

"An NIH funder perspective"

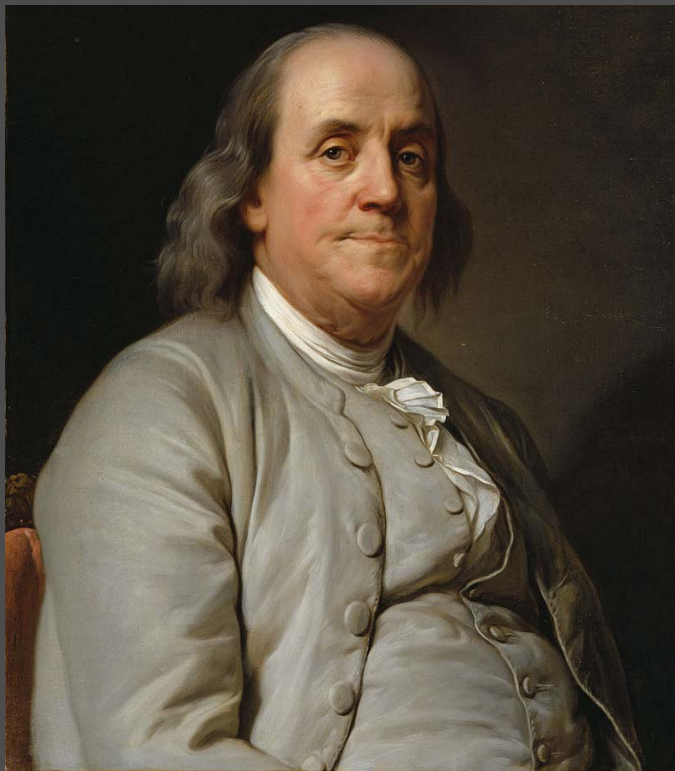
Disclaimer

Opinions I will voice are not official opinions of NIH

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Guideline: A general rule, principle, or piece of advice

"The people heard it, and approved the doctrine, and immediately practiced the contrary."



Benjamin Franklin



THE WAY TO WEALTH
OR
POOR RICHARD IMPROVED

First printed 1758

Checklist: A list of items required, things to be done, or points to be considered, used as a reminder

Consolidated standards of reporting trials (CONSORT) and the completeness of reporting of randomised controlled trials (RCTs) published in medical journals (Review)

Turner *et al.* 2013



Allocation Concealment:

Non-endorsing journal: 22%

Endorsing Journals: 45%

The 2010 CONSORT guidelines checklist

Allocation
Concealment
is just one out
of 38 items



Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	_____
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	_____
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	_____
	2b	Specific objectives or hypotheses	_____
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	_____
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	_____
Participants	4a	Eligibility criteria for participants	_____
	4b	Settings and locations where the data were collected	_____
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	_____
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	_____
	6b	Any changes to trial outcomes after the trial commenced, with reasons	_____
Sample size	7a	How sample size was determined	_____
	7b	When applicable, explanation of any interim analyses and stopping guidelines	_____
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	_____
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	_____
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	_____
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	_____
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	_____
	11b	If relevant, description of the similarity of interventions	_____
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	_____
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	_____
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	_____
	13b	For each group, losses and exclusions after randomisation, together with reasons	_____
Recruitment	14a	Dates defining the periods of recruitment and follow-up	_____
	14b	Why the trial ended or was stopped	_____
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	_____
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	_____
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	_____
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	_____
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	_____
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	_____
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	_____
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	_____
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	_____
Other information			
Registration	23	Registration number and name of trial registry	_____
Protocol	24	Where the full trial protocol can be accessed, if available	_____
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	_____

Improving adherence to checklists and guidelines



Less can be more (stage priorities)



All stakeholders share responsibility

“At a minimum studies should report on:

- ☐ sample-size estimation
- ☐ whether and how animals were randomized
- ☐ whether investigators were blind to the treatment
- ☐ and the handling of data”

Improving adherence to checklists and guidelines



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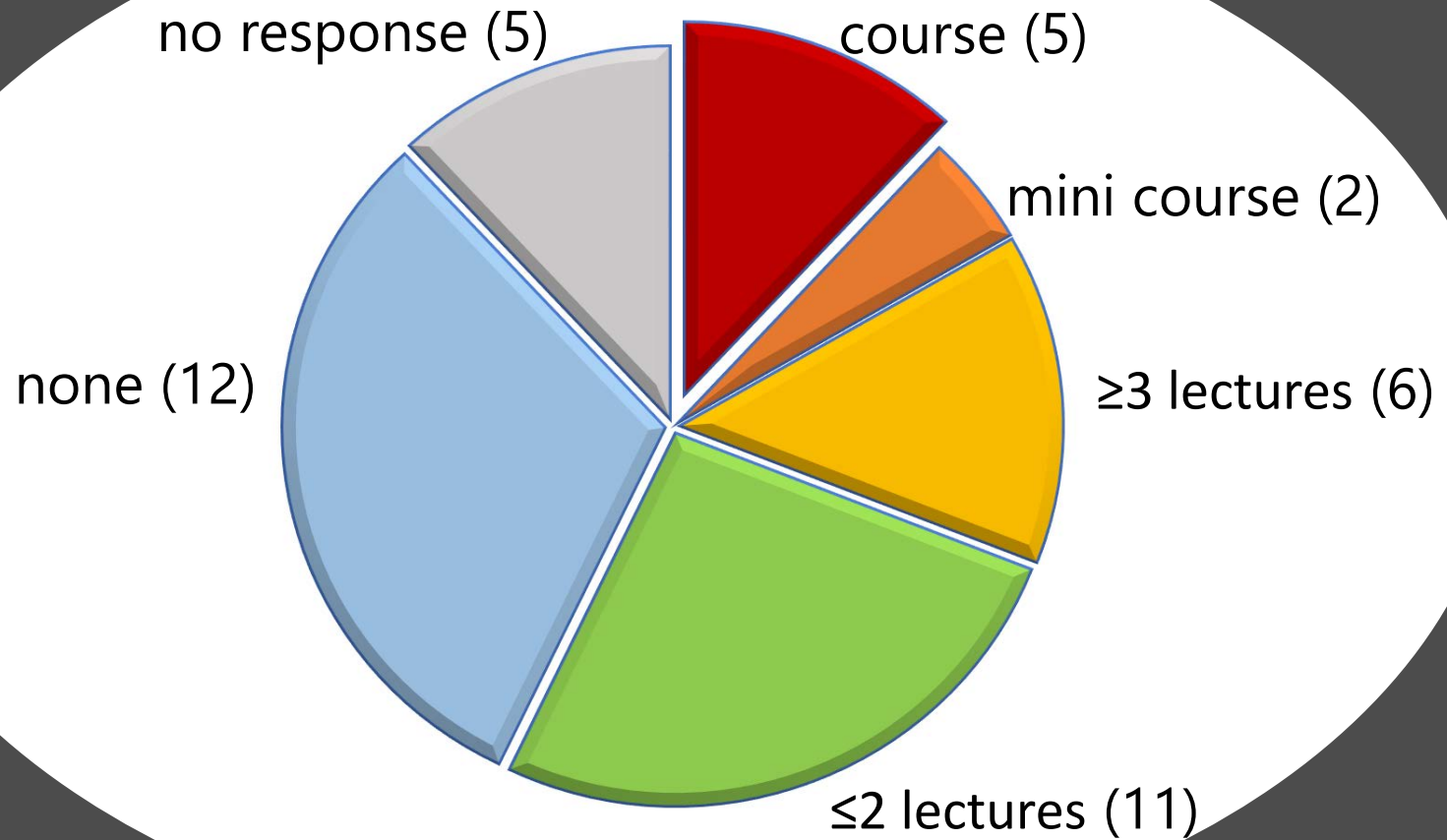


A change to the incentive structure

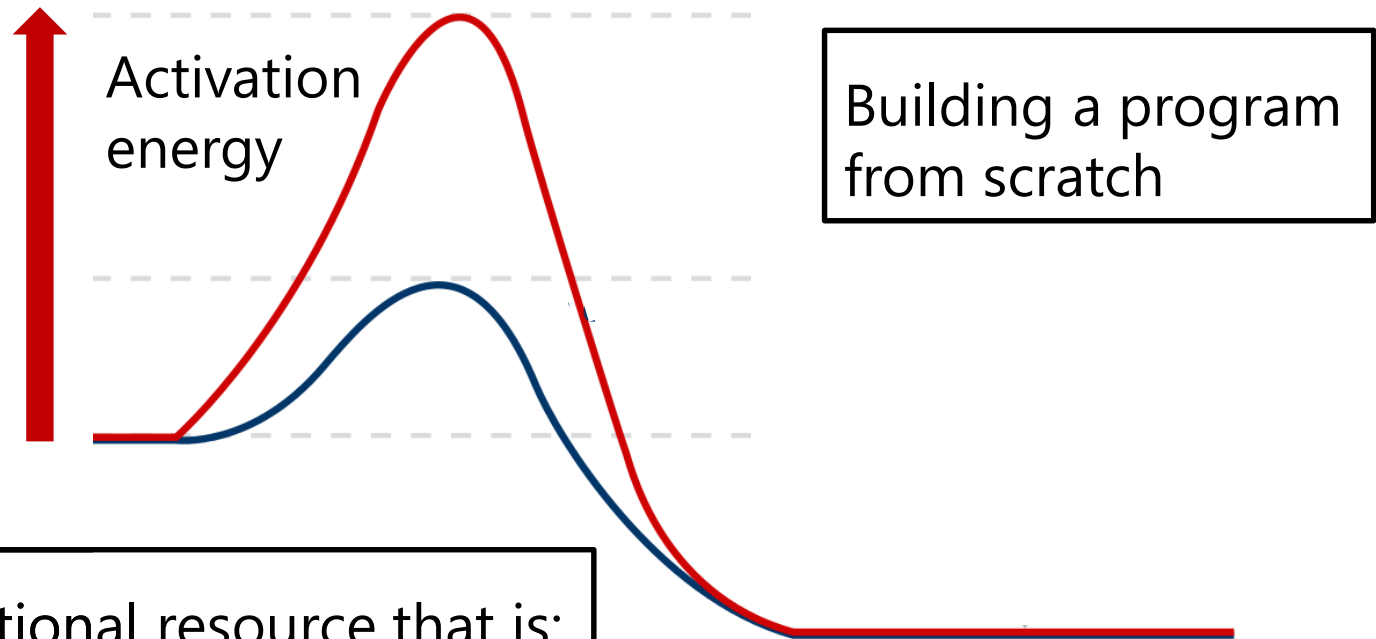


Education!

Survey of formal training in the **principles of rigorous research**
at Institutions with neuroscience training grants (n=41)



It is not easy to build a program from scratch



A free educational resource that is:

- comprehensive
- modular
- adaptable
- upgradable

A fundamental change to the reward system is warranted



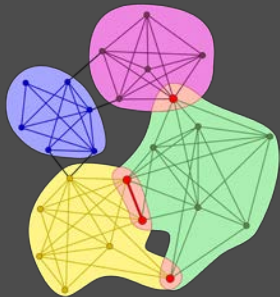
An effective educational platform should target all career stages



Progress will require a culture change at all academic, publishing, and funding organizational levels



Academic institutions need to play a proactive role in changing the culture



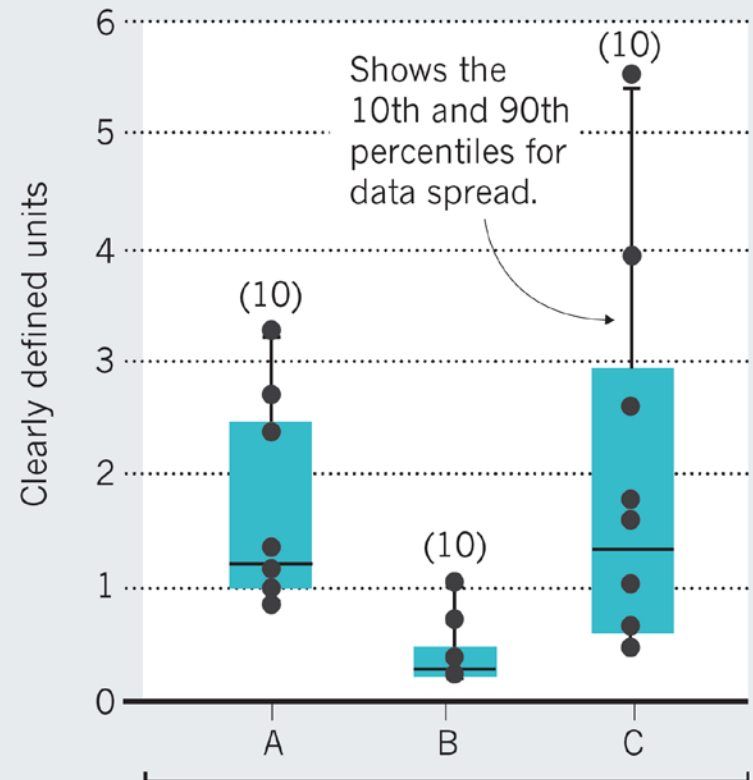
Call for the establishment of communities of champions within and across institutions to share resources, change culture, and support better training at all academic levels

Shake up conferences

Emojis, smartphone technologies and revamped guidelines would boost transparency at scientific meetings, say **Shai D. Silberberg** and colleagues.

Nature 2017; 548: 153-154

B *More transparency*



'Rigour emojis' instantly show that the experiments were randomized, blinded and part of a confirmatory study.