

Should Uninsured Patients be offered Clinical trials?

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Background: Accruing patients to clinical trials without health insurance raises several ethical issues. While uninsured patients deserve the same options as their insured peers, when considering whether to offer a clinical trial, care must be taken to evaluate the uninsured patient's ability to afford the standard of care treatment during the trial and his/her access to the study drug post-trial if it proves safe and efficacious. Patients without insurance who participate in research trials may be less likely to benefit from the findings, since the uninsured patient may be unable to afford the drug if it is approved and marketable. This is less likely the case for cancer treatments, since these trials can last for years, but it is a concern for research that unfolds in shorter duration such as for diabetes treatments [1]. In the case of diabetes, uninsured patients may not be able to afford insulin, so a trial may be the only access to medication. In cases such as these, uninsured patients may feel they have to enter the study but may have no chance of benefiting from its results. It is worth restating that the participants should be selected based on the scientific needs of the study and independently of the participant's financial status. In research ethics, justice is the fair selection of research participants; therefore, insurance status should not be a determinant of patient eligibility. However, ethically, the patients should have the potential to benefit from the outcome of the study in which they contributed. Therefore, the PI must be able to evaluate and present the likelihoods of benefits and risks to these patients not only regarding costs and side effects in the trial, but also after the trial with regards to accessibility to the agent if it proves safe and efficacious.

Scenario: A low income family with no health insurance finds out the family member who supports the family has been diagnosed with a malignant disease. Normally, the family pays out of pocket for health expenses, however, affordability of treatment for this disease type is unrealistic both due to the cost of the treatment and the patient's inability to continue working.

Expert Opinion: This story isn't uncommon, as 8.8% of Americans were uninsured in 2017, with African Americans, Asians, and Hispanics having the lowest rates of insurance coverage [2]. By the fourth quarter of 2018 the uninsured rate had risen to 13.7% [3]. Furthermore, 28% of working-age adults in the US with year round health insurance were still considered underinsured in 2016. Given the situation of this patient, the only option for treatment may be to enroll in a clinical trial. From an investigator's perspective, justice must be upheld during patient accrual with the fair selection of research participants, so it is ethical to enroll uninsured patients in clinical trials. At the same time, however, uninsured patients don't have the same options available to them as their insured counterparts. The uninsured patient's need to enroll in the trial, unknown costs not covered by the trial, and the potential unavailability of the study drug after trial for the patient all raise concerns of exploitation. Coercion, namely when one person overtly threatens another to gain compliance [4], isn't a factor in this case. Undue influence, however, may be. Undue influence can result when the reward for participating in the trial is excessive and induces participation in the study when the patient would otherwise have not enrolled [4, 5]. In this case, uninsured patients with less options are more susceptible to inducements because participating in the trial may be the only affordable way to obtain treatment. It's likely that this

problem can be circumvented with a comprehensive presentation to the patient before enrollment. Not every procedure in a clinical trial is covered by the sponsor, and the costs attributed to standard of care will likely have to be paid for by the patient. Therefore, these costs should be presented to the patient upfront, dispelling a possible misconception that the trial is entirely free. Alternatives to enrollment should be presented regardless of the level of their desire to partake in the trial. These patients have options, potentially including financial assistance for uncovered costs of the trial or of other treatment from social work, all of which should be clearly identified and discussed with every patient prior to enrollment. Because there are difficult ethical issues surrounding inclusion of un- and underinsured patients in biomedical research, there is a the need for more research regarding protection and inclusive practice with these patients [6].

Recommendation: The patient should be offered the clinical trial, but the informed consent process must be extensive, including the cost of procedures not covered by the trial and an explanation of other treatment options and how they might be paid for. A consultation with Social Work is also recommended so that alternative sources of payment for treatment can be explored.

References

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