevention, and periodically evaluates and updates safety procedures.

Hemodialysis Units: Hemodialysis units present a great risk of hepatitis B for patients and staff. Most infections in patients are subclinical, and a large percentage of them result in persistent HBsAg-positivity. Staff commonly have overt hepatitis, often hampering operations.
HBV can be introduced into the units by patients, staff, or infective blood, plasma, or blood products. Once seeded, HBV can be spread among patients and staff by personal contact or parenteral exposure.

**Surveillance:** Continuous surveillance of patients and staff for HBV infection is essential. Those who are seronegative should be tested periodically for HBsAg, anti-HBs, and, possibly, SGOT and/or SGPT. The frequency of testing depends on whether hepatitis B is occurring. If no hepatitis B infections among patients or staff develop in 6-12 months of testing, routine sampling intervals of 2-4 months would be reasonable. If antigen or antibody does appear, HBV spread is probably occurring, and more frequent (e.g., monthly) sampling should be undertaken.

It is useful to screen new hemodialysis patients and staff for HBsAg and anti-HBs before admission to the unit. This provides baseline information on their susceptibility or potential infectiousness and the need to institute precautions.

**Records:** Detailed records of patient management (e.g., machine and other equipment assignments and dates of use) will be essential to determine whether any infections are related to specific procedures. Records should also include complete descriptions of mishaps (needle punctures, membrane leaks-ruptures, etc.).

**Staff:** Highest quality aseptic technique is fundamental to prevent HBV spread. Protective clothing should be used but changed on a regular basis and whenever obviously contaminated. It should not be worn outside the unit. Using gloves during procedures where there is contact with blood such as handling shunts, drawing blood, or cleaning or dismantling dialysis machines, has been shown to decrease the risk of HBV infection. A fresh pair of gloves should be used with each patient. However, gloves are not a substitute for good technique and proper personal hygiene. Surgical-type masks or other facial coverings may decrease the risk of infection when splattering of blood occurs. Abrasions, lacerations, and other breaks in the skin should be bandaged to protect them from contact with infectious material.

**Operating Procedures:** Operating procedures should minimize the amount of close personal contact among patients and staff. Overcrowding is to be avoided, and individual equipment and supplies used whenever possible. Patients and staff should not eat, drink, or smoke in the immediate hemodialysis area.

Susceptible patients should be separated from known HBsAg-positive patients or those whose antigen status is unknown. If practical, staff should be assigned to attend HBsAg-positive or HBsAg-negative patients, but not both, during the same shift. Staff with anti-HBs might preferentially be assigned to HBsAg-positive patients. Until their antigen/antibody status is known, new patients should be managed in areas separate from those being used for chronic hemodialysis.

After each use, equipment which cannot be heat or gas sterilized should be washed to remove adherent material and cleaned with a disinfectant solution. Non-permeable disposable diaphragms can prevent contamination of equipment such as venous pressure monitors.

**Institutions for the Mentally Retarded:** Viral hepatitis, both sporadic and epidemic, has long been known to occur in custodial institutions for the mentally retarded and poses a risk for both patients and staff. The risk of infection appears to increase with the duration of institutionalization. Practical precautions are needed to reduce transmission of HBV from HBsAg-positive mentally retarded residents to persons such as teachers, classmates, and parents who come in close personal contact. In general and until more definitive information on the infectiousness of persons with HBsAg becomes available, it is important to avoid placing unwarranted limitations or restrictions on HBsAg-positive retarded persons.

**Surveillance:** Serologic surveys of institutionalized persons are not considered necessary as a routine procedure. However, in institutions where hepatitis B infection has been shown to be endemic, periodic screening of residents will be helpful in identifying high-risk areas, in investigating hepatitis outbreaks, and in evaluating the effectiveness of control measures.

Since persons who are antigen-positive may become negative even after 6 or more months of positivity, each HBsAg-positive person should be retested periodically to determine whether the antigen persists. Once seroconversion to anti-HBs occurs, any specific hepatitis precautions can be removed.

**Control Measures:** Parents and personnel responsible for the care of institutionalized mentally retarded persons must be aware of the need for good hygienic practices. This is especially important after caring for open wounds or having contact with blood or blood-contaminated fluids and before eating or handling food. Personal toiletry articles should not be shared. No special procedures need be observed for laundering clothing or linens, although all blood-contaminated items should be handled with appropriate precautions (gloves, etc.). No other restrictions need be imposed on antigen-positive residents when they participate in routine activities such as special education programs and in nursery, day care, or foster care facilities.

Physicians, dentists, laboratory workers, and others providing care for known antigen-positive persons should be so advised so that adequate precautions can be exercised during patient contact or specimen handling. Because of the likelihood of contact with unrecognized HBsAg-positive persons or specimens, health workers in institutions should always be alert to the risk of hepatitis B and use appropriate protective measures.

