NICE National Institute for Health and Care Excellence

Process – where are we now?

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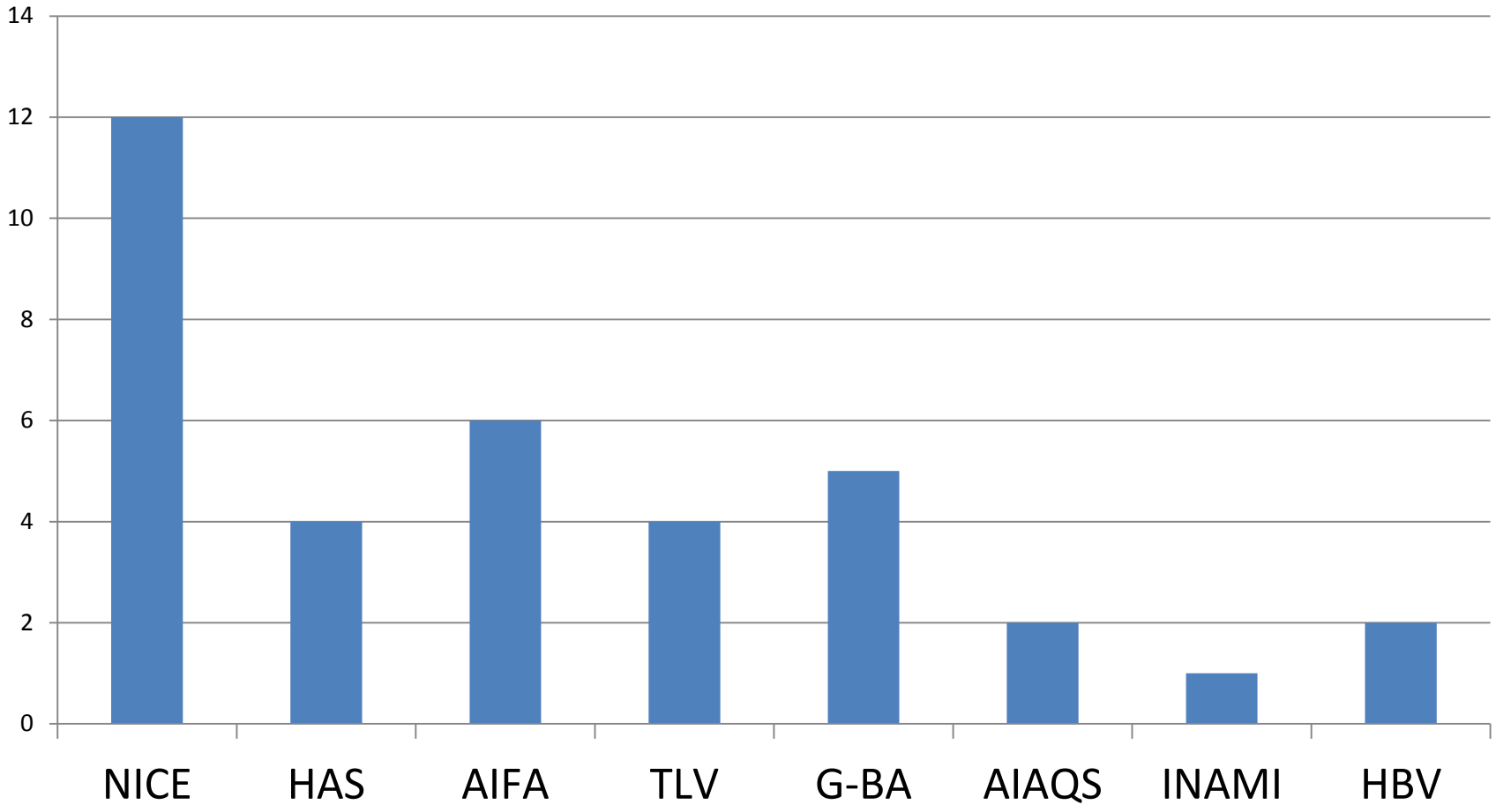
HTA participants at EMA meetings



What has worked well?

- Existing EMA process has made it relatively easy for HTAs to join in
- Opportunity to hear the views and reasoning of regulators and other HTA agencies
- Possibility to give more helpful advice as a consequence of understanding the different view points

Areas for improvement?

- Process needs to support delivery of high quality advice:
  - difficulty of accommodating changing proposals
  - having appropriate expertise at the meeting
  - limited time to explore issues with the company
  - advice outputs in different formats – no mechanism for formal exchange

Areas for improvement?

- Inviting HTA agencies changes the nature of the meeting
  - regulatory and health outcomes teams in companies need to work together to maximise the benefit from the advice meeting
- Process needs to accommodate needs of all participants

Agreed Policy Position

Who ?

When ?

Where ?

What ?

How ?

Process

Policy Issues

- Each agency has their own policy position
- Heads of our agencies have to feel comfortable with the process for producing advice in their name

Mechanism required for engaging the senior executives of our agencies

Process

- Requires the highest levels of procedural rigour
- Agencies are entering into a contractural arrangement with a company
- Programme plan essential
- Dedicated resources

Scaling up from proof of concept to production line is procedurally complex and challenging

Conclusions

- Lots of useful experience to date
- We are still in “early development” stage in working towards a European advice model.
- Policy decisions needed to support the delivery of a high quality advice process
- Dedicated resources required