A recent paper in the BMJ suggests guidelines based on incomplete reporting and extending hope of benefit to specific populations without testing this. Sadly this may lead to patient deaths and do more harm than good. The cycle is then perpetuated by reviewers and guideline creators who use the curated available “evidence” to suggest roles of practice for clinicians, insurance systems and international regulators. Sometime the questions we need to ask are about the data and the assumptions that we do not have access too. A lack of transparency in registering and reporting clinical trials can hasten patient deaths.

The paper Thrombolysis in acute ischaemic stroke: time for a rethink? reports that systematic reviews and guidelines have concluded through the evidence available to them that thrombolysis with alteplase (t-PA) up to 4.5 hours after the onset of ischaemic stroke is beneficial. It is reported to increase the likelihood of being functionally independent and not increase the 90 day risk of mortality. We need to consider if this is real evidence and if it applies to the population for whom the intervention is intended. The problem starts when the guidelines go beyond the marketing authorization, for alteplase which is limited to 0-3 hours after the onset of a stroke. In some other countries including the UK and Australia this license was extended to 4.5 hours but the background of evidence for this extension remains unclear. Even though multiple stroke guidelines support this practice the research warrants re-investigating.
Key messages

- “Use of alteplase 3-4.5 hours after stroke is supported by guidelines and meta-analyses based on analyses that do not directly examine treatment in this time frame

- Direct comparisons of alteplase with no alteplase at 3-4.5 hours after stroke suggest an absolute increase in mortality of 2% and no clear benefit (people die)

- Recommendations to use alteplase 3-4.5 hours after stroke should be re-evaluated”

The key messages were taken from the paper which is available without cost here. You can sign up to support the All Trials initiative where the public can let researchers know that they expect clinical trials to be registered and reported. At this time:

- Only 13% of clinical trials report results on time
- Clinical trial results remain hidden when drugs are abandoned