Research and measurement

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Content

- What is research?
- Requirements to do research
- Data collection using measures
- Research into measures
- Up to three specific research projects

Messages

- Primary requirements are:
  - Focus on method and design
  - Open mind; hypothesis may be wrong
- Personal strengths needed are:
  - Systematic approach to everything
  - Ability to solve practical problems
- You can do good research
- Money helps (!)
  - but **only** if other features already present

Research

- *"the systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions"* (OED)
- It is the process of **discovery**
  - Answering a question
  - Testing a hypothesis
  - Reducing uncertainty about the world
- (Western) scientific method since 1500

Research

- Answers a question,
  - How reliable is this test?
- Which should be framed as a hypothesis
  - The data from the same person obtained by two people will be within 6% of each other
- Before – no idea
- After – results will be +/- 10% of ‘truth’

Clinical research requires:

- Development of a specific question
  - As well-defined as possible
    - Keep on making it more precise
- It possible (and it usually is) give
  - Two possible answers (your hypotheses)
    - As specific as possible
  - Defines the data you need
    - What you need to measure

Clinical research requires

- Next need to choose method
  - Appropriate design for question
    - E.g. randomized controlled trial
- Then need to choose measures
  - Data needed to
    - test hypothesis (outcome/data of interest)
    - help interpret main data – e.g. prognostic data
    - Help generalization/use – descriptive data

Clinical research requires:

- A systematic approach to:
  - Collection of data
    - Same set of data on **all** patients
    - At same times, etc
  - Analysis of data
    - Correct handling of data
    - Appropriate comparisons or statistical tests
  - Interpretation of data
    - Unbiased

Research requires:

- A systematic approach to:
  - Presentation of output
    - Writing – description and arguing from data
    - Presentation of data – tables, figures etc
  - Criticism and comment
    - Before presentation, **and**
    - After presentation, including data sharing

Primary resource

- **Personal** commitment:
  - Of time and effort
  - To research process and integrity
  - To accepting the data and conclusions
    - Even if not what expected or wanted
  - To presenting, discussing and sharing data
- It is **not** about being clever
- It is about being careful and (self-)critical

Advice

- Ask anyone and everyone (use Google)
  - Listen carefully, but decide for yourself
- Use : http://www.equator-network.org/
- Read widely, make notes, write out ideas
- Seek advice again
- The more time and effort spent before starting, the better the research

Data collection tools (measures)

