THE ART AND SCIENCE OF READING A SCIENTIFIC JOURNAL ARTICLE

FEBRUARY 9, 2023

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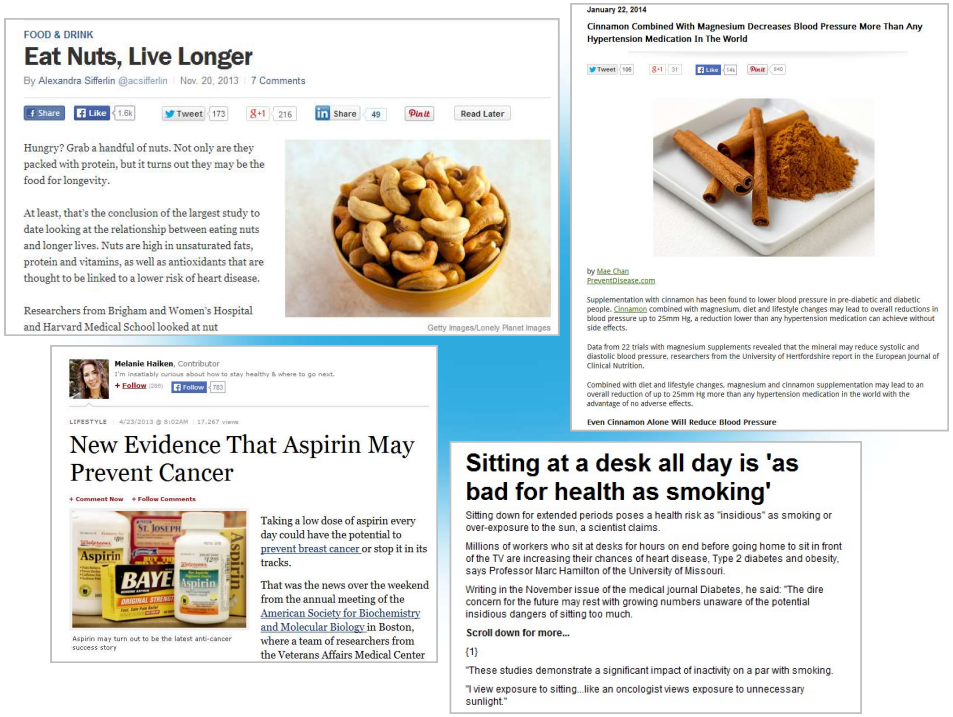
LEARNING OBJECTIVES

- Describe the process of evidence-based medicine, the hierarchy of evidence of study designs and the two major branches of analytic epidemiology
- Identify the formal sections of a research article and the key elements to look for in each section
- Recognize the difference between statistical significance and clinical significance

WE ENCOUNTER “RESEARCH” EVERY DAY



FOOD & DRINK

Eat Nuts, Live Longer

By Alexandra Sifferlin @acsifferlin | Nov. 20, 2013 | 7 Comments

Share Like 1.6k Tweet 173 +1 216 Share 49 Pin it Read Later

Hungry? Grab a handful of nuts. Not only are they packed with protein, but it turns out they may be the food for longevity.

At least, that's the conclusion of the largest study to date looking at the relationship between eating nuts and longer lives. Nuts are high in unsaturated fats, protein and vitamins, as well as antioxidants that are thought to be linked to a lower risk of heart disease.

Researchers from Brigham and Women's Hospital and Harvard Medical School looked at nut

Getty Images/Lonely Planet Images

January 22, 2014

Cinnamon Combined With Magnesium Decreases Blood Pressure More Than Any Hypertension Medication In The World

Tweet 108 +1 31 Like 146 Pin it 840

by Mae Chan
PreventDisease.com

Supplementation with cinnamon has been found to lower blood pressure in pre-diabetic and diabetic people. Cinnamon combined with magnesium, diet and lifestyle changes may lead to overall reductions in blood pressure up to 25mm Hg, a reduction lower than any hypertension medication can achieve without side effects.

Data from 22 trials with magnesium supplements revealed that the mineral may reduce systolic and diastolic blood pressure, researchers from the University of Hertfordshire report in the European Journal of Clinical Nutrition.

Combined with diet and lifestyle changes, magnesium and cinnamon supplementation may lead to an overall reduction of up to 25mm Hg more than any hypertension medication in the world with the advantage of no adverse effects.

Even Cinnamon Alone Will Reduce Blood Pressure

Melanie Haiken, Contributor
I'm insatiably curious about how to stay healthy & where to go next.
+ Follow (289) Follow 783

LIFESTYLE | 4/23/2013 @ 8:02AM | 17,267 views

New Evidence That Aspirin May Prevent Cancer

+ Comment Now + Follow Comments

Aspirin may turn out to be the latest anti-cancer success story

Taking a low dose of aspirin every day could have the potential to prevent breast cancer or stop it in its tracks.

That was the news over the weekend from the annual meeting of the American Society for Biochemistry and Molecular Biology in Boston, where a team of researchers from the Veterans Affairs Medical Center

Sitting at a desk all day is 'as bad for health as smoking'

Sitting down for extended periods poses a health risk as "insidious" as smoking or over-exposure to the sun, a scientist claims.