**Community Placement Programs, Nursing Homes:** Because residents of institutions for the retarded more frequently are HBsAg-positive than non-institutionalized populations, they should be tested for HBsAg before
Management of High-Risk Persons and Populations

Certain persons and groups, particularly those involved in health care, are at greater risk than the general population of acquiring hepatitis B; this is because of occupational and environmental exposures. Since most hepatitis B infections are subclinical and 5%-10% of those infected may develop persistent HBsAg, there may also be an increased risk of hepatitis B for the general population brought into contact with HBsAg-positive individuals in health care settings. Precautions against spreading HBV infection currently depend on awareness of personal risks and use of good hygienic practices.

Management of persons with persistent HBsAg who work in environments and under circumstances where there are many chances for transmitting HBV infection (e.g., regular contact with blood, involvement with parenteral and surgical procedures, etc.) require special consideration. As has been emphasized, the presence of HBsAg is sufficient reason for personal precautions, but not necessarily evidence of a substantial hepatitis risk for contacts or associates. It is extremely important to prevent misunderstanding and unreasonable management of persons or population groups with HBsAg. Since it now appears that individuals who have persisting HBsAg may become negative even after 6 or more months of positivity, each antigen-positive person should be retested periodically (e.g., every 6 months) to determine whether antigen persists.

General Recommendations: Persons working where there is a high risk of hepatitis B infection (especially hemodialysis or hematology-oncology units and clinical laboratories) need to be fully aware of the risks and to use good hygienic practices to minimize any chance for infection. It is reasonable to keep such “high risk” population groups under serologic surveillance for hepatitis B infection in order to be able to detect and investigate problems as quickly as possible. On the other hand, there is no need to routinely test health professionals and hospital employees not working in high-risk areas.

Health personnel observed to be HBsAg-positive should not be restricted from patient contact solely on the basis of this serologic finding. Rather, their personal procedures and practices should always reflect an awareness of the potential for transmitting HBV and include rigorous efforts to reduce any chance that transmission might occur. Knowing that contact with blood or serum containing HBV is the likely cause of hepatitis B infections, scrupulous aseptic technique, avoidance of personal hand injuries, and use of gloves in office-based minor surgery, dental procedures, wound dressing, etc. have obvious value.

Health personnel clearly associated epidemiologically with HBV transmission obviously pose a greater risk for patients and associates and must be evaluated carefully with respect to continuing risks. In these instances, more restrictive measures (e.g., limiting or eliminating some types of procedures or contact with patients) may be needed. Obviously, each such episode will have to be dealt with separately and recommendations and control measures tailored to the specific conditions.

Health Care Personnel (Dentists, Nurses, Physicians, Technicians, Etc.): Recent investigations of hepatitis B among contacts of antigen-positive health personnel demonstrate that HBV transmission does occur but seems to be very rare. There appears to be considerable variation in the likelihood that persons with persistent HBsAg will spread infection. The risk depends in part on the kind and extent of contact with susceptibles. In the few instances where epidemiologic evidence linked health workers in specific hospital or dental environments to hepatitis B cases, infection seemed to have been caused by a presumably minute amount of blood or serum which was transferred during routine procedures. Minor hand injuries have generally been thought to be the source of infective blood which then is introduced by oral or percutaneous routes.

Food Handlers: There is no evidence that HBsAg-positive food handlers pose a health risk to the general public, and transmission of hepatitis B by food has not been documented. Nonetheless, it is prudent to restrict food handlers with acute hepatitis B from working while ill. Food handlers with persistent HBsAg, like all antigen-positive persons, should be educated about HBV transmission, the need for attention to good personal hygiene, avoidance of hand injuries, etc.

Pregnant Women: Women with hepatitis B infection during pregnancy sometimes transmit the infection to their infants. The risk is highest when an acute illness occurs during the third trimester. Infected newborns who may be HBsAg-negative at birth generally become HBsAg-positive 1 to 2 months later in the absence of clinical hepatitis. Most infants who become HBsAg-positive develop persistent HBsAg, and many eventually have histopathologic evidence of inflammatory liver disease. For these reasons, seronegative pregnant women working in high-risk environments should be transferred to work areas where the risk is lower for the duration of pregnancy.

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transfer to other institutions or discharge to community placement programs or nursing homes. Information on their antigen status will alert health personnel and others who have close contact with them in community programs to use precautions when there is a risk of hepatitis B. HBsAg-positive persons should be given the same consideration for placement programs or nursing homes as those who are negative. Parents and personnel in contact with antigen-positive retarded persons should be informed of the risk of hepatitis B and given instruction in control and prevention. (HBsAg-positive residents in community programs should be managed as are those in institutions; see above.)
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Institutions


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