

tPA Consent

As of August 2007, our 4 hospitals have recently started using a special t-PA consent form.

We don't consent tPA since it's FDA-approved.

Yes, there is a different consent form. The MI Stroke Network had placed this on their website for dissemination:

We have a separate consent. I have talked to others who use the main treatment consent.

We were told at a meeting I attended (CAPTURE) that because the TPA is an accepted standard of care for stroke that it does not require a signed consent but documentation of an understanding of the risks is necessary. This can be done in the doctor's notes -- I also have my nurses document it as well if they are in the room when the provider speaks to the patient and/or family.

We did have a consent for tPA but the doctors are just stating the risk factors in the progress note and whether or not the pt/family is agreeable.

Regarding the need for a separate consent form for TPA; approximately 50% of those emergency departments that use TPA for ischemic stroke require a separate consent form. TPA is the only FDA approved medication that I know of that is subject to this. Historically this came about because of EM physicians and neurologists concerns about the increased incidence of SICH, and some how it has stuck.

More concerning than "to consent, or not to consent", is how we document on patients who are NOT candidates for TPA. In general, we do a good job of filling out "stroke packets" on patients who may be candidates for treatment but do not necessarily use the same detail on the patients that are one or two days from symptom onset. There is reasonable evidence that many more physicians (EM and neurologists) are caught in malpractice litigation for having NOT given TPA than for having given it and caused a known complication (SICH). In my opinion, every ischemic stroke patient's chart (that does not receive therapy) should have a line ... "this patient is not a candidate for TPA/Mechanical/IA because..."

Yes. As I understand it, it's not necessary but our neurologists wanted one from the very beginning.

I was taught the same thing, that tPA because it is a FDA approved drug you don't need to obtain consent. You should document though that the risks and benefits were explained in detail to the patient and patient's family.