Millions of workers who sit at desks for hours on end before going home to sit in front of the TV are increasing their chances of heart disease, Type 2 diabetes and obesity, says Professor Marc Hamilton of the University of Missouri.

Writing in the November issue of the medical journal Diabetes, he said: "The dire concern for the future may rest with growing numbers unaware of the potential insidious dangers of sitting too much.

Scroll down for more...

(1)

"These studies demonstrate a significant impact of inactivity on a par with smoking.

"I view exposure to sitting...like an oncologist views exposure to unnecessary sunlight."

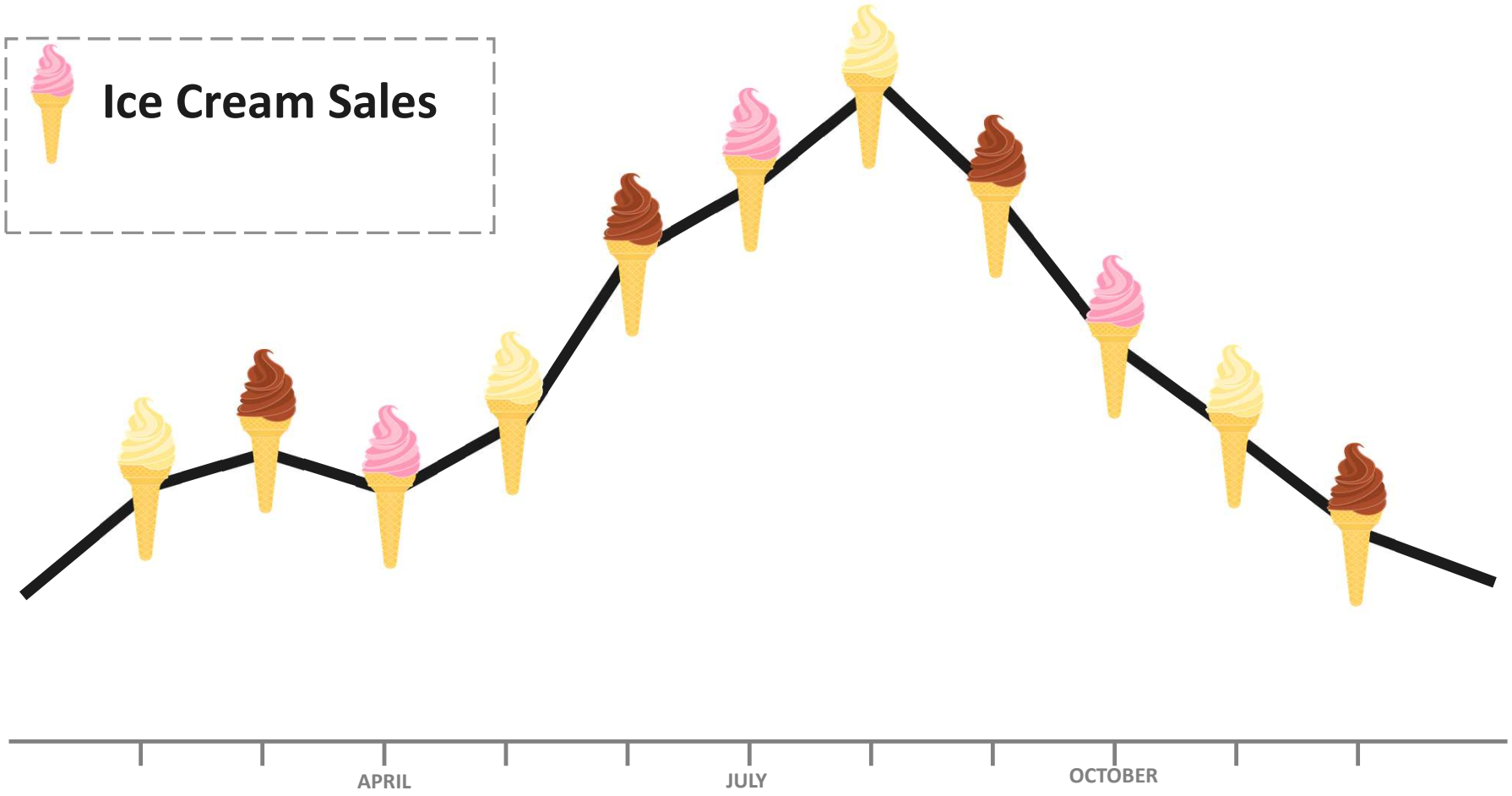
RESEARCH: Identify and quantify the relationship between an **exposure** and an **outcome**

- Nuts and longevity
- Aspirin and cancer
- Cinnamon/magnesium and hypertension
- Sitting and heart disease

