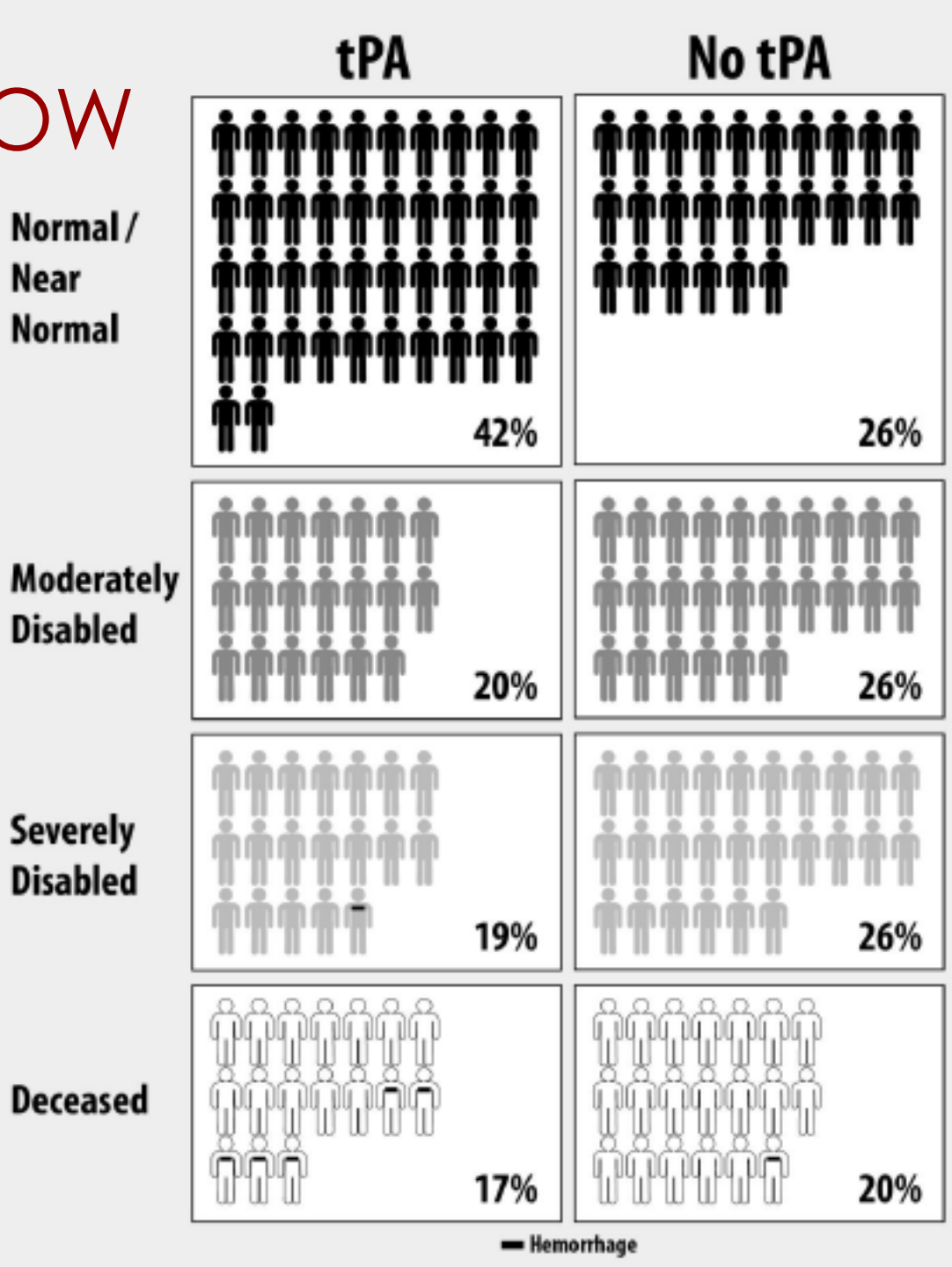
RISKS & BENEFITS of TPA

- tPA is considered standard-of-care for patients with functionally disabling stroke symptoms or ≤ 4.5 hours duration without listed contraindications
- Written informed consent is **NOT** required. Rather, it is suggested that there be a brief discussion of risks and benefits emphasizing the institutional recommendation to administer the drug (aka informed refusal)
- Visual aids and shared decision-making can help streamline the discussion
- Use this to discuss with patient/family:

"tPA is the only FDA approved medication for the treatment of stroke. The FDA has approved it for use up to 3 hours of stroke onset, however most medical societies and institutions around the world support its use up to 4.5 hours of onset. On the whole, more patients are helped than harmed from this medication and it is our recommendation that your loved one receive this medication as fast as possible. The major risk of getting tPA is bleeding, which can occur anywhere is the body and can be significant enough to cause symptoms in 5-8% of patients. This may be severe enough to require transfusion of blood products. tPA can also cause an allergic reaction in 1-5% of patients, which rarely can be severe. If you would like more information, I would be happy to show you a visual aid which summarizes the data on the use of tPA in stroke."

0-3 HOUR WINDOW

- **Use this to discuss with patient/family:**
- **This shows the 3 month outcomes of 100 patients treated within 3 hours of stroke onset:**
  - Patients treated with tPA are between 1.5 and 2x as likely to return to normal or near normal function at 3 months
  - **1 in 7** patients who receive tPA have an improvement in outcome due to the drug
  - The effects of the drug are time-dependent. If the drug can be given within 1.5 hours of onset, the chance of improvement increases to **1 in 3**
  - **1 in 18** patients who received tPA had significant bleeding due to the drug
  - The risk of dying from the stroke is similar regardless of the treatment
  - tPA increases the chances of functional independence, but with a 10-fold increase in risk of bleeding



3-4.5 HOUR WINDOW

- **Use this to discuss with patient/family:**
- **In the 3-4.5 hour window:**
  - tPA has been shown to be beneficial up to 4.5 hours from symptom onset
  - Though only FDA-approved up to 3 hours from onset, many international medical societies, including the American Stroke Association, have endorsed its use in select patients
  - In one study, 52% of those given tPA returned to normal or near normal at 3 months, compared 45% given placebo. This was statistically significant
  - **1 in 14** patients who received tPA had an improvement in outcome because of the drug
  - **1 in 22** patients who received tPA had significant bleeding due to the drug
  - The risk of dying from the stroke is similar regardless of the treatment
  - tPA increases the chances of functional independence, but with a 10-fold increase in risk of bleeding