GETTING STUDIES RIGHT TO SUPPORT DRUGS, DEVICES, AND BIOLOGICAL PRODUCTS IN HEALTHCARE

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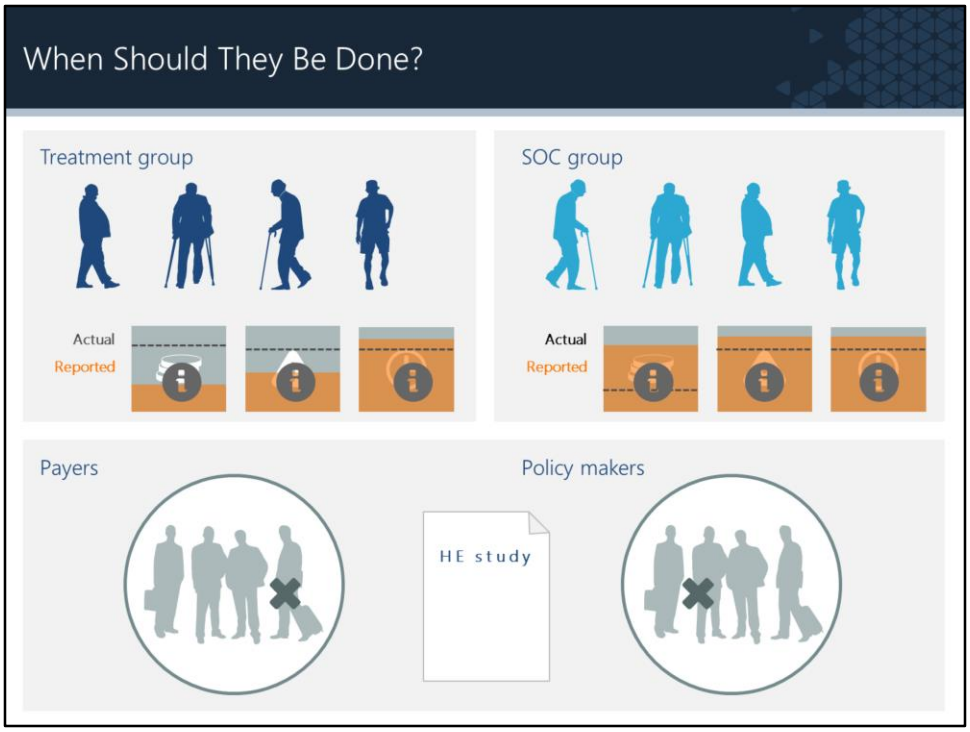
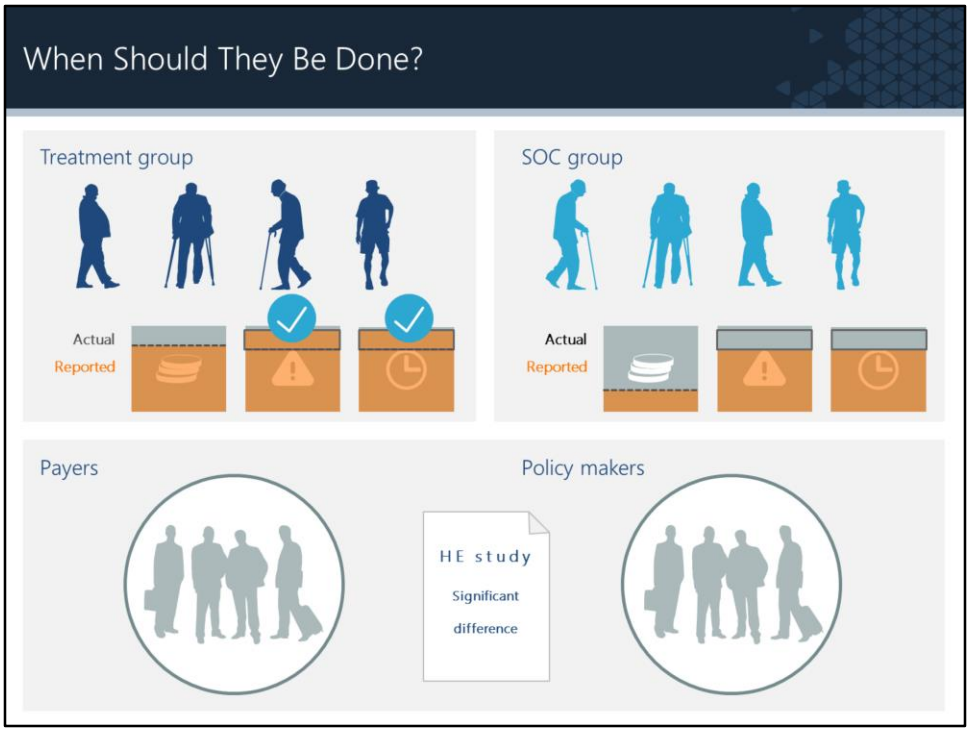
HEALTH ECONOMIC ANALYSIS