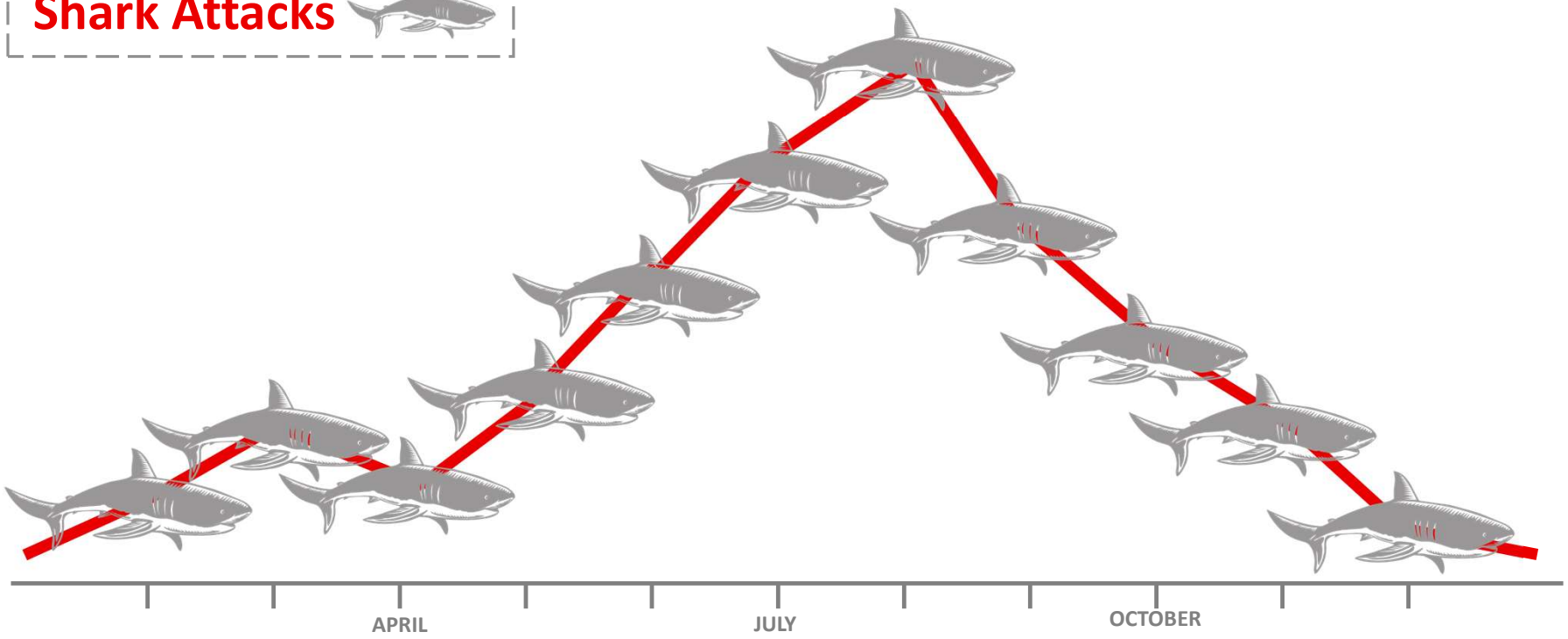
We use this information to make

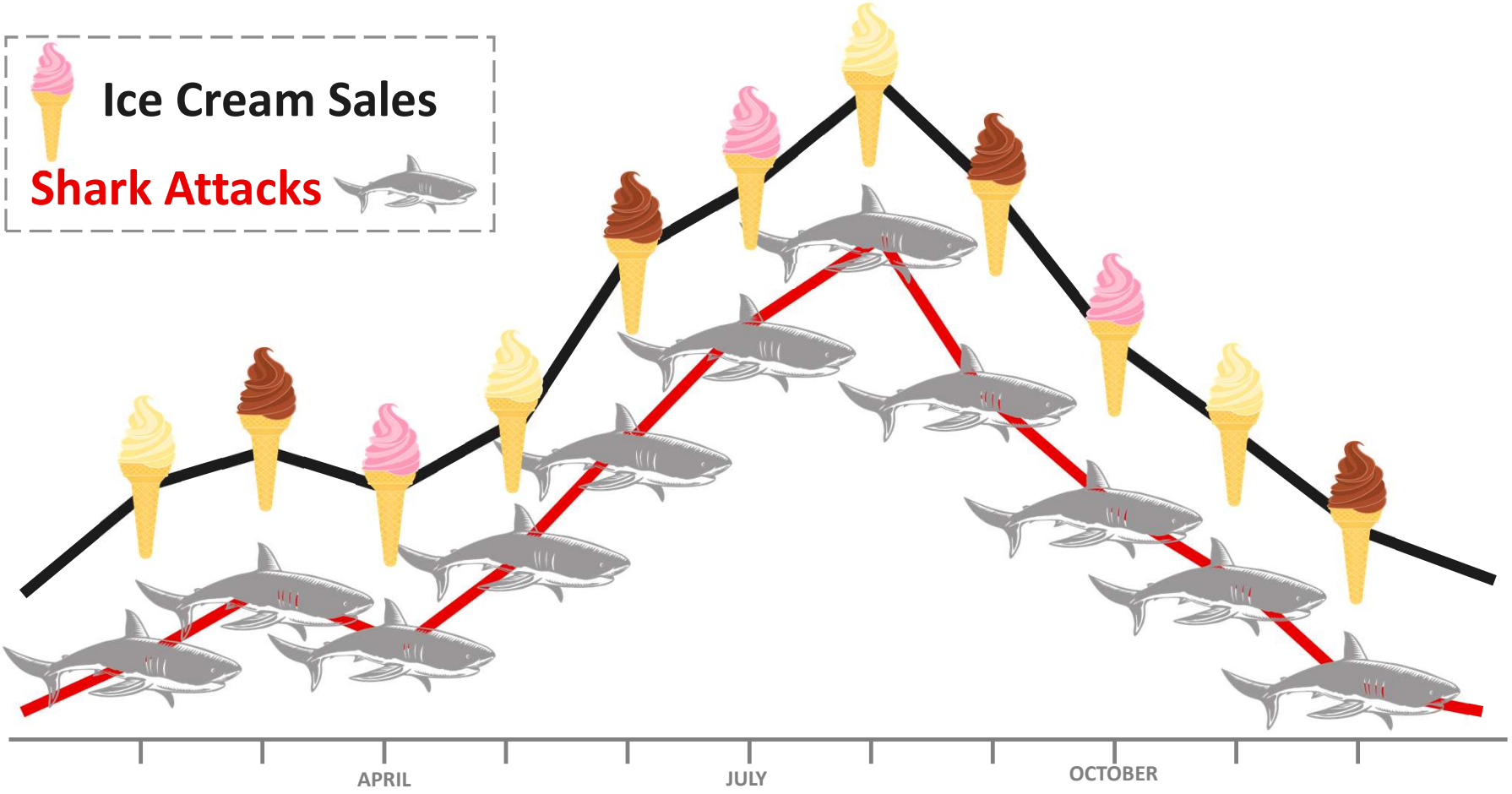
inferences and **draw conclusions**

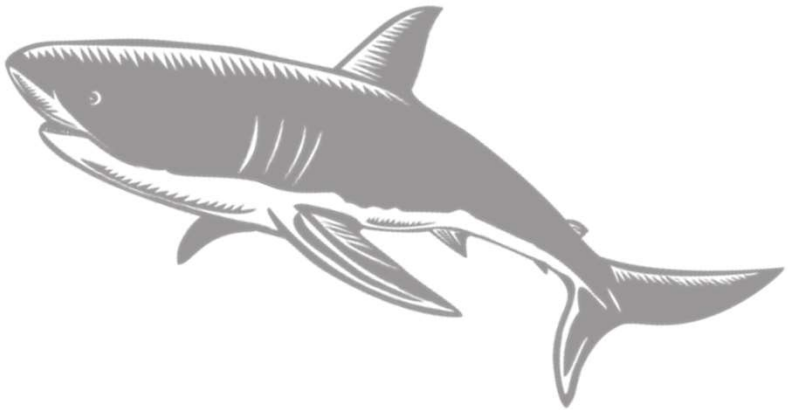
so that we can make decisions



Shark Attacks







Eat Ice Cream → **Taste Better** → **Attacked by Shark**

DON’T EAT ICE CREAM
BEFORE SWIMMING IN THE OCEAN!

MAKING INFERENCES & DRAWING CONCLUSIONS

Uncritical acceptance of conclusions

leads to

the incorporation of misinformation

into our body of knowledge.

Professional practice and policies are guided by our body of knowledge.

Meltzoff J. *Critical thinking about research: psychology and related fields*. American Psychological Association; 2018.

AUTHORITATIVE MISINFORMATION

"It is time to close the book on infectious diseases, and declare the war against pestilence won."

Dr. W. H. Stewart, US Surgeon General, 1965–1969

"If excessive smoking actually plays a role in the production of lung cancer, it seems to be a minor one."

Dr. W. C. Heuper, National Cancer Institute, 1954

WHY IS EVIDENCE-BASED PRACTICE IMPORTANT?

EVIDENCE-BASED HEALTH CARE

EVIDENCE-BASED MEDICINE

The use of mathematical estimates of the risk of benefit and harm, derived from high-quality research on population samples to ***inform clinical decision-making***

Greenhalgh T. *How to read a paper*. 6th ed. John Wiley & Sons Ltd; 2019.

THE PROCESS OF EVIDENCE-BASED MEDICINE

Convert our information needs into **answerable questions**

Track down the **best evidence** with which to answer the questions

Appraise the evidence critically to **assess its validity** and **usefulness**

Implement the results of this appraisal in our clinical practice

Evaluate performance

Sackett DL, Haynes RB. *On the need for evidence-based medicine*. BMJ Evidence-Based Medicine. 1995;1:4-5

