

Case Study: Ethics in Nanomedicine

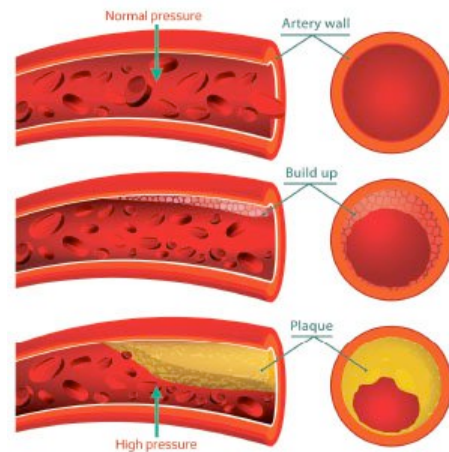
Background

For ethical reasons, nanomedicines are researched heavily before studies are done on humans. It is very difficult to assess whether a nanomaterial is safe to use on humans as each type of nanomaterial is different and can have very different properties from other types of nanomaterials. The same type of nanomaterial can even display different physical and chemical properties if they come in different shapes or sizes. For example, a nanomaterial that is 20nm in size might not be toxic to humans but the same nanomaterial in a slightly smaller size of 1nm might be toxic to humans.

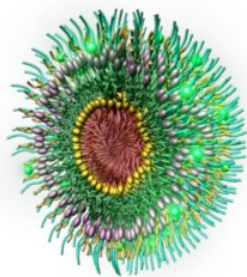
Nanomaterials can also behave very differently inside a living organism than they do in a lab dish. Chemical and physical properties of nanomaterials also depend on the environment they are in and therefore, can change size or shape when they are inside an organism. For example, the 20nm size nanomaterial might separate into many 1nm sized nanomaterials once inside the body of an organism resulting in the nanoparticle to behave in unexpected ways.

The Scene: Atherosclerosis Treatment with Nanomedicine

*Arteries are blood vessels that carry oxygen-rich blood to your heart and other parts of your body and plaque is made up of fat, cholesterol, calcium, and other substances found in the blood (NHLBI, 2015). Over time, plaque can build up in the artery and harden, making the artery narrower and may eventually lead to a blockage. Particles of this plaque can also unexpectedly rupture and break loose, travelling to other parts of the body and possibly causing a blockage which may lead to an acute heart attack or stroke.



You are a senior researcher at the Nanohealth Center of Advanced Medical Technology. You and your team of senior scientists and engineers have been working on a new drug consisting of a nanomaterial that is aimed at detecting and treating arterial plaque (clogged arteries).



Your new nanomedicine is called a 'micelle'. Your nanomedicine is made up of a group of lipid based molecules that form a sphere and a piece of protein (a peptide) on the surface. This peptide will bind to the plaque.

Your team has carried out many invitro tests to research the effects of this nanomedicine. Your team has also recently fed mice a constant high fat diet to allow plaque to build in their arteries. Micelles were then injected into the mice. You allowed 3 hours for the micelles to circulate the body and attach themselves to plaque. When the results were gathered, your team found that the micelles had not only attached to plaque but they had attached to plaque that is most likely to rupture. Identifying areas of plaque that are likely to rupture could save many lives. Your team now wishes to hold human trials and you have a dozen volunteers who all suffer from severe atherosclerosis. However, as this is the first human trial of this kind, the government have assigned an ethical committee to review your research and decide whether or not to progress with the trial.

Your task:

Form groups of 3-4. Your group will be the team of researchers, scientists and engineers of the micelles. You must present your research to the ethical committee and provide evidence that the nanomedicine is safe and ethical to be used in human trials.

Between your team, you must:

- describe the in vitro tests you have run
 - present the pros and cons of your trial
 - any risks or ethical concerns
 - present your view on why you think the trial should go ahead
- *remember, the benefits must outweigh the risks in order to progress with the trial

Research that may help your case:

- research on the number of heart attacks, strokes in the nation
- research on the process of invitro
- similar studies that have been successful
- ethical boundaries

Describe the in vitro tests you have run:

Present the pros and cons of your trial:

Any risks or ethical concerns:

Present your view on why you think the trial should go ahead:
