



COVID-19 Prevention and Treatment Guidelines for Individuals who have Decision-Making Challenges

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Regarding consent for COVID vaccination and treatment and post exposure prophylaxis with monoclonal antibodies (mAb) for COVID-19 vulnerable populations with decision-making challenges, including those who may be residents/patients in a psychiatric hospital, psychiatric unit, Adult Foster Care (AFC) setting, nursing home, home for the aged, and other settings:

The following guidelines are issued to ensure equitable access to prevention and treatment strategies for individual with decision-making challenges as evolving data shows a heightened risk of COVID-19 for certain populations, along with the proven effectiveness of vaccine prevention strategies and rapid access to monoclonal antibody (mAb) therapy treatment in reducing morbidity and mortality.

There are currently FDA approved prevention strategies for COVID-19, namely vaccinations. There is also emergency use authorization (EUA) from the FDA for monoclonal antibody (mAb) treatments and post exposure prophylaxis for individuals who have been determined to be positive for COVID-19 and with increased risk of medical morbidity and fatality.

The FDA must ensure that recipients of the vaccine under an Emergency Use Authorization are informed, to the extent practicable given the applicable circumstances, that FDA has authorized emergency use of the vaccine, of the known and potential benefits and risks, the extent to which such benefits and risks are unknown, that they have the option to accept or refuse the vaccine, and any of the available alternatives to the product. Typically, this information is communicated in a patient "fact sheet." The FDA posts these fact sheets on their website.

It is important to remember when a person is offered vaccination or treatment for COVID-19, that adults of sound mind are permitted to refuse medical treatments and procedures. To ensure that recipients are informed, an explanation of the risks and benefits of the treatment, as well as the risks of refusal of such interventions are required. All adults are presumed competent, and therefore should be allowed to decline prevention and treatment, presuming their decision-making is sound. Individuals, regardless of setting, that may be at risk of decision-making challenges must be evaluated for decision-making capacity if they have not been previously adjudicated a legally incapacitated person. Clinicians providing care for Individuals in psychiatric hospitals, AFC settings, nursing homes, homes for the aged, long-term care facilities and other similar settings should have heightened attention that individuals in those settings may be at increased risk for decision-making challenges, and many may have already been determined to lack decision-making capacity and be assigned guardians with medical decision-making authority by probate courts.

Given the risks of negative outcomes associated with COVID-19 for individuals with serious mental illness, intellectual and developmental disabilities, substance use disorders, and older adults, it is vitally important that an individual refusing prevention and treatment interventions be evaluated for decision-making capacity if they have not been previously adjudicated a legally incapacitated person.

A legally authorized decision-maker (e.g., a guardian or parent) should be consulted and may consent on behalf of patients that have been determined to lack capacity to make medical decisions. Medical professionals should make an attempt to obtain the patient's assent to treatment before the providing the medical intervention. However, a legally authorized substitute decision-maker does have the authority to consent to medical interventions recommended by medical professionals and medical professional may provide those intervention in the absence of the patient's assent as these interventions yield benefits that outweigh their risks and can lead to lifesaving results.

Ongoing education and dialogue over time regarding COVID-19 and its risks, the risks/benefits of the vaccine and, when indicated, monoclonal antibody treatment and any alternative treatments and risks of the refusal of those interventions should be provided to the patient and legally authorized decision maker.

General Guidelines:

- 1) Regarding vaccine administration:
 - a. Provide information about vaccine, its benefits and risks, the extent to which such benefits and risks are unknown, as well as any available alternatives to the product
 - b. Explain how the vaccine will be administered
 - c. Explain the risk of not getting vaccinated including the risks of acquiring COVID-19 with and without vaccine, and about the prognosis of COVID-19 with and without vaccine
 - d. Document all conversations in the medical record of the patient
- 2) Regarding monoclonal antibody treatment:
 - a. Provide information about mAb treatment, its risks and benefits, and COVID-19 and its risks without treatment
 - b. Explain how mAb will be administered with a step-by-step explanation
 - c. Explain information about what will happen following the treatment
 - d. Document all conversations in the medical record
- 3) Assess whether individual is an individual who requires decision-making supports
Does the individual have a guardian?
 - a. If a minor, the youth is unable to consent independently, and thus providers should identify who has proper parental/legal authorization to consent to treatment
- 4) If the individual has a legally authorized decision-maker, have they authorized the vaccine or the treatment in writing?
 - a. If yes, proceed with the vaccine or the mAb treatment if the incapacitated

individual assents (agrees based on verbalization or actions)

- b. If yes, but the incapacitated individual is not assenting, notify the guardian or legally authorized decision-maker, consider further education and engagement of the incapacitated individual, but proceed with the vaccine or the mAb treatment with guardian/parental consent
 - c. If no, and the vaccine or treatment has been declined by the legally authorized decision-maker, these interventions would not be administered
- 5) If individual is an adult without a guardian, have they been assessed for decision-making ability?
- a. If yes, but the person appears to lack decision-making ability, is there a healthcare proxy/advance directive to invoke?
 - b. If yes, but the person appears to lack decision-making ability, and there is no
 - c. healthcare proxy/advance directive, pursue guardianship through the probate court
 - d. If an alternative decision-maker is assigned, proceed to steps delineated in (4) above