DRAWING INFERENCES AND CONCLUSIONS

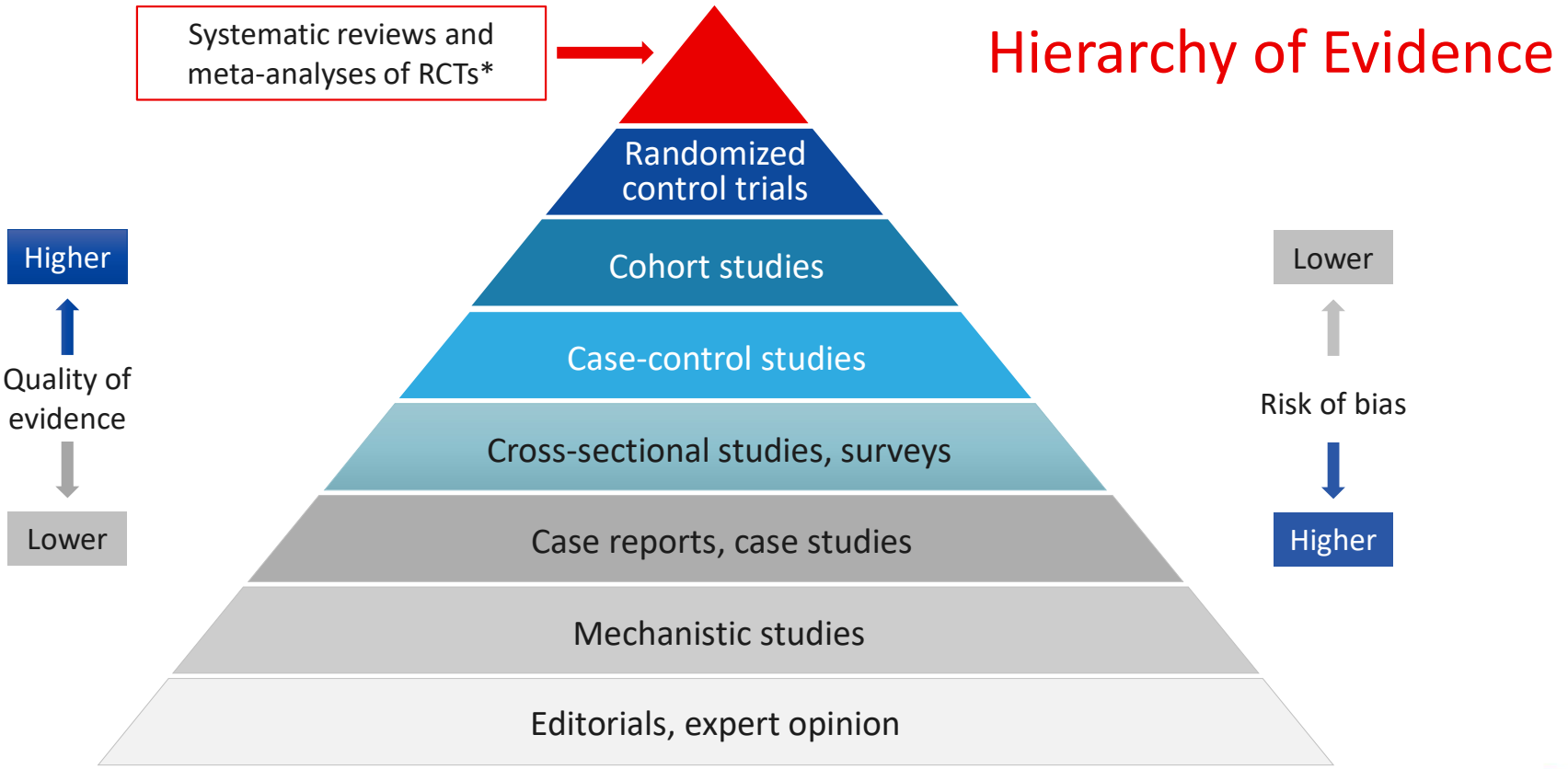
THINK LIKE A DETECTIVE!

You must use 2 things:

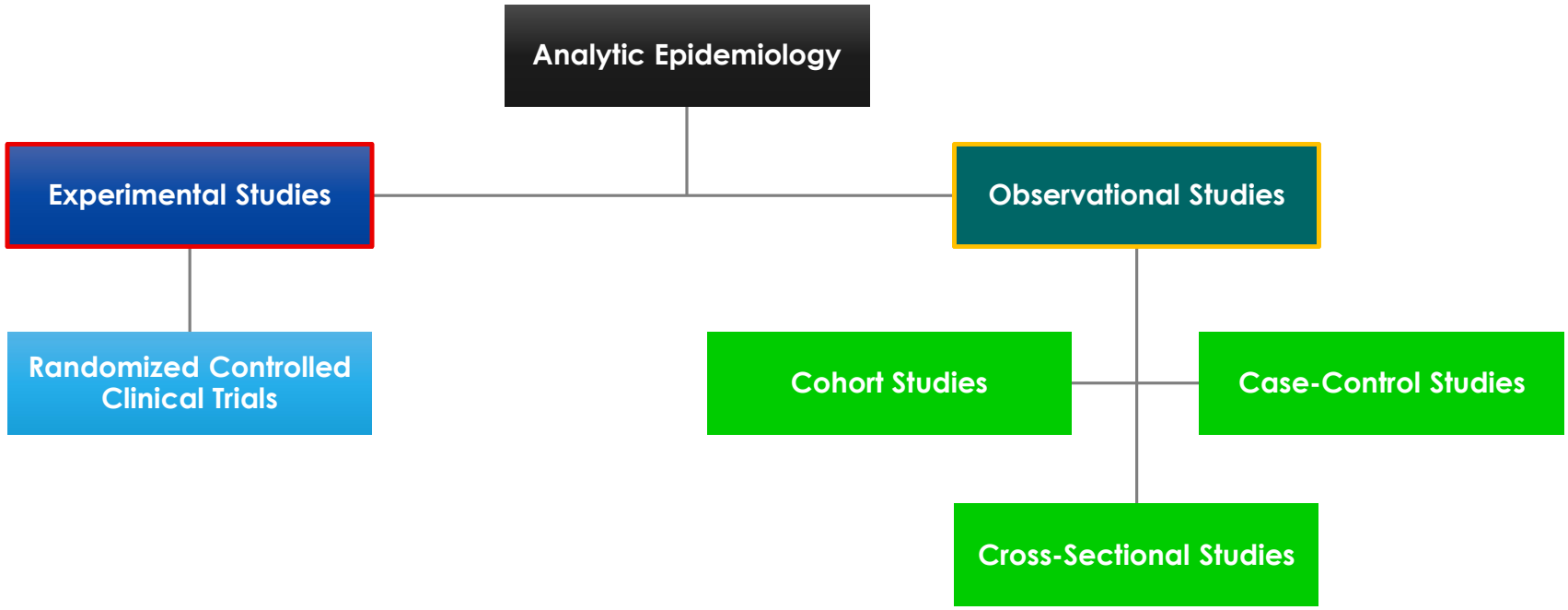
1. What you know in your head, and
2. What you have read in text in order to answer the question