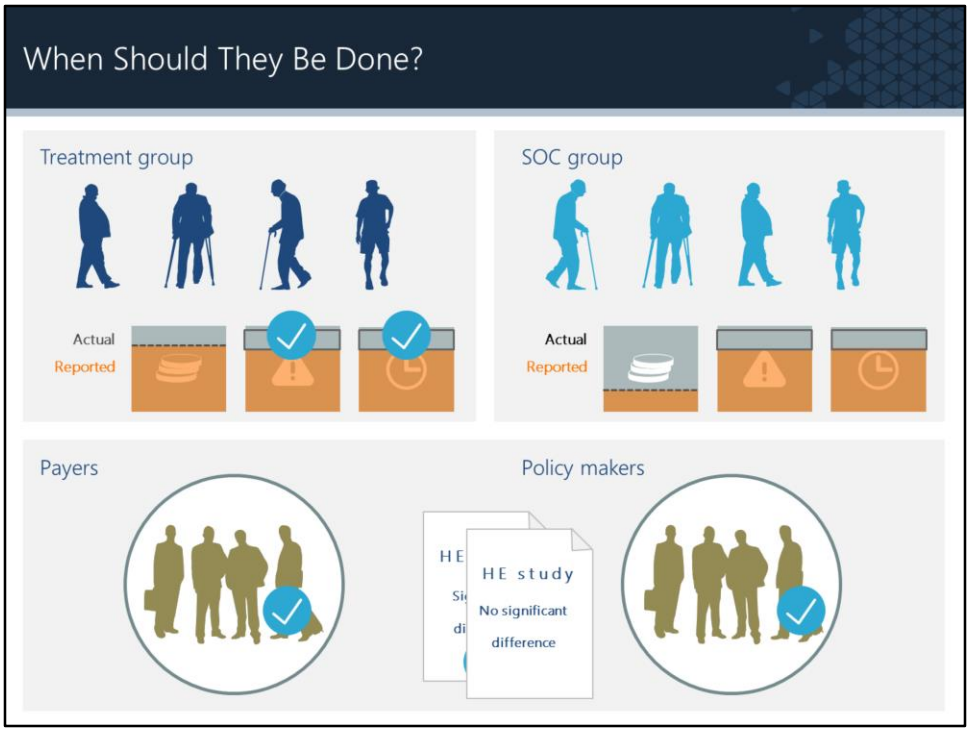


0- This is the hardest question to answer. There are very few US academic programs designed specifically to equip professionals with a comprehensive grounding in of both health care knowledge and hardcore economic analytical techniques

1- HE studies must be credible, and inflating small differences can get you into much trouble, unless sensitivity analysis is very good.



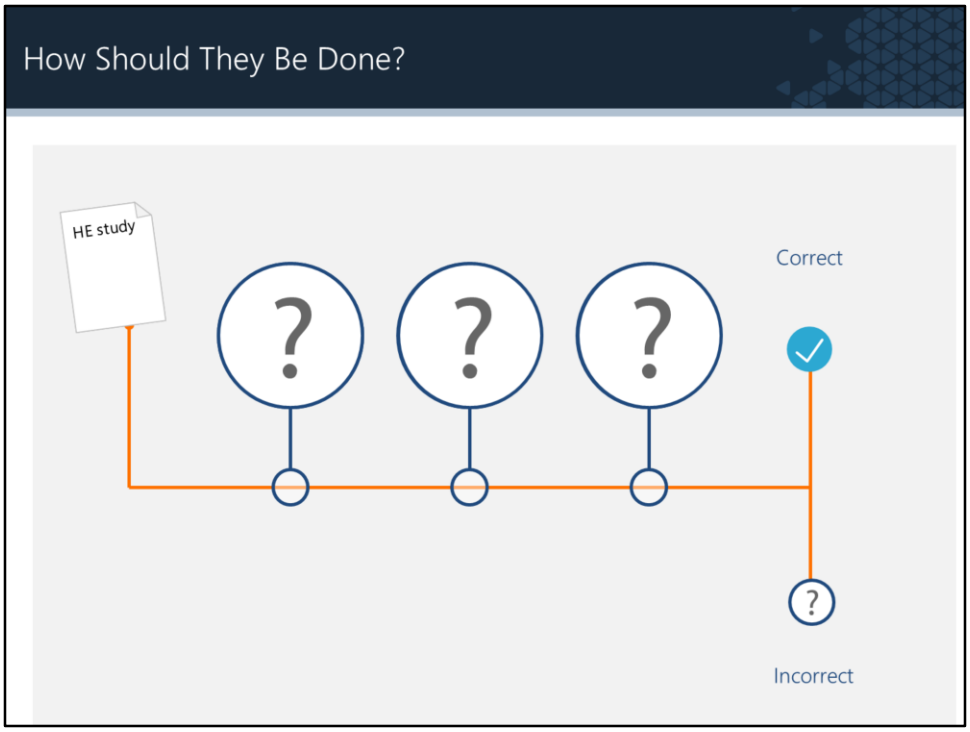
0- Worth doing when clear differences emerge between populations or between populations treated with different devices or interventions as far as cost, safety, or effectiveness is concerned



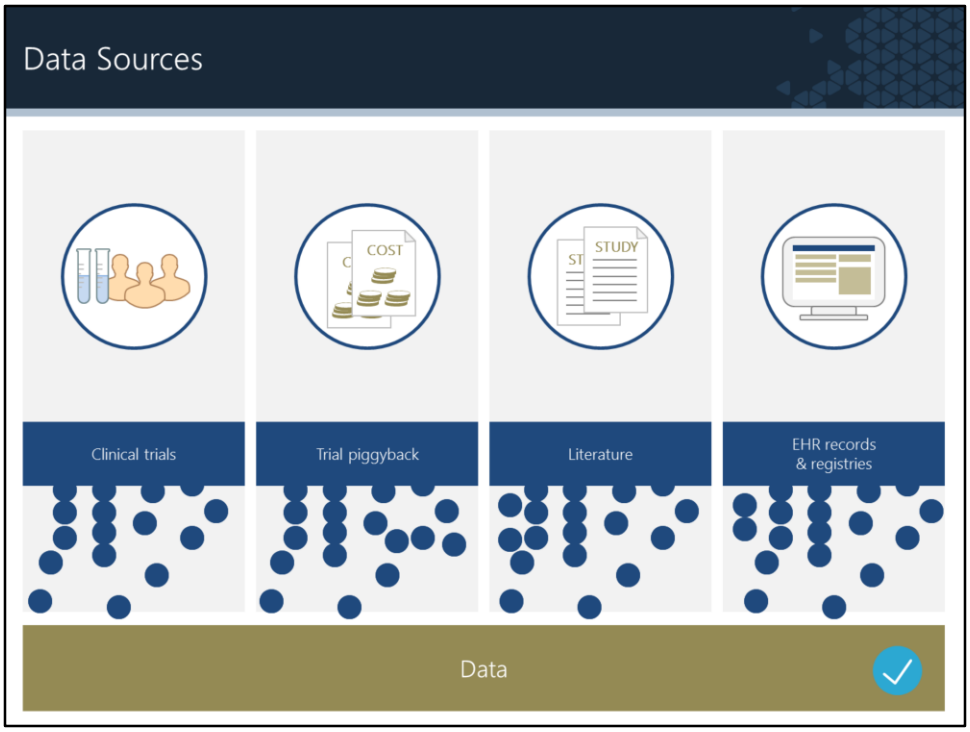
OR

0- To show that there are little or no differences.

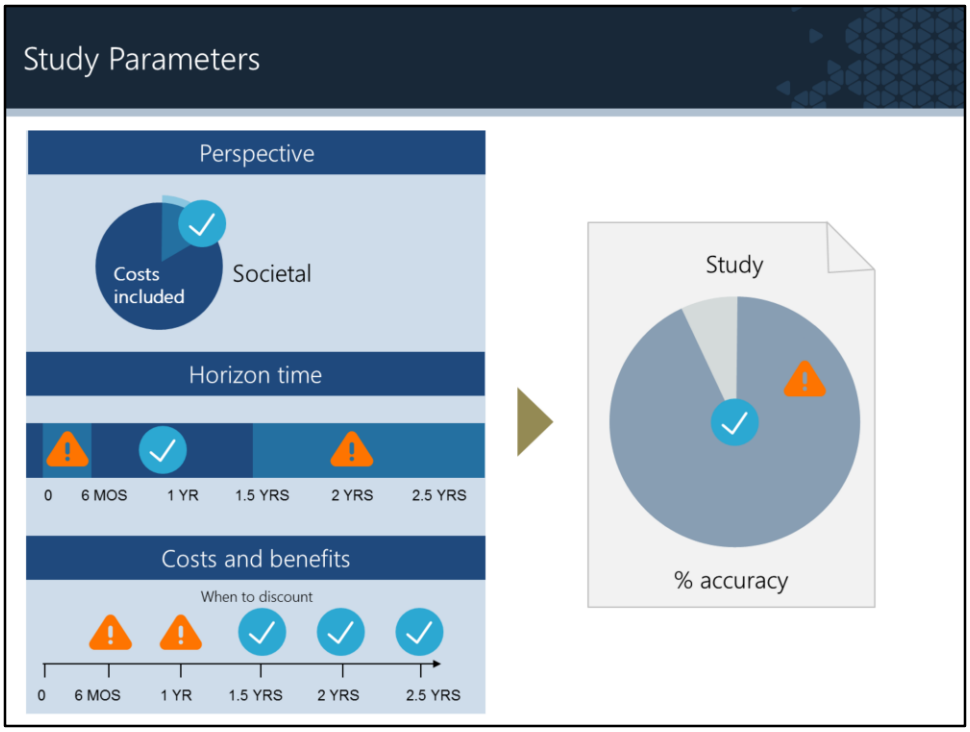
1- Largely done to influence payers or policymakers



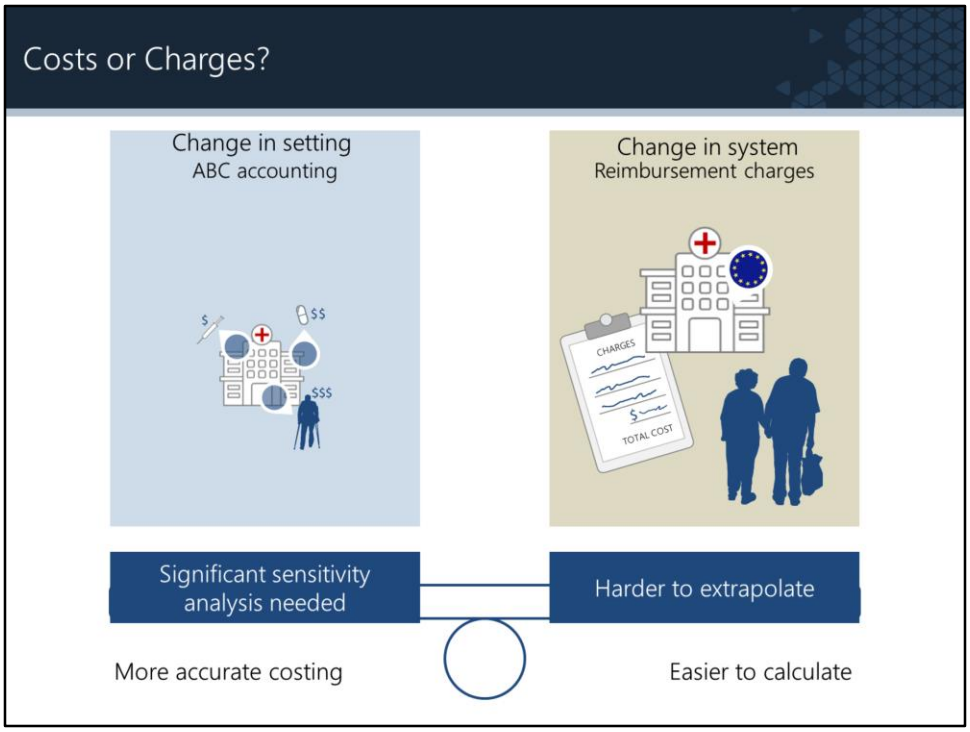
0- The overall HE structure must be logical, sound, and based on acceptable scientific evidence and economic principles, otherwise they will end up poor quality.
1- HE studies should follow things like ISPOR guidelines, PICO: *Population, Intervention (or prognostic factor/exposure), Comparison, Outcomes* and they must contain cost or other economic data and benefits



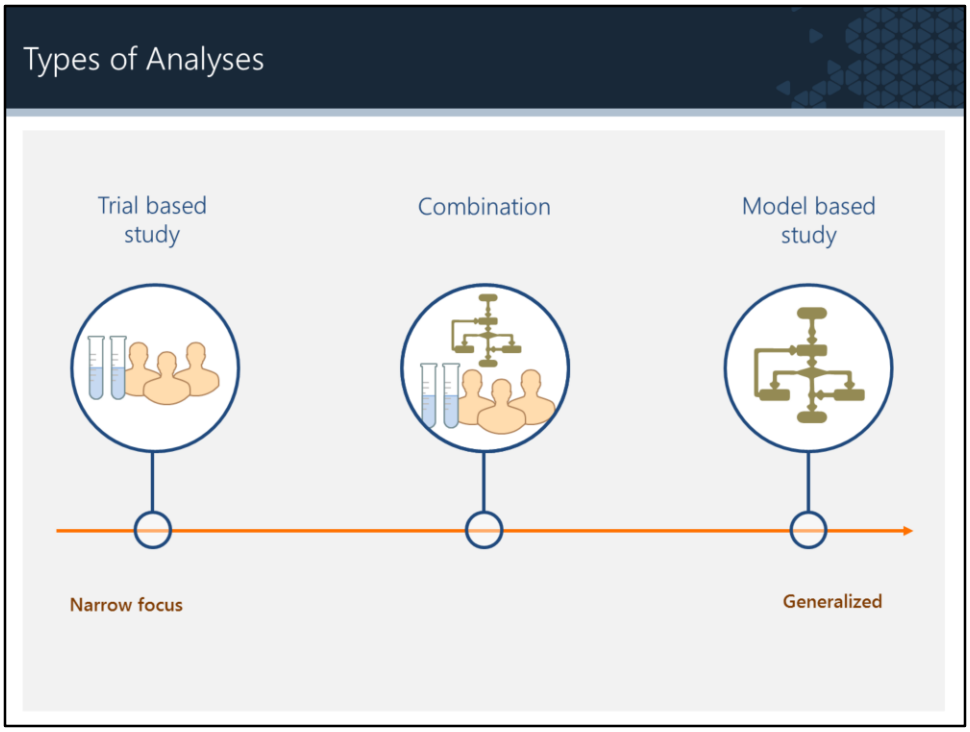
0- Clinical trials (e.g., clinical outcomes, complications, safety, QoL, etc.)
1- Costs can also be collected prospectively from a trial piggyback
2- Additional information can be abstracted from the literature
3- Registries and EHR records can also be used as the basis for outcomes
4- Together these sources can be used to collect your data



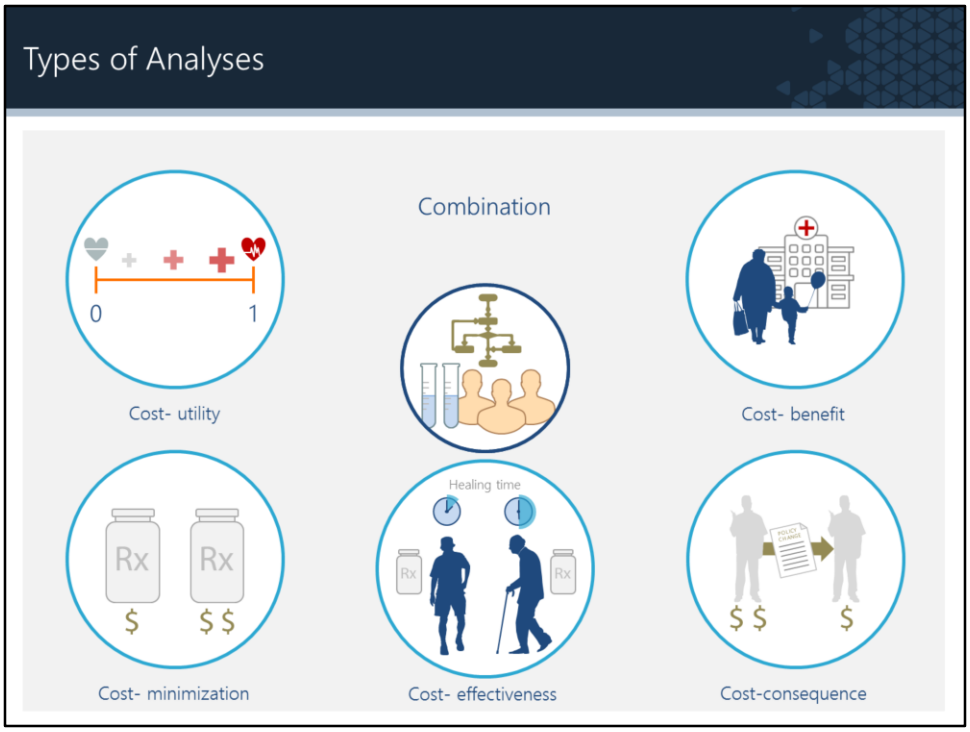
0- Perspective: third party payer is most common perspective
1- Many studies are too short, or too long for the methodology being used
2- There is no universal agreement on when costs should be discounted or rates
3- Societal perspective is more encompassing, horizon time should be long enough capture costs and benefits that relevant to the goal of the HE study, and costs and benefits should be discounted after 1 year. This enables higher accuracy with your study.



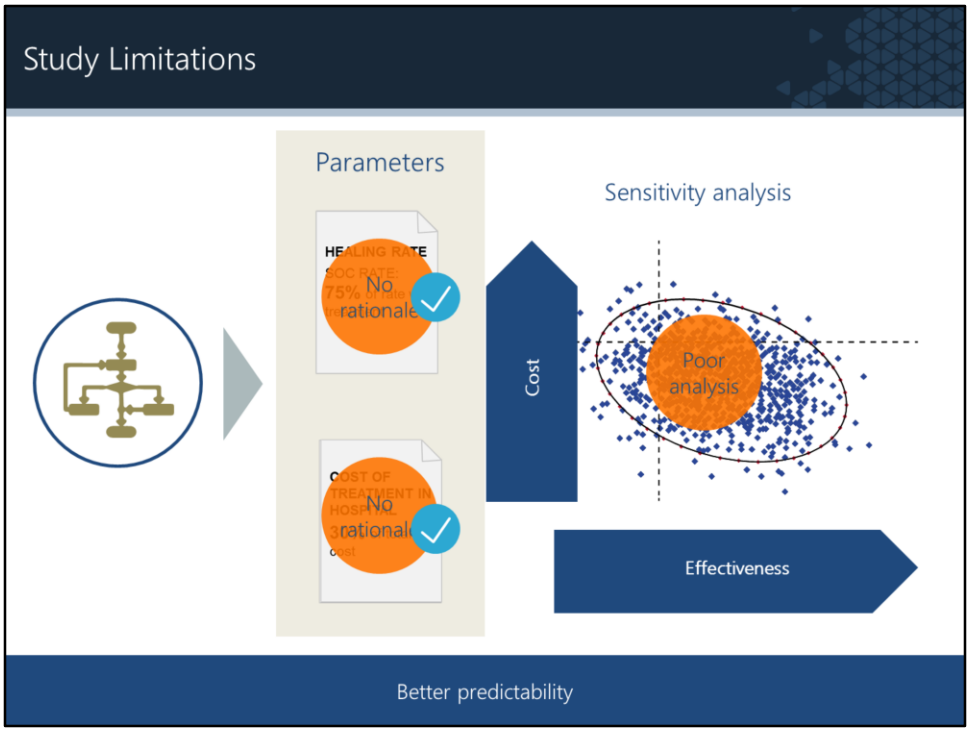
0- ABC costing is more accurate,
1- but use of reimbursement charges is easier (and common)
2- ABC costing requires significant sensitivity analysis to account for different costs in different settings or countries, and use of reimbursement charges may be harder to extrapolate to other systems/countries



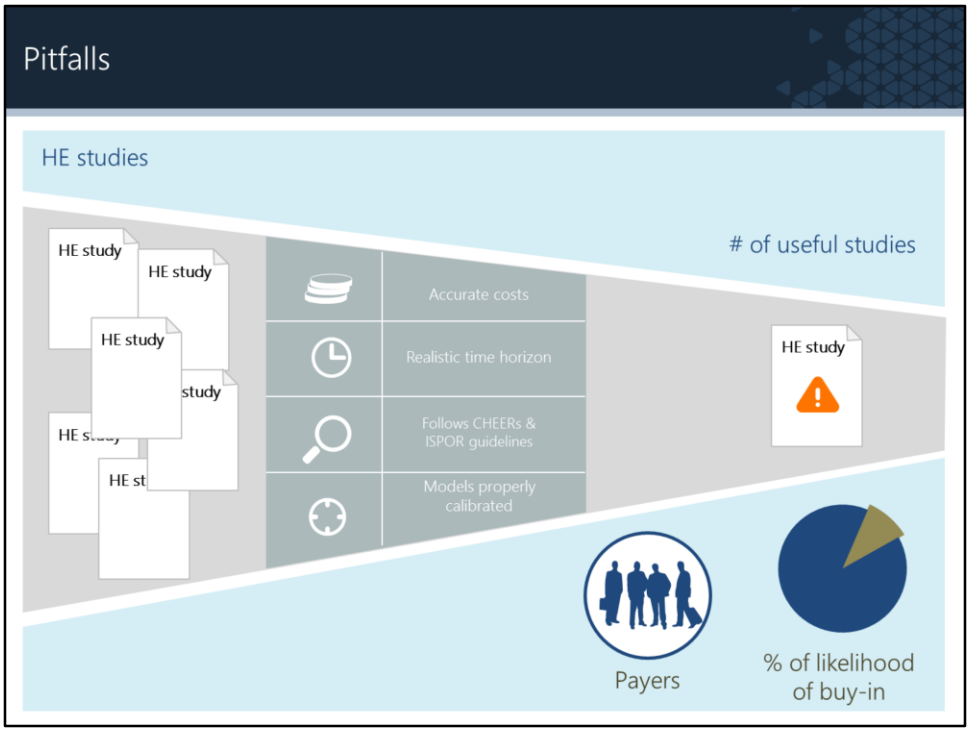
0- Studies can be wholly trial based, wholly model-based,
1- or a combination. Models are more generalizable if conducted well but trial-based studies are likely to be more accurate within a narrow focus.



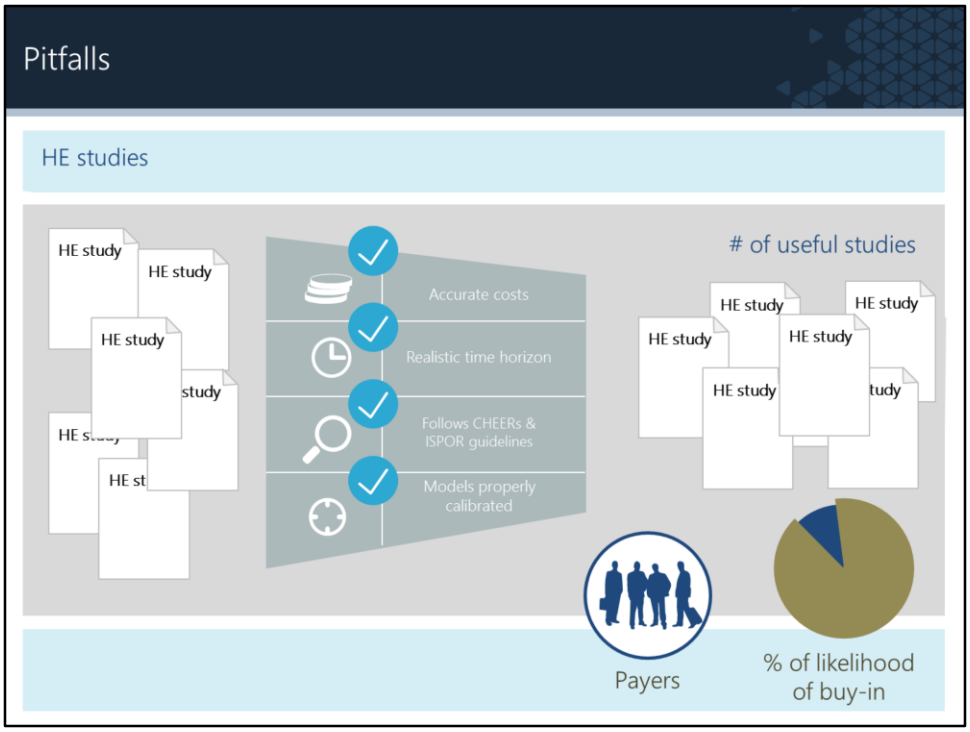
0- Several types of study are frequently done: Cost-minimization (less often these days)
1- Cost-effectiveness
2- Cost-utility
3- Cost-benefit
4- Cost consequence



0- Although basic limitations come from structure and assumptions, a really good sensitivity analysis is needed. Sensitivity analysis starts with the base model and describes what happens when various model inputs or parameters are changed systematically. Arbitrary changes without rationale are not helpful.
1- Requires much rationality in regard to amount of change in order to have better predictability



0- Many HE studies that have been published in the literature are practically worthless.
1- They don't follow guidelines and suggestions, and this leads to only a small percentage of studies being useful.



0- All relevant costs should be included not just a few, time horizon must be realistic, HE studies should follow CHEERs and ISPOR guidelines, and models need to be properly calibrated and described so they can be reproduced

1- this will lead to payers being more likely to buy in when studies are better quality.

ANY QUESTIONS?

Email us at info@strategic-solutions-inc.com or call us at 1-307-587-5352 (office hours Monday through Friday, 9am-5pm, Mountain Time, (GMT-7)