# Potential Solutions and Actions & Further Commitment needed to overcome the problems

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# Use of thrombolytics (alteplase) in acute ischemic stroke

- Shown to be effective in 1995
- Approved by FDA in 1996
- Endorsed by guidelines in 1997<sup>1</sup>

#### **Acute Stroke therapy**

Treatment	Recommendations	Level of evidence	Grade
rt-Pa	Intravenous rt-PA (0.9mg/kg, maximum 90mg), with 10% of the dose given as a bolus followed by a 60-minute infusion, is recommended within 4.5 hours of onset of ischaemic stroke. (new recommendation)	I	Α



#### Piracetam for acute ischemic stroke<sup>3</sup>

#### Main results

We included three trials involving 1002 patients, with one trial contributing 93% of the data. Participants' ages ranged from 40 to 85 years, and both sexes were equally represented. Piracetam was associated with a statistically non-significant increase in death at one month (approximately 31% increase, 95% confidence interval 81% increase to 5% reduction). This trend was no longer apparent in the large trial after correction for imbalance in stroke severity. Limited data showed no difference between the treatment and control groups for functional outcome, dependence or proportion of patients dead or dependent. Adverse effects were not reported.

#### Authors' conclusions

There is some suggestion (but no statistically significant result) of an unfavourable effect of piracetam on early death, but this may have been caused by baseline differences in stroke severity in the trials. There is not enough evidence to assess the effect of piracetam on dependence.

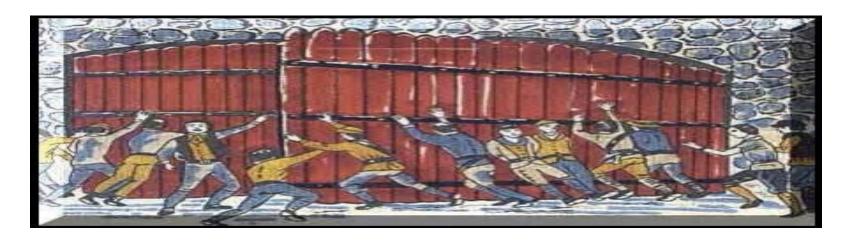


DRUGS

**DEVICES** 

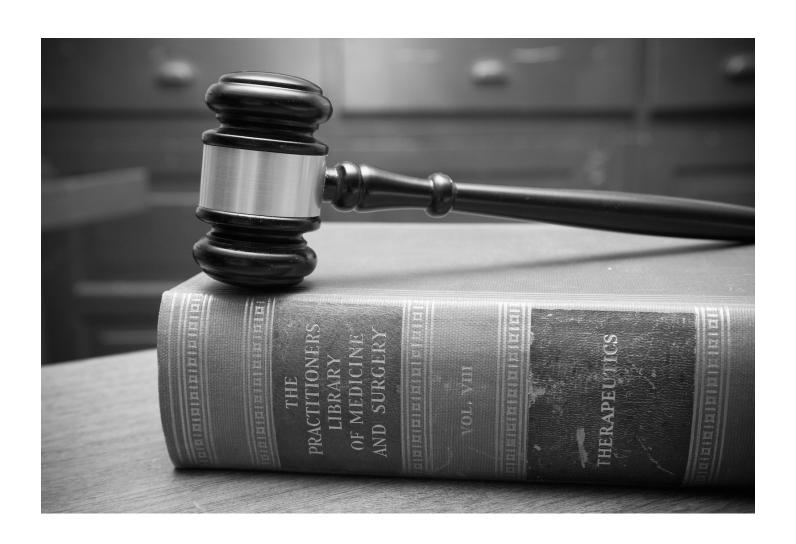
PROCEDURES

DIAGNOSTICS





# Regulations



#### Legislations

- Drugs under the purview of the National Pharmaceutical Regulatory Agency
- Regulation of medical devices under Medical Device Act 2012
- Traditional and Complementary Medicine Act 2016 (Control of Drugs and Cosmetics Regulation in 1984)



PATIENTS	HEALTH CARE PROVIDERS	RESEARCHERS
TECHNOLOGY DEVELOPERS	HEALTH TECHNOLOGY ASSESSMENTS	PAYERS
POLICY MAKERS	CARERS	PUBLIC

#### Patient, Carers and Public

- Input to questions, methods, results and assessment
- Improvement in overall health literacy understand the need to test treatment
- Translation of testing treatment into local languages – Malay translation



#### Health care providers

- Training in EBM and critical appraisal
- Change in attitudes and behaviour
- Incorporation into undergraduate and postgraduate training
- Workshops to teach skills
- Access to information primary sources/clinical decision support systems/guidance



#### Researchers

- Data production use of registries, real-world data
- Data synthesis skilled information experts, statisticians, health economists, input from practitioners, patients, public.

#### HTA assessors

- Collaborations skilled information experts, researchers, statisticians, health economists, input from practitioners, patients, public.
- HTA assessments independent without conflict of interest, timeliness, transparent
- Not only cost-containment but focus on value

## Policy makers and Payers

- Training on evidence and health technology assessment
- Refocus on value
- Provide adequate support work culture has significant impact

### **Technology Developers**

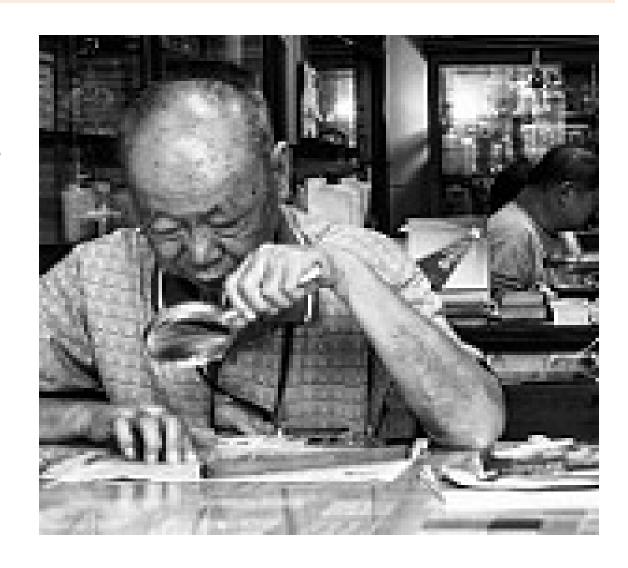
- Focus is on increasing shareholder value
- Tension due to conflicts of interest
- Need to adhere to legislations and regulations
- If they understand the "rules of the road", then they can plan accordingly.

#### Continuing Professional Development

- Malaysia has linked CPD to the renewal of the Annual Practising Certificate and recertification of specialist registration
- Includes publication, reviewing activities and attending CME events
- Mandatory as part of the amendments to the Medical Act 2012

#### Audit

- Monitor
   outcomes –
   clinical, costs,
   resources,
   equipment,
   prescriptions
   etc.
- Check for variation in practice





#### References

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- 2. Ministry of Health Malaysia. Clinical Practice Guidelines on the Management of Ischemic Stroke. 2<sup>nd</sup> Edition. 2012.
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