RESEARCH AND STUDY DESIGNS

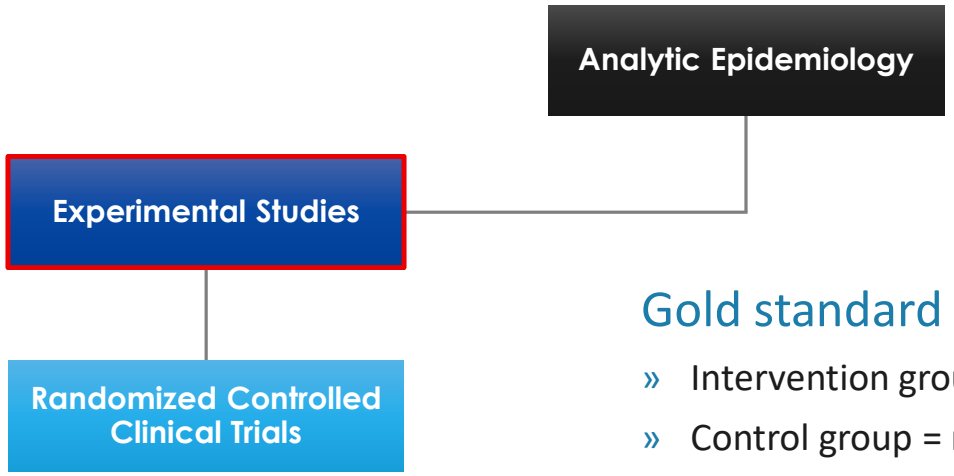
EPIDEMIOLOGIC STUDY DESIGNS



ANALYTIC BRANCH OF EPIDEMIOLOGY



BRANCHES OF EPIDEMIOLOGY

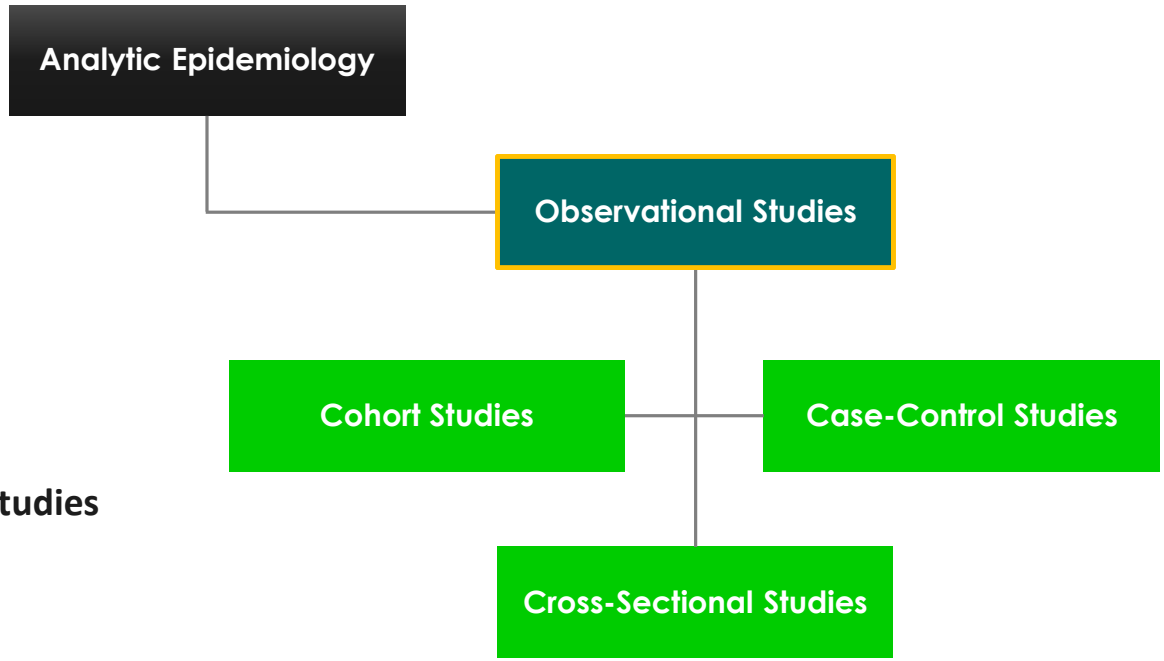


Gold standard of study designs

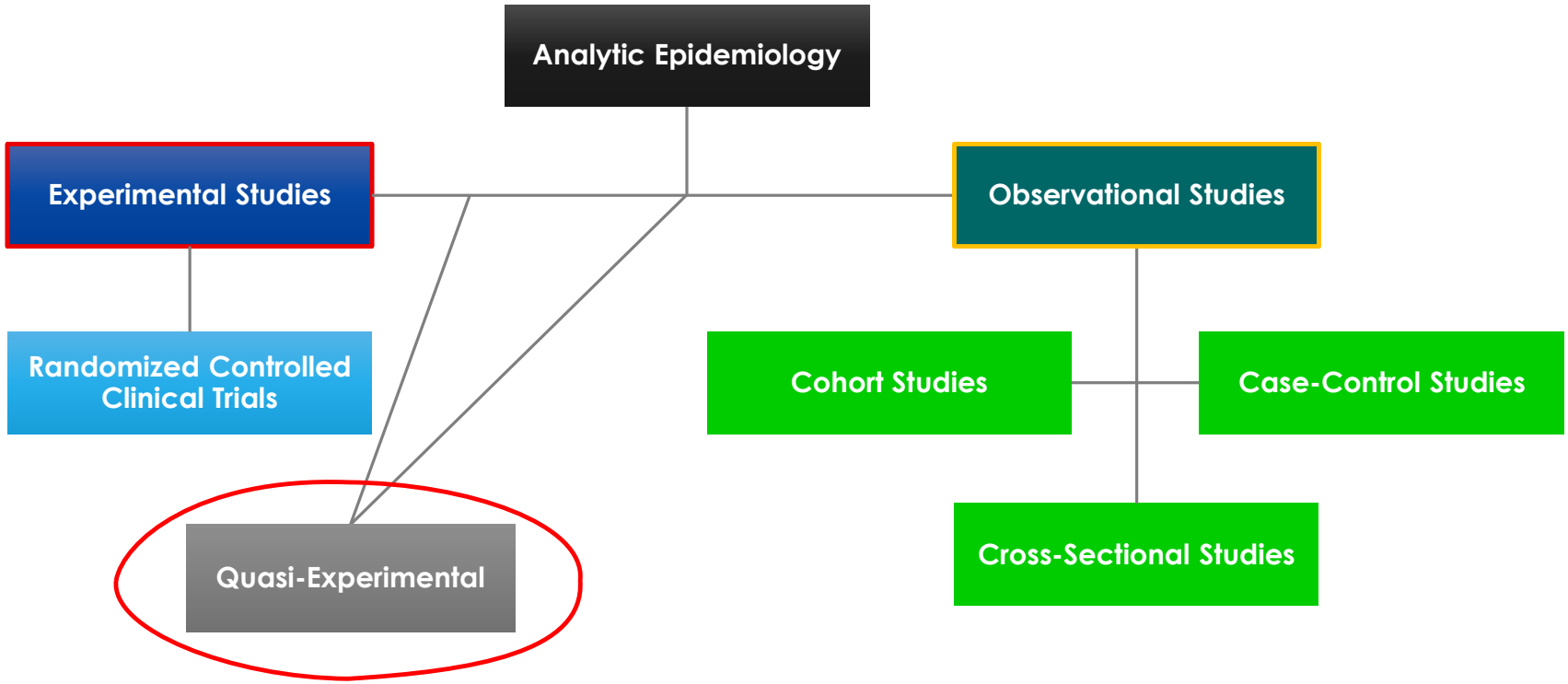
- Intervention group = exposure/intervention dictated
- Control group = no exposure/intervention
- **Participant randomization** controls bias and confounding
- Blinding
- Ethically appropriate only when exposures/intervention are hypothesized to be beneficial or at least not harmful
- **Can state cause and effect**

BRANCHES OF EPIDEMIOLOGY

- Exposures and outcomes are observed
- No intervention, no control group
- Ethically appropriate when exposures are hypothesized to be harmful
- **Used most often in infection prevention studies**
- **Cannot determine cause and effect, only correlation/association**

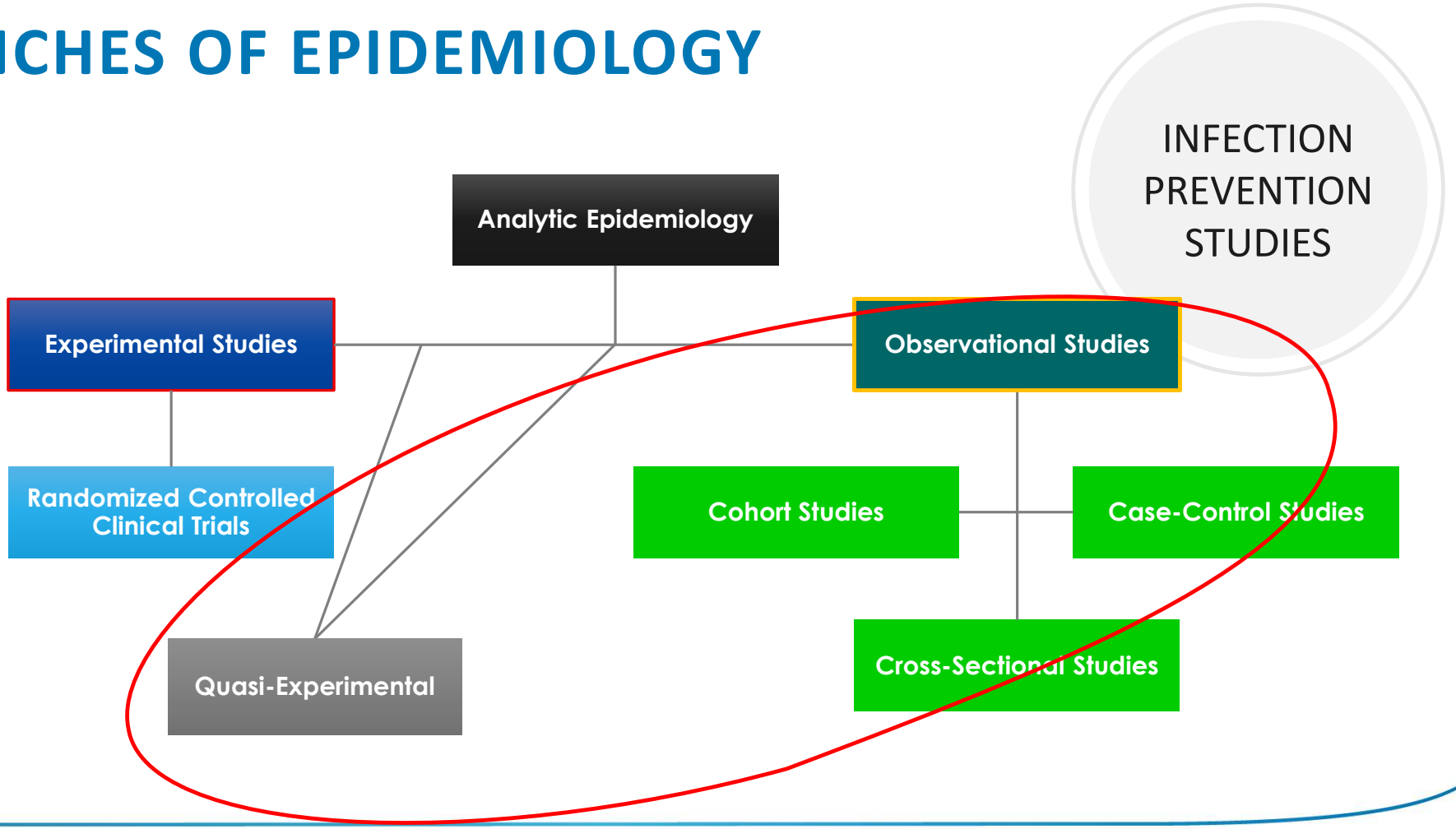


BRANCHES OF EPIDEMIOLOGY



Meltzoff J. *Critical thinking about research: psychology and related fields*. American Psychological Association; 2018.

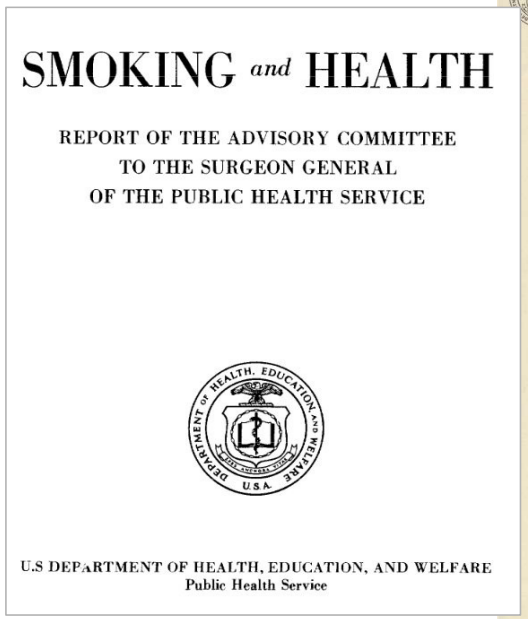
BRANCHES OF EPIDEMIOLOGY

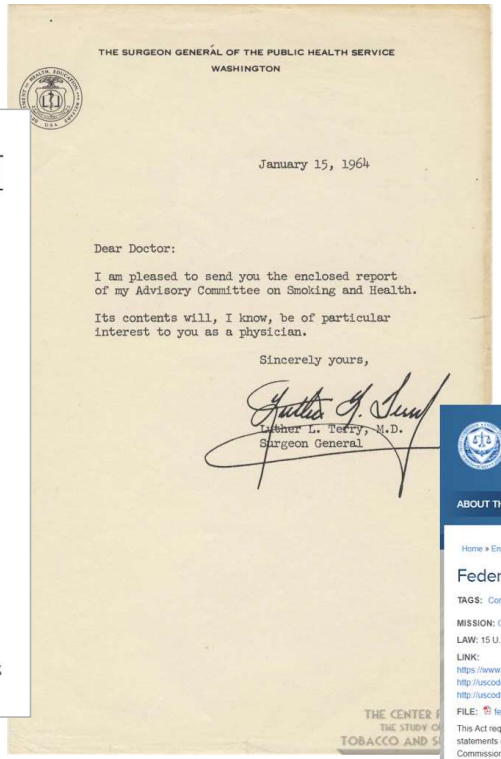


CAUSATION VS CORRELATION

Does this mean observational studies ***cannot guide*** professional