Treatment as Prevention: Protecting patient autonomy

June 7, 2011 By Joseph Sonnabend, MD

Patient autonomy is just a particular instance of individual autonomy, a term that may sound pretty dry and academic but if we used the term individual freedom we would essentially be talking about the same thing.

Respect for the autonomy of the individual may be the most important of the principles that form the foundation of medical ethics. (1)

One attribute of personal autonomy is: “the capacity to be one’s own person, to live one’s life according to reasons and motives that are taken as one’s own and not the product of manipulative or distorting external forces.” (2)

There is no disagreement about the importance of respect for individual autonomy but as I’ll explain, it seems that its pre-eminence is being questioned in some proposals to use antiretroviral treatment to prevent transmission of HIV.

The recent demonstration that antiretroviral treatment can prevent transmission of HIV among serodiscordant heterosexual couples is great news. However, when the person offered treatment has not yet been shown to personally benefit from it, an ethical issue needs to be addressed. This is because it has yet to be reliably shown that for people with greater than 350 CD4 lymphocytes, starting treatment immediately rather than deferring it confers a net benefit; indeed, it may even prove to be harmful. START is a randomized controlled trial now enrolling that will provide needed information, but we will have to wait several years for its results.

The issue isn’t whether people with greater than 350 CD4 lymphocytes should or should not receive treatment. A respect for their autonomy means that the decision whether or not to do so is made by them and is made free from coercion.

A recent issue of the Journal, Public Health Ethics (3) is devoted to ethical issues associated with the proposal that a program of universal testing and treatment of infected individuals could bring an end to the HIV/AIDS epidemic. Such a proposal would involve the treatment of healthier HIV infected individuals not at this time known to personally benefit from antiviral medications which could even harm them.

In an article in the journal referred to above, public health ethics is said to require an approach where respect for individual autonomy is not paramount; a commitment to the supremacy of individual autonomy could have no place where the “primacy of collective wellbeing is the starting point”.

In that case I wonder just how desirable a collective wellbeing would be where individual rights were subservient to whatever was defined as the collective good.

I can only hope that this goes nowhere, as abandoning the pre-eminence of respect for individual autonomy opens the door to tyranny, paternalistic or otherwise. Individual freedoms have been hard won, and we should always be aware of harms that have been perpetrated in the name of the public good, even leaving alone the problem of who defines what constitutes the public good.

In public health, medical research and medical practice, concern for individual autonomy remains paramount. The only commonly agreed acceptable exemption is the restriction of personal freedoms to prevent harm to others such as limiting the movement of individuals with highly communicable diseases where the harm that may be done to others is considerable. That is of course outside the criminal justice system, among individuals who are free.

People have the right to make decisions about their treatment, their participation in a research study, or in a public health intervention, free from coercion.

Providing misleading information is a form of coercion; withholding information may also be coercive.

Providers of health care have an obligation to provide patients with honest information to inform their decisions. This must include information about what is known about the risks and benefits of treatment, as well as what remains conjectural.

Information and the strength of the evidence upon which it rests:

It’s not enough to simply provide individuals with information concerning the benefits and risks of a particular treatment. In order for the information to be useful we must also indicate the strength of the evidence on which the information rests. (4)

The most reliable evidence regarding the effects of a particular treatment is provided by results of randomized controlled clinical trials. This is because the treatment in question has been put to the test in a protocol that minimizes bias; we can therefore have a greater degree of confidence that effects observed are in fact caused by the treatment.

Unfortunately information derived from randomized controlled trials is often unavailable. The clinical trial may not yet have been completed, or for whatever reasons the trial cannot be undertaken.

When this is the case we have to consider evidence of inferior quality, for example, evidence derived from reviews of patient records or observational studies, and the opinion of experts.

Observational studies are beset with interpretative difficulties because subjects are not randomly assigned to receive one or another kind of intervention. The particular reasons why participants were selected for study may influence the outcome rather than the effects of the intervention.

Expert opinion:

In all the systems I have seen that grade the quality of different kinds of evidence, expert opinion is at the bottom of the list.

But expert opinion can be valuable to an individual in coming to a treatment decision when evidence of the highest quality is not available. The advice of one’s physician can be valuable even when there is reliable evidence.

Generally, evidence comes from studies of populations, providing a result that is generally applicable. But a personal physician knows the details of individual patients and can fine tune the results obtained from clinical trials to the needs of an individual patient.

It’s absolutely appropriate to seek advice from one’s physician. Many individuals, maybe most, entrust their physicians to make the best treatment recommendations for them. This is after all what we expect from our doctors.

Respect for patient autonomy means that patients have the right to make their own decisions regarding their treatment if they choose to do so, and that we provide whatever evidence is available to inform their decisions.

HPTN 052

HPTN 052 is the study which demonstrated the efficacy of antiretroviral treatment in preventing transmission of HIV among serodiscordant heterosexual couples. Although the result was not unexpected it is nonetheless significant because it was obtained from a randomized controlled clinical trial.

We now know that the uninfected partners of individuals with greater than 350 CD4 lymphocytes will benefit from treatment of the HIV positive partner. At this time we can only have an opinion about whether starting treatment immediately or deferring it will benefit or harm the infected partner with greater than 350 CD4s or be without effect - apart from cost.

Most of the jubilant reports of the results of HPTN 052 do not mention the problem facing the healthier HIV positive partner in coming to a decision.

Do the commentators just assume that it’s been established that all infected individuals receive a net benefit from treatment irrespective of CD4 numbers? Or do they not believe it to be important that patients make their own decisions regarding their treatment?

I wish I could say I was startled to read in one newsletter that “For treatment as prevention to work..... people need to be convinced that early treatment is in their interest.”

Convincing people to take a possibly perilous course of action based merely on opinion and evidence of inferior quality is a step on a road that ends with enforcement.

A respect for individual autonomy means that we respect the right of individuals to make decisions on their own behalf, free from even subtle coercion. Our obligation as providers of health care information is to not only provide information, but also an indication of the quality of the evidence supporting it.

At this time we do not know that individuals with greater than 350 CD4 lymphocytes receive a net benefit from antiviral treatment. There is evidence that they may, but until this is put to the test in a randomized controlled trial such as START, we must not mislead them by trying to convince them that “early treatment is in their interest”.

Given adequate information, a person with greater than 500 CD4 lymphocytes may reasonably decide to take antiretroviral drugs to lessen the risk of infecting a partner even knowing that there may be no personal benefit or that there is a possibility of harm.

At the end of the day what’s of central importance is that we respect our patient’s right to make choices about his or her treatment, and provide honest information to inform that choice, recognizing the difference between expert opinion and established fact.

Ever since Beauchamp and Childress published the first edition of their classic text, Principles of Biomedical Ethics, in 1979 four principles, beneficence, nonmaleficence, justice and respect for autonomy have provided a frequently used framework for discussions on medical ethics

These are defined as follows:

Respect for autonomy: respecting the decision-making capacities of autonomous persons; enabling individuals to make reasoned informed choices.

Beneficence: this considers the balancing of benefits of treatment against the risks and costs; the healthcare professional should act in a way that benefits the patient

Non maleficence: avoiding the causation of harm; the healthcare professional should not harm the patient. All treatment involves some harm, even if minimal, but the harm should not be disproportionate to the benefits of treatment.

Justice: distributing benefits, risks and costs fairly; the notion that patients in similar positions should be treated in a similar manner.

Beauchamp and Childress; Principles Biomedical Ethics, OUP, 5th edition

Christman, J, 2001“Autonomy in Moral and Political Philosophy”, The Stanford Encyclopedia of Philosophy (Fall 2007 Edition) , Edward N. Zalta (ed.), URL = <http://plato.stanford.edu/archives/fall2007/entries/autonomy-moral/>.

http://phe.oxfordjournals.org/content/3/3.toc

Several systems have been devised to grade the quality of evidence.For example: http://www.cebm.net/index.aspx?o=1025 The GRADE working group has been working on assessing the quality of evidence since 2000. http://www.gradeworkinggroup.org/index.htm