# Medicolegal Issues in Acute Stroke Care

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Can a hospital or physician be sued for not giving tPA?





#### You bet!

#### In fact . . .

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## Gets \$1 Million for Suffering - Woman Claims CAT Scan Ended Her Psychic Powers

March 29, 1986

PHILADELPHIA — A woman who blamed a CAT scan for loss of her psychic powers has been awarded more than \$1 million by a jury, but a "shocked" hospital attorney said Friday that the verdict will be appealed.

"If the verdict is allowed to stand, it's an outrage and an example of why the American tort system has to be changed," said Richard R. Galli, an attorney for Temple University Hospital, where the CAT scan, a type of X-ray, was performed.





#### And it's not just about the law.

#### This is truly a *medicolegal* issue . . .

There is a lingering difference of opinion in the medical literature.

This may have arisen in part as a reaction to "standard of care" assumption.

Is IV tPA "standard of care" for acute ischemic stroke?

If so, how do we explain the following?

Only 1-2% stroke patients receive it.

Only 10-20% of those presenting within 3 hours receive it.





#### Controversy in the medical community continues to this day.

American Academy of Emergency Medicine

Evidence insufficient to define tPA as "standard of care"

Canadian Association of Emergency Physicians

More evidence is needed to give tPA outside research context

American Heart Association / American Stroke Association

Evidence overwhelmingly supports tPA (Class I since 2000)

Joint Commission

Bases certification criteria on AHA/ASA guidelines





#### What is "standard of care"?

The level at which the average prudent provider in a given community would practice

The way similarly qualified physicians in <u>that</u> community would have managed the patient's care under the same or similar conditions

**Example:** Treatment standards in public hospitals to ensure all patients receive appropriate care regardless of financial means





#### So does "standard of care" differ from hospital to hospital?

The short answer is yes.

Standard of care is local.

It may be different across hospitals.

It may be different across different groups.





#### What is malpractice?

- 1. A duty was owed.
- 2. A duty was breached.
- 3. The breach resulted in injury.
- 4. The injury led to damages.





#### What is malpractice?

**Malpractice:** Any treatment that fails to conform to the standard of care within the profession and results in harm

**Maloccurrence:** A negative outcome that occurs as part of the natural history of the condition

Sometimes there is a fine line between poor care and risks inherent to the disease.





#### NEUROLOGY/BRIEF RESEARCH REPORT

#### Empirical Characteristics of Litigation Involving Tissue Plasminogen Activator and Ischemic Stroke

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Study objective: The use of tissue plasminogen activator (tPA) in potential stroke victims by emergency physicians is controversial. One factor that may represent a barrier to use is medicolegal concerns resulting from adverse outcomes. The jury verdicts, settlements, and other adjudications associated with tPA and stroke care are assessed to determine the characteristics of these cases, including whether cases arose from adverse consequences associated with tPA or failure to provide tPA.

**Methods:** Using 7 primary jury verdict, settlement, and other adjudication legal databases, lawsuits involving tPA and stroke were collected for analysis of the clinical circumstances of the litigation, the causes of action against providers, the basis for liability, and the presence of emergency physicians and neurologist consultation in the litigation.

Results: Thirty-three cases were found involving tPA ischemic stroke therapy. In 29 (88%) of these cases, patient injury was claimed to have resulted from failure to treat with tPA. Emergency physicians were the most common physician defendants. Defendants prevailed in 21 (64%) cases, and among the 12 with results favorable to the plaintiff, 10 (83%) involved failure to treat and 2 (17%) claimed injury from treatment with tPA.

Conclusion: The available evidence concerning litigation involving stroke therapy with tPA indicates liability is predominantly associated with failure to provide tPA, rather than adverse events associated with its use. [Ann Emerg Med. 2008;52:160-164.]

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33 cases involving a question of tPA in acute ischemic stroke

In 29 cases (88%) injury claimed to be from failure to treat with tPA

ED physicians most common physician defendants

21 cases (64%) favorable to defendant

12 cases (36%) favorable to plaintiff

10 of 12 (83%) involved failure to treat with tPA

2 of 12 (17%) claimed injury from tPA





Case	Verdict, Settlement, Adjudication	Year	Liability, \$
1	Verdict-defendant	1999	
2	Verdict-plaintiff	2000	315,000
3	Verdict-defendant	2001	
4	Verdict-defendant	2001	
5	Verdict-defendant	2001	
6	Settlement	2002	100,000
7	Verdict-defendant	2002	
8	Verdict-defendant	2003	
9	Verdict-defendant	2003	
10	Verdict-defendant	2003	
11	Verdict-defendant	2003	
12	Verdict-defendant	2003	
13	Verdict-defendant	2003	
14	Verdict-plaintiff	2003	5,000,000
15	Verdict-plaintiff	2004	3,100,000
16	Verdict-plaintiff	2004	969,77
17	Verdict-plaintiff	2004	5,200,000
18	Verdict-plaintiff	2005	1,500,00
19	Verdict-defendant	2005	
20	Verdict-defendant	2005	
21	Verdict-defendant	2005	
22	Verdict-defendant	2005	
23	Verdict-defendant	2005	
24	Verdict-plaintiff	2005	1,256,55
25	Verdict-defendant	2005	
26	Verdict-defendant	2005	
27	Verdict-defendant	2005	
28	Verdict-plaintiff	2006	30,000,00
29	Verdict-defendant	2006	
30	Verdict-plaintiff	2006	2,110,70
31	Verdict-defendant	2006	
32	Arbitration	2007	421,570
33	Settlement	2007	17,550,000





19 of 33 cases (58%) involved ED physicians

6 of 33 cases (18%) involved neurologists.

In all 6, the ED physician was named as a defendant as well.

In 22 of 33 (67%), ED physicians' evaluation and treatment at issue

10 of 22 (46%) did not involve a neurology consultation.





In 22 of 33 (67%), failure or delay in stroke diagnosis

In 29 of 33 (88%), failure to treat with tPA

In 21 of 33 (64%), failure or delay in diagnosis and failure to treat with tPA

In 3 of 33 (9%), complication of tPA





#### Consent and documentation

Written consent not required

Standard of care, FDA-approved etc.

Discussion of risks and benefits

Consistent approach





#### Basic rules to avoid legal action

Document conversations.

Document clear plan of care.

Document reasons for giving or withholding tPA.

Document verbal informed consent.

Do not point fingers in the chart.

Do not alter the chart.

Do not avoid families when things go wrong.

Cultivate bedside manner.





#### Conclusion

You can be sued for anything.

Malpractice is when you cause harm by not adhering to local standard.

Document, document, document.

Be clear in your plan and reasoning.

Be consistent.