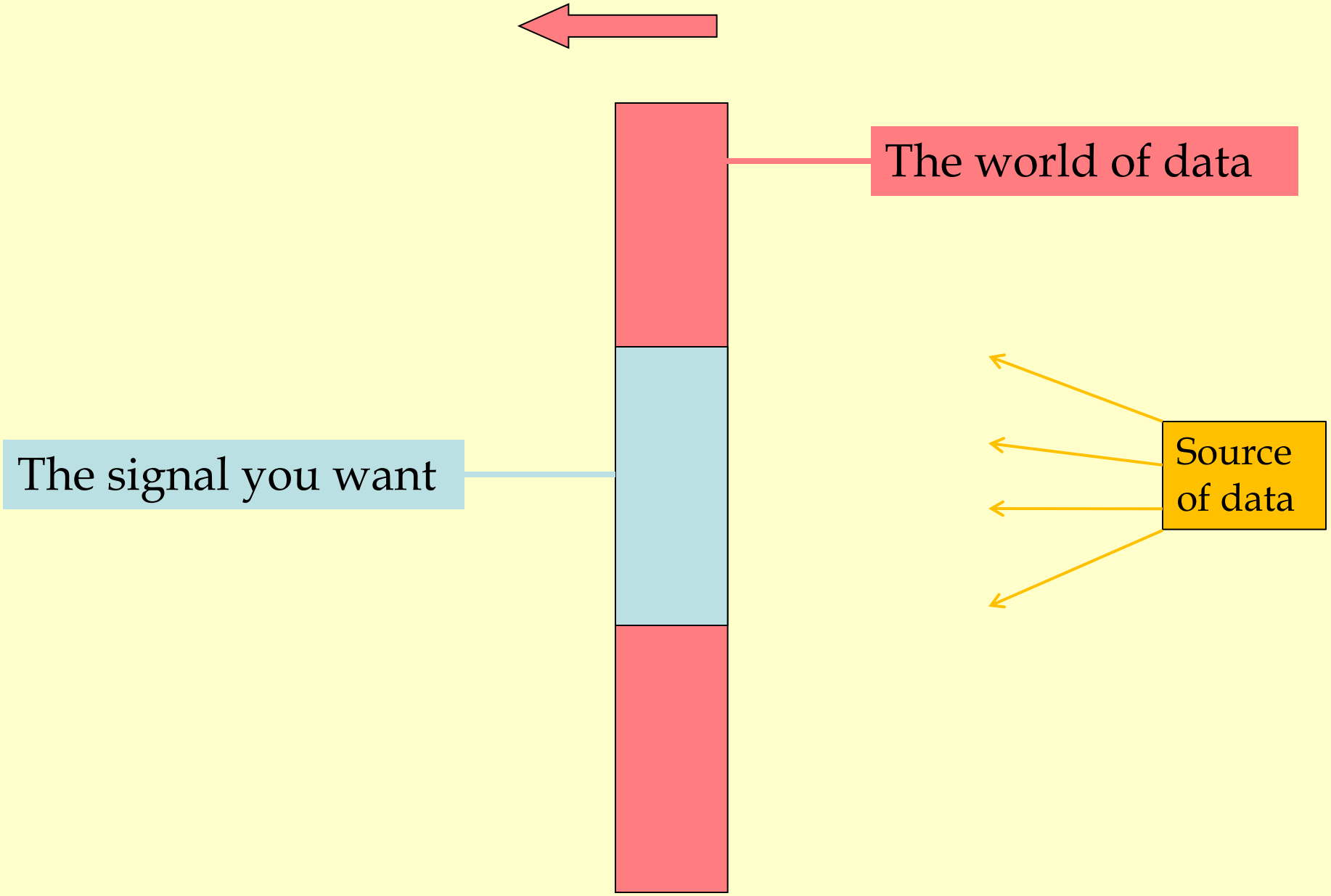
Signal

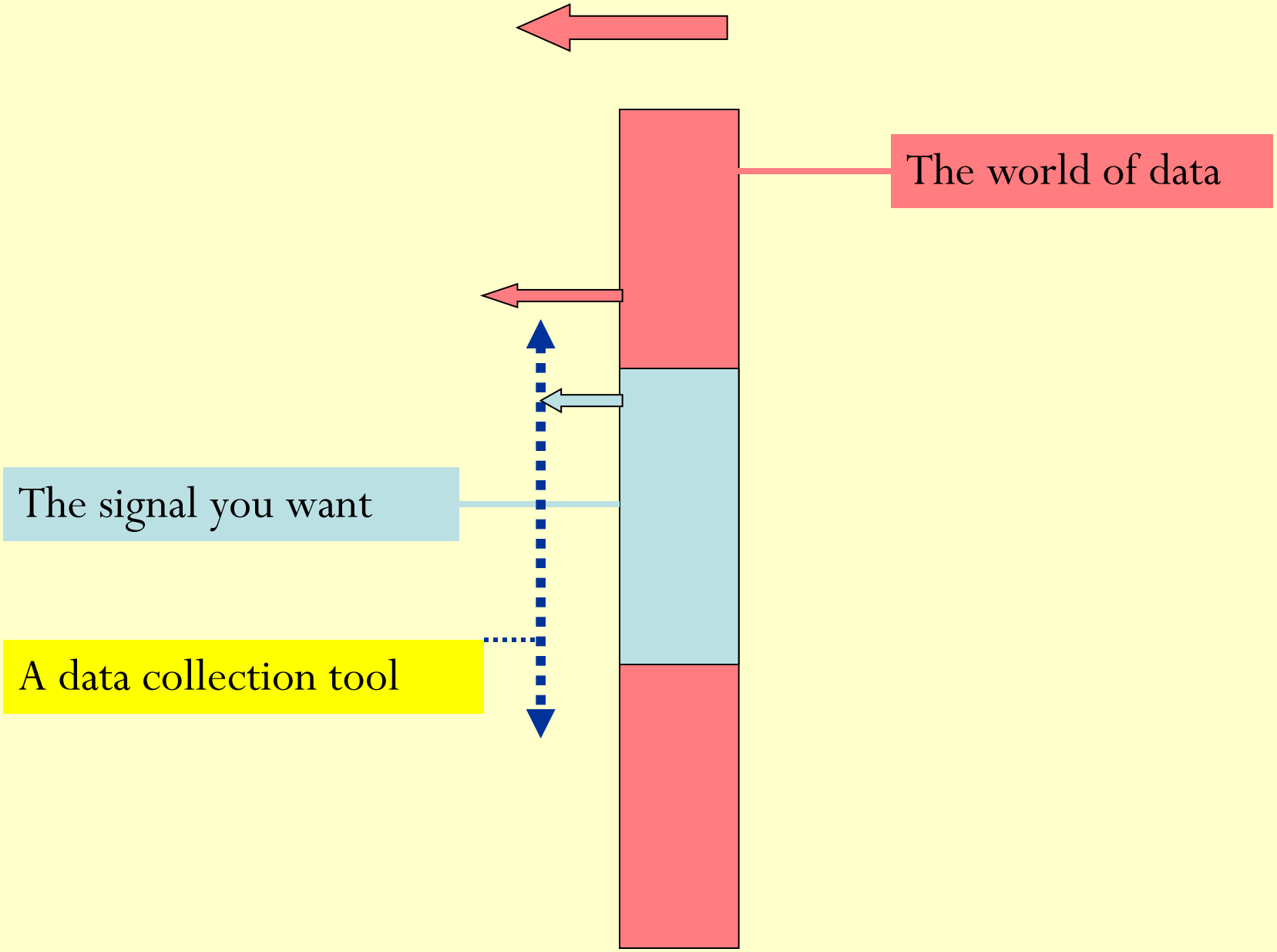
Noise

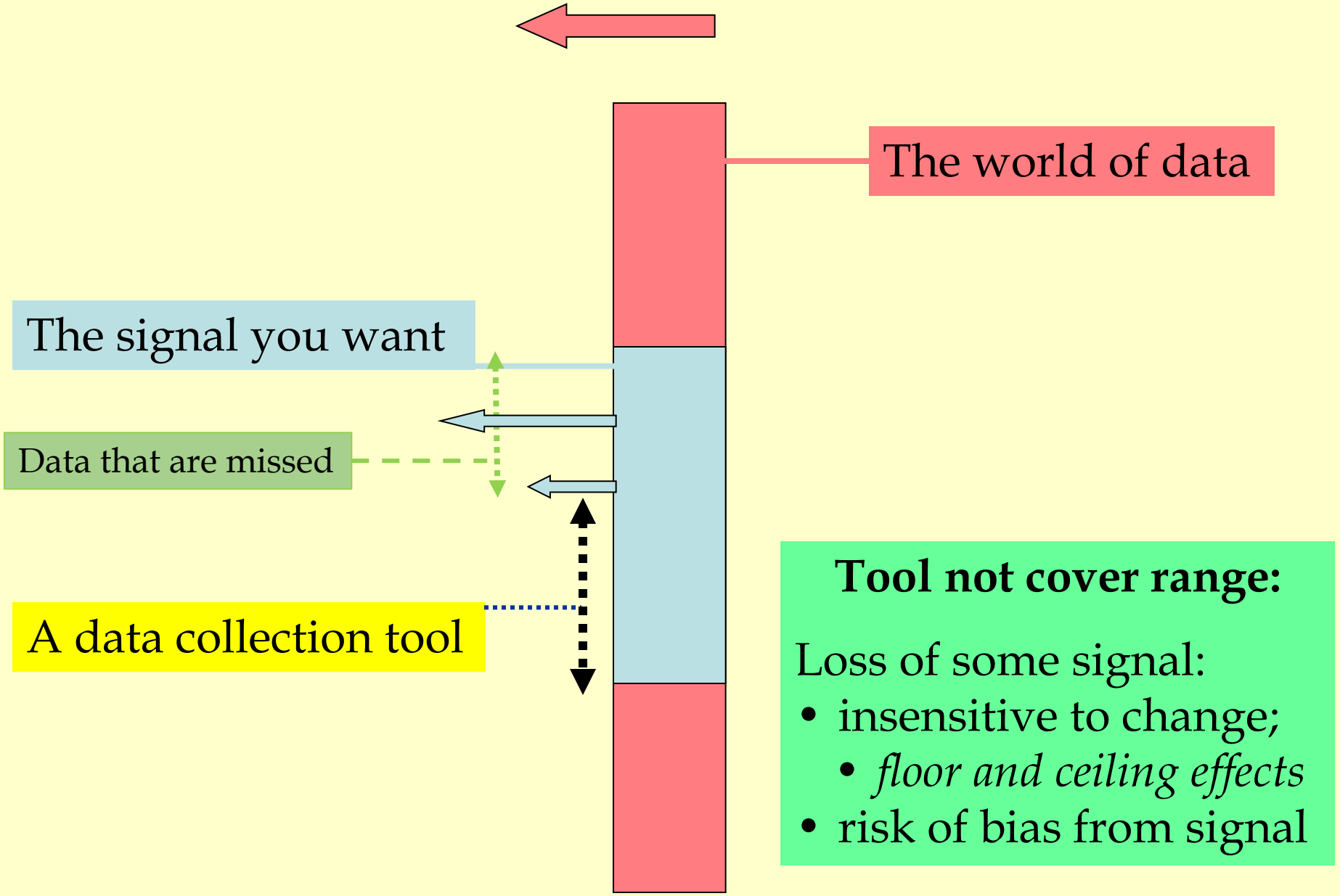
Bias

Signal, noise, bias

- Data contain both signal and noise
- **Signal** = data required (adds information)
- **Noise** = all else (hides information)
  - Lost data, wrong data, irrelevant data, duplicate data, random data
- **Bias** = selective data (distorts information)
- **Data collection tool** should:
  - Maximise signal:noise ratio
  - Minimise bias in signal


The world of data
The signal you want
Source
of data

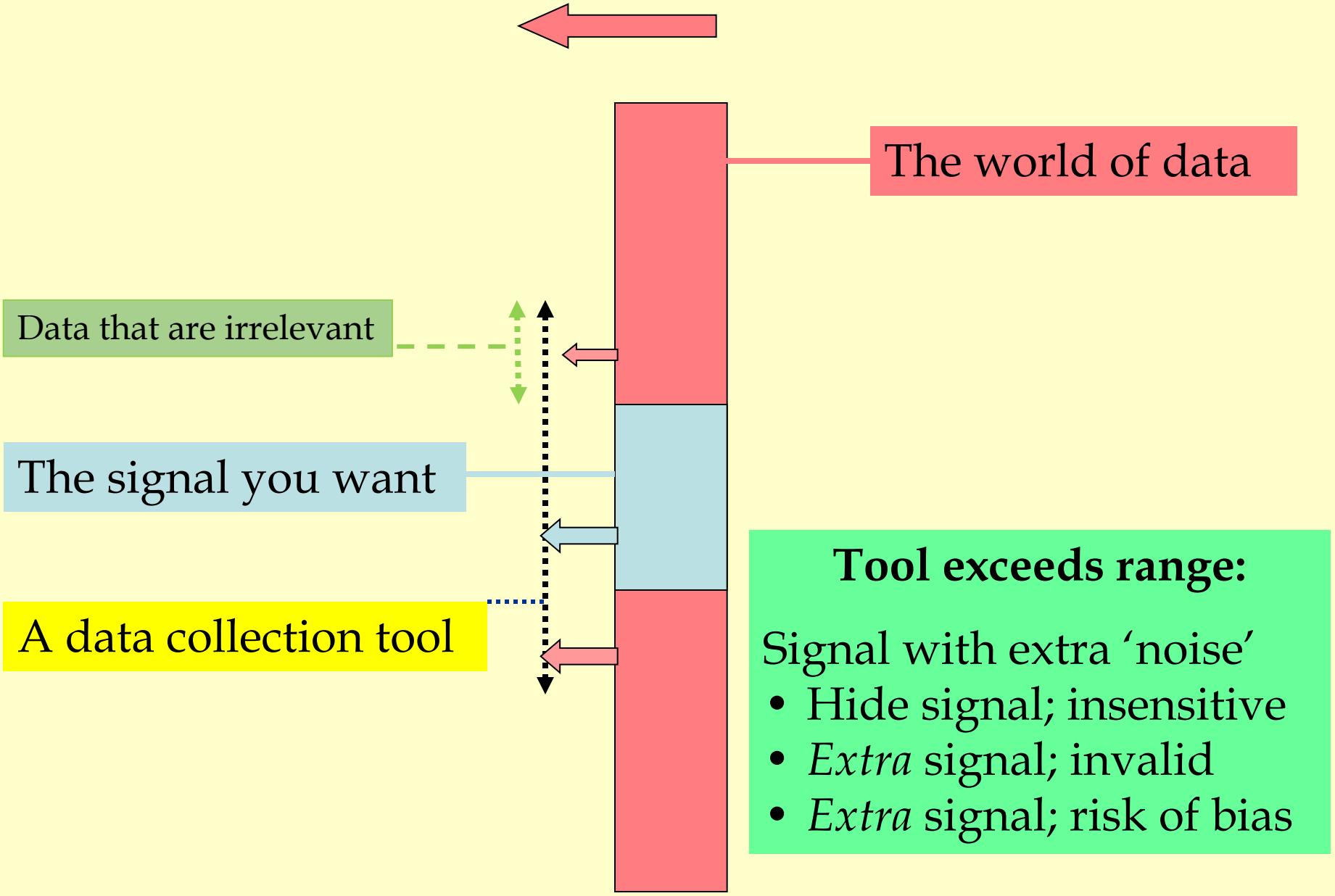

The world of data
The signal you want
A data collection tool



Tool not cover range:

Loss of some signal:

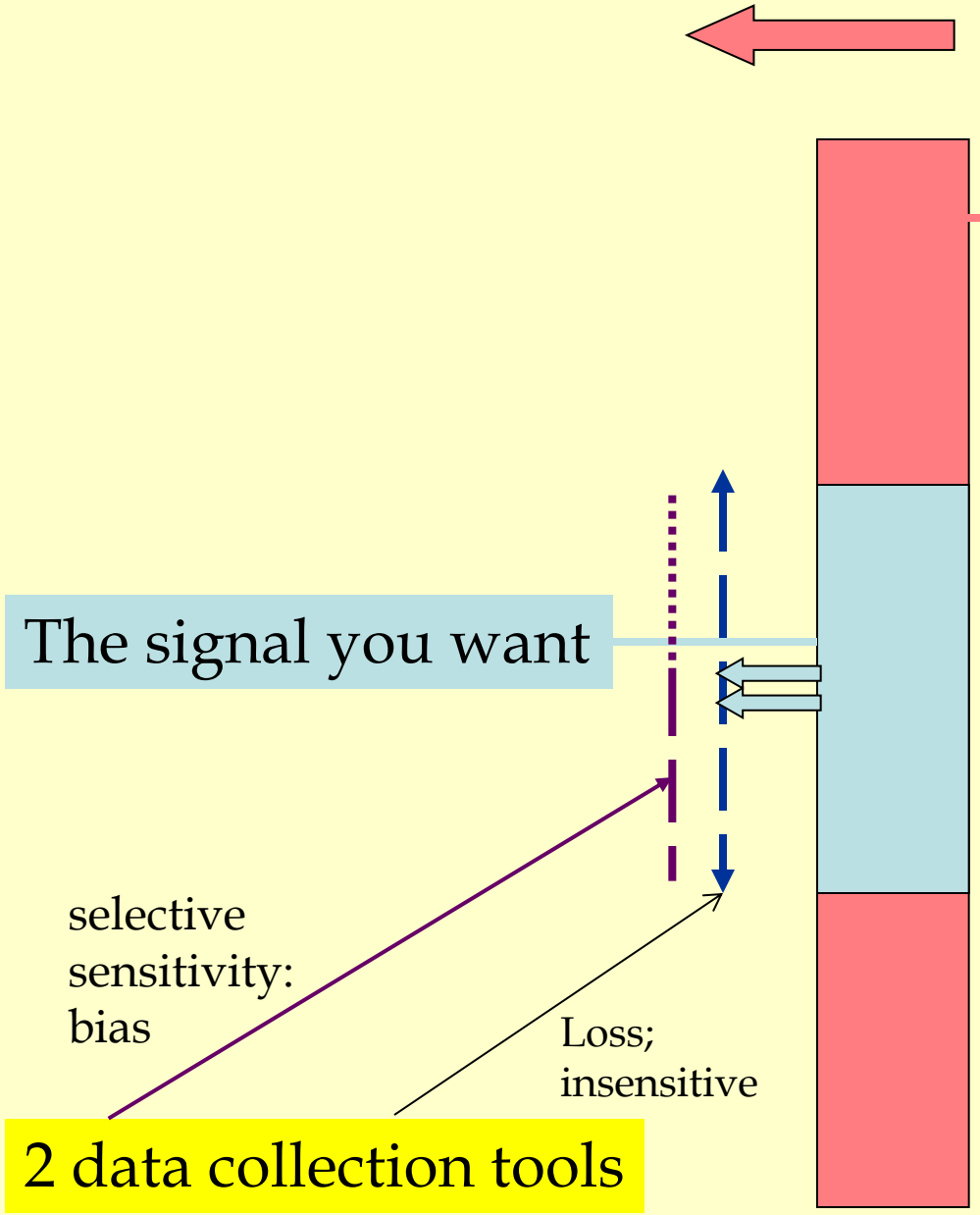
- insensitive to change;
  - *floor and ceiling effects*
- risk of bias from signal



Tool exceeds range:

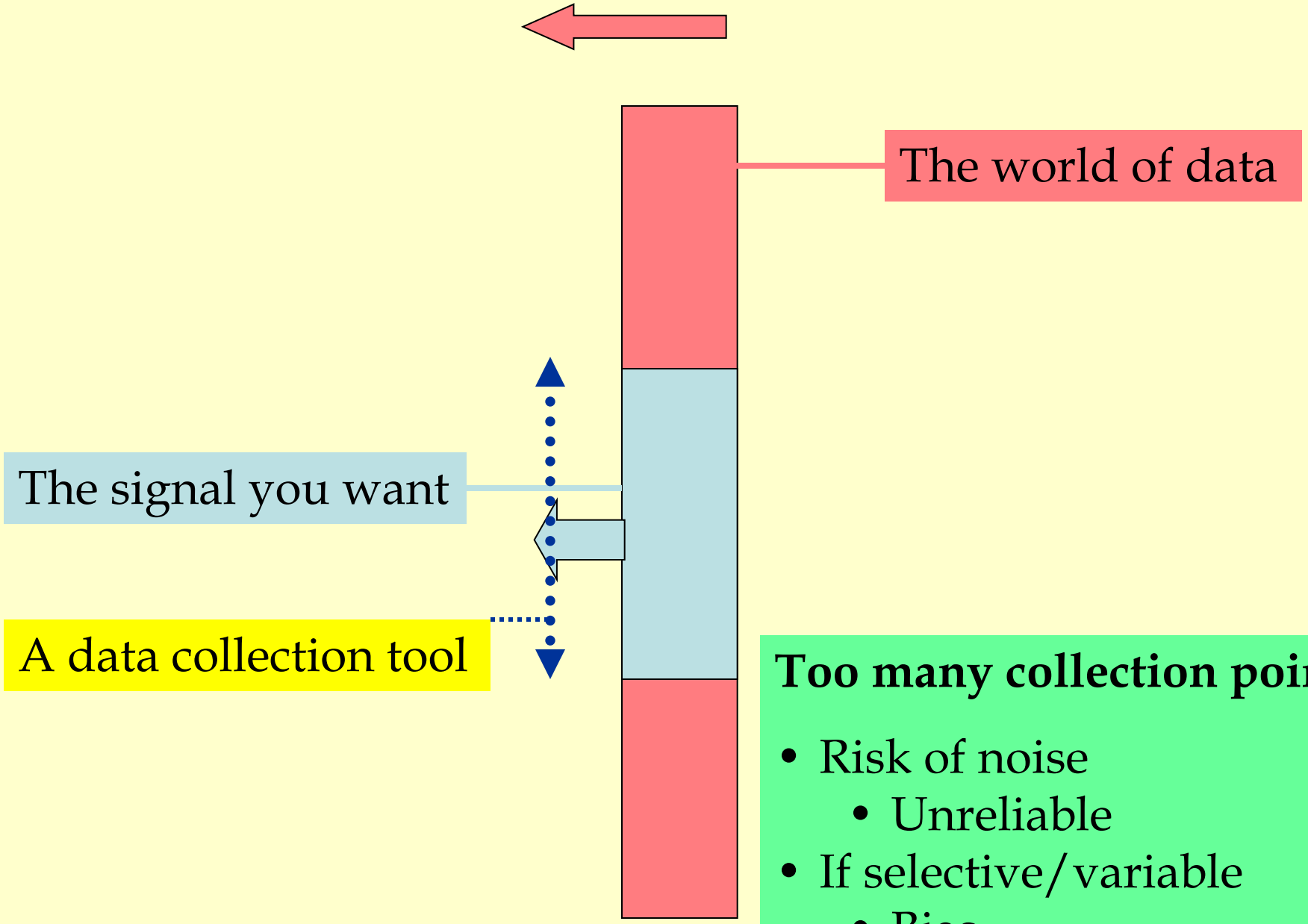
Signal with extra 'noise'

- Hide signal; insensitive
- *Extra* signal; invalid
- *Extra* signal; risk of bias



Too few collection points:

- Lose signal
  - insensitive
- Selective sensitivity =
  - bias



Too many collection points

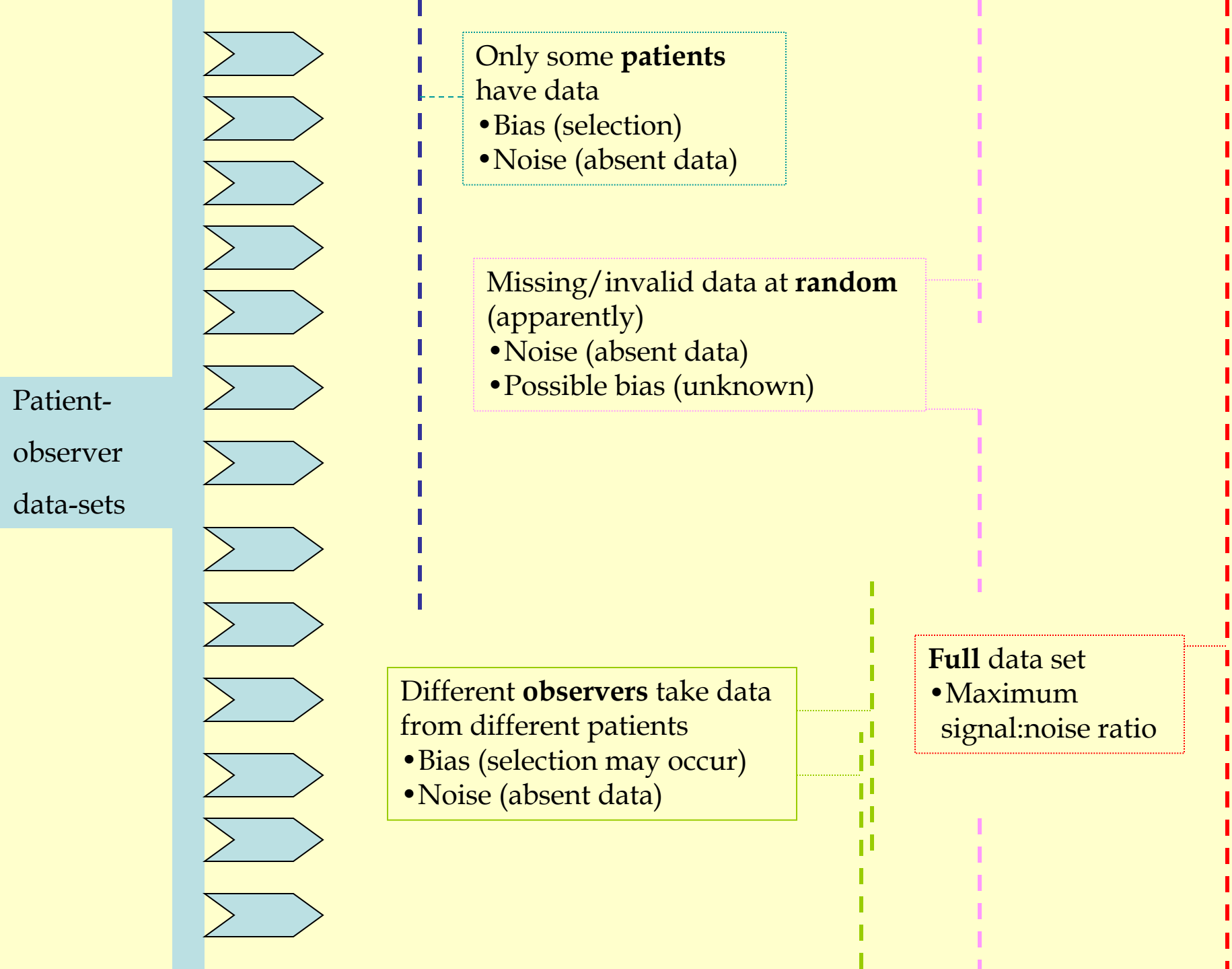
- Risk of noise
  - Unreliable
- If selective/variable
  - Bias

Good practice requires

- Full set of data from an individual patient

AND (if appropriate)

- Full set of data from the whole group (i.e. data from all patients)


Only some **patients** have data
• Bias (selection)
• Noise (absent data)
Missing/invalid data at **random** (apparently)
• Noise (absent data)
• Possible bias (unknown)
Patient-observer data-sets
Different **observers** take data from different patients
• Bias (selection may occur)
• Noise (absent data)
Full data set
• Maximum signal:noise ratio

Optimise signal - individual

- Collect data
  - Across whole range of data wanted
  - With equal weight across range
  - **Without** any additional data (noise)
  - With appropriate level of **discrimination**
    - Adequate to detect expected change/difference
    - **Not** any more sensitive (adds noise)

Optimise signal

- Avoid data loss
  - Short ‘tests’
    - More patients & testers complete them
  - Simple ‘tests’
    - Less patients **and** less testers give up/fatigue
  - Relevant ‘tests’
    - More likely to complete it (relevant to **both** parties)
  - Easy to complete
    - Less prone to generating error

Reduce noise

- Avoid:
  - Loss of data
    - 'unassessable', 'mistakes filling in form' etc
  - Irrelevant data
    - Within data collection tool
    - Unecessary data collection tool
  - Excess sensitivity
    - Data collection tools being more discriminatory than underlying data-packages

Validity

- The extent to which the data collected answers the question asked
  - **Not intrinsic to the data collection tool**
- Depends upon extent to which data tool
  - Collects data relevant to question
  - Covers whole range of possible data
  - Excludes any data not related to question

Validity applies to the data, not the tool

A good data collection tool

- Is simple to use, for patient and assessor
- Is restricted in its coverage to one domain
- Is obviously relevant

- Has good lay-out
- Is short (one page)
- Has built-in instructions, and does not require special training

A good data collection tool

- Is designed or selected to answer a specific question
  - Collects full set of data from **every** person
  - Only collects relevant data
  - Has appropriate level of discrimination
  - Has unbiased intervals if possible

Messages – think before acting

- Analyse the situation thoroughly
  - Use appropriate model(s)
    - Holistic biopschosocial model of illness;
    - Input, structure, process, outcome;
    - Process of health care;
    - Factors affecting outcome;

Message – think before acting

- Specify the question accurately
  - Identify the data needed to answer question
  - Choose a data collection tool (or tools) that
    - collect appropriate data
    - Are simple
- To answer question:
  - Use appropriate study **design**.
  - Collect minimum data needed to **interpret** outcome data

Research opportunities

- Simple research possible
- By you!

Rehabilitation measures

- There are very many (thousands) of measures
  - Often 100s of the same construct e.g. mobility
- There are very few studies that:
  - Compare measures in terms of
    - Consistency (reliability)
    - Sensitivity to change or difference
    - Feasibility – time, data completeness etc
    - Validity – ability to answer question

Massive research opportunity

- Choose 3-5 existing measures of a construct
  - e.g. strength, mobility, ADL, hand function
- Use all 3-5 measures in a population
  - Where **change** is expected
    - With treatment, or as occurs naturally
  - Where **difference** between two populations is expected
    - Different severity, different disease

Collect two data sets

- Either
  - Same patients on two occasions, **or**
  - Two different patient groups, same time
- Compare them

Design

- How repeatable is the measure:
  - Between different assessors?
  - By same assessor on two occasions?
- Assessor ‘A’ collects data
- Leave short interval (no change expected)
- Assessor ‘A’ **or** assessor ‘B’ collects data

Analysis

- Mean (SD) difference
- Correlation
  - Intraclass Correlation Coefficient (ICC)
- Scatterplot, or Bland-Altman plot

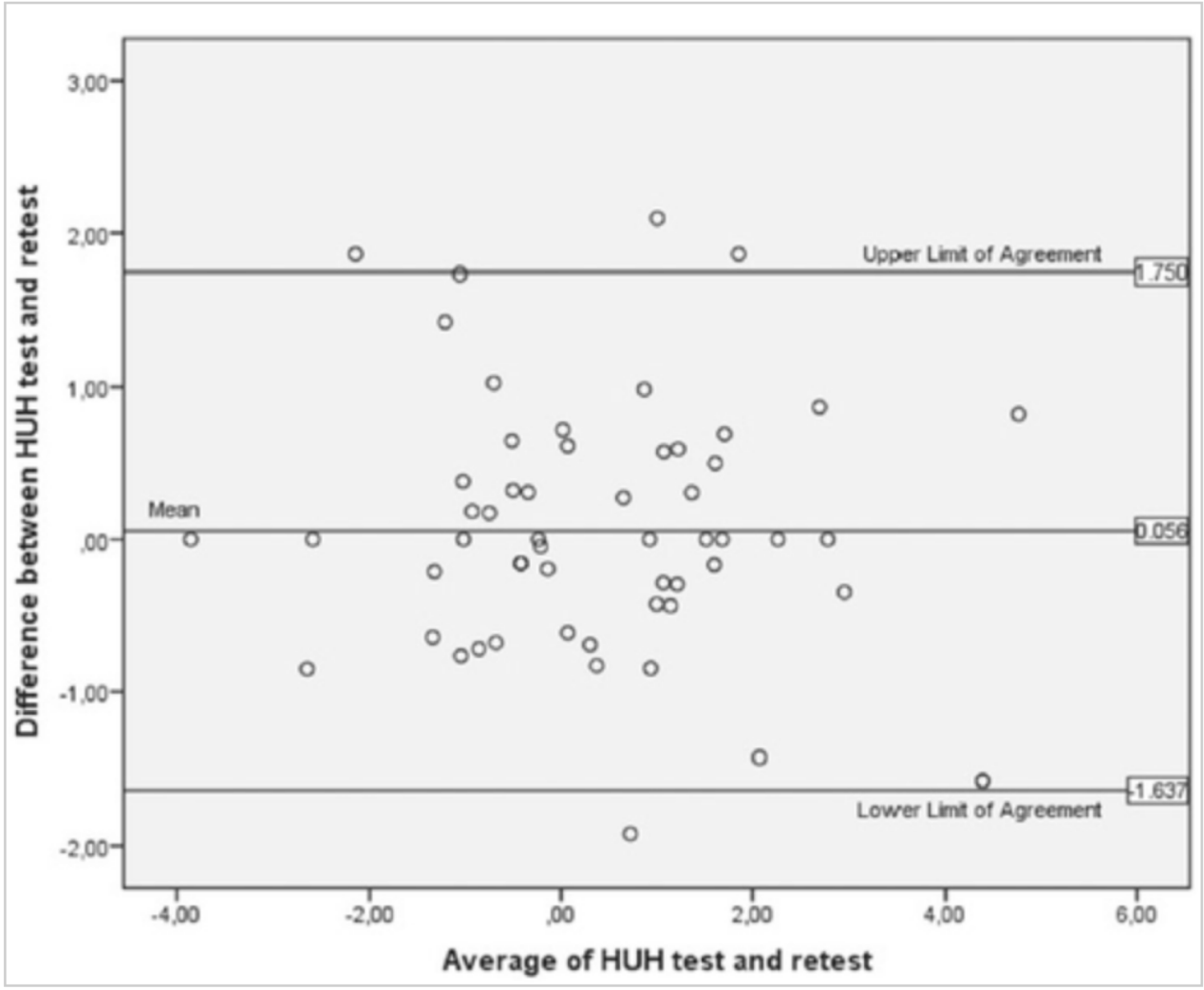
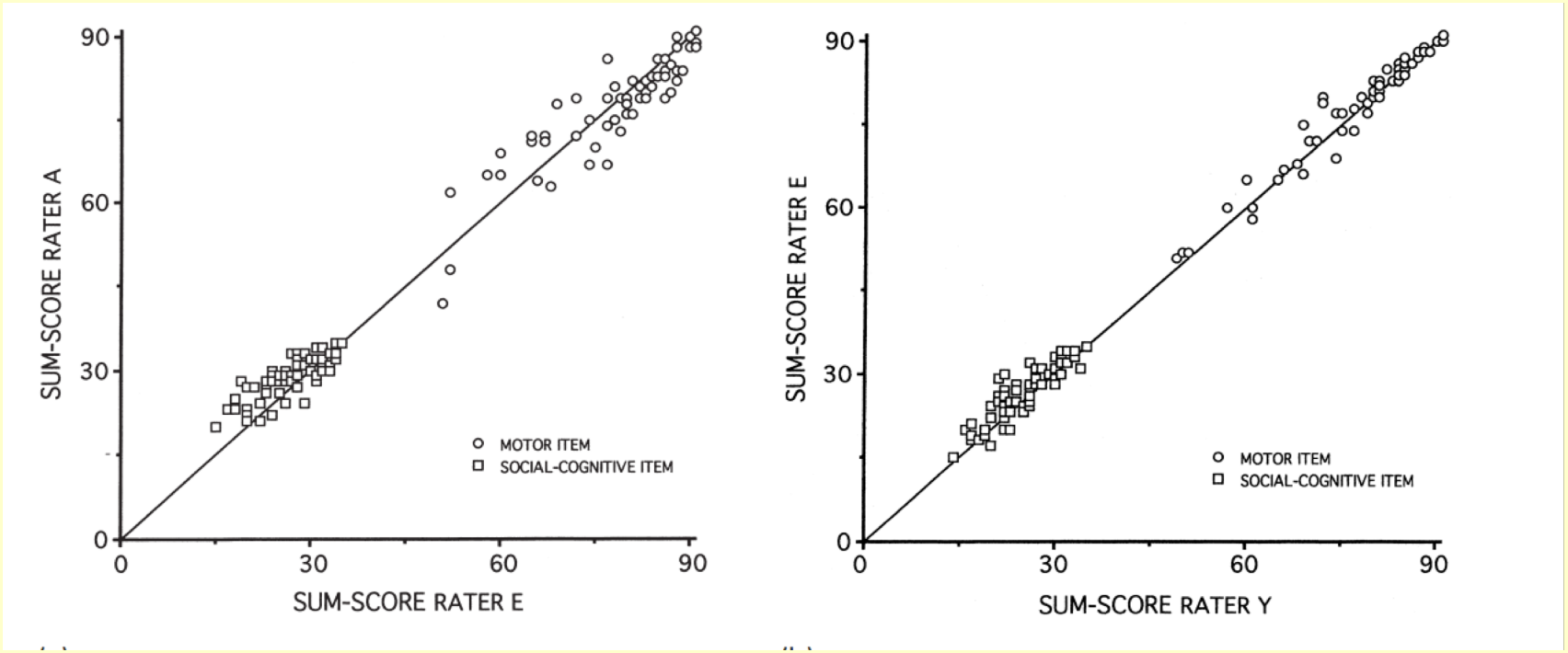


Figure 2. Bland–Altman plot showing agreement between the Hand-Use-at-Home Questionnaire (HUH) test and retest. (Limits of agreement are located at ±2 standard deviations from the mean difference.)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SUM-SCORE RATER E
MOTOR ITEM
SOCIAL-COGNITIVE ITEM
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SUM-SCORE RATER E
SUM-SCORE RATER Y
MOTOR ITEM
SOCIAL-COGNITIVE ITEM

Research into measures

- Collect data to compare
  - Test-retest (intra-rater, inter-rater) consistency
  - Ability to detect change (or difference)
  - Time taken to complete tests
  - Rate of data errors and missing values
  - Acceptability/relevance to patient/clinician

Research into measures - 2

- Systematic review of measures used
  - Compare published values concerning
    - Validity (does it work)
    - Consistency (reliability)
    - Sensitivity
    - Utility
    - Feasibility

Example - ADL

- Many measures of Personal Activities of Daily Living (PADL)
  - Activities such as feeding, continence, dressing, walking and washing
- Two major ones:
  - Barthel ADL index
  - Functional Independence measure (FIM)
    - Includes 'cognition', speech etc

Activities of Daily Living - 2

- Review of FIM and Barthel (non-systematic, not published) showed:
  - Both are same in all domains
  - Barthel takes 1-2 minutes
  - FIM takes 15-20 minutes, multiple people
- Therefore FIM more cost, no benefit

- **But** (commercial) drive to use FIM

Study on patients

- Could involve 100 rehabilitation patients
- Design
  - Each assessment by different person
  - Assessment at 0, 8 and 16 weeks
- Data
  - FIM & Barthel at each time point
  - Time taken to collect data
  - Patient's global impression of change

Study - measure

- Analysis
  - Consistency/reliability at each time point
  - Absolute score each point
  - Mean (SD) change score
  - Relationship with change score
  - Etc
- Would be published easily

Learning from this

- Importance (and difficulty) of
  - collecting data systematically
    - And variation in data
  - Ensuring capture all patients
  - Research bureaucracy
  - Design, practical problems, layout of forms
  - Recording process and writing up

Evaluation trial

- Sleep is poor in most inpatients
- Poor sleep may affect health, recovery, length of stay etc
- Evidence from RCTs restricted to ITU & use of eye shades and ear plugs

Question

- Would routine provision of eye shades and ear plugs to everyone admitted to hospital for any reason be beneficial?
- Hypotheses:
  - compared with patients without aids, treated patients will:
    - Sleep better, stay less time, use less sedation
    - Fall less

Study on patients

- Recruit 400 admissions (any reason, 16+y)
- Design
  - RCT, blinded observers
  - Follow-up to discharge or four weeks if still in
- Data
  - Sleep questionnaire Days 1, 4, 7, 14, 28 **and** at discharge
  - Falls – from hospital incident register

Sleep study

- Analysis
  - Compare two groups t-test, ANOVA
  - Falls data

- Has been done on 200 people for about £10,000 (840,000 Rub)
  - paid for a nurse for 10 weeks

Natural history - variability

- People with multiple sclerosis fluctuate
- So do people with chronic fatigue syndrome

- What level of variability is ‘natural’?
- What factors relate to variability?

Cohort study

- Recruit 50 of each diagnosis
- Design:
  - After baseline assessment
  - Daily record by text/smartphone
  - Over 3 months
- And
  - 2 hourly record over 7 days (random in 3 months)

Cohort study

- Data
  - Numerical rating scales (0-7)
  - Mood, 2-3 symptoms
  - Functional rating (e.g. how well did you ..)
  - Fatigue rating
  - Maybe grip strength, reaction speed
  - Overall ‘well-being’

Cohort study

- Data analysis
  - Get statistical advice!
  - Look for variability, and associations

Evidence

- Google scholar says
  - I have published over 350 cited papers
  - In top ten are **five** (numbers 1, 3, 7, 8, 10)
  - Which were completed with **no funding**
  - Referred to a total of 5367 times
    - Top paper cited 1997 times

Two studies

- The Barthel ADL Index: a reliability study
- C Collin, DT Wade, S Davies, V Horne
- International disability studies 1998;10:61-63
  - 1997 cites

- Dysphagia in acute stroke.
- C Gordon, RL Hewer, DT Wade
- Br Med J (Clin Res Ed) 1987;295:411-414
  - 785 cites

Time

- Spending time doing research improves clinical care
  - More critical approach to evidence
  - Keeps one interested
  - Service improves from more systematic approach

Conclusions

- Look for something from daily practice:
  - Something about natural history, treatment, diagnostic process, assessment
- Do an initial search
  - If no definite answer, start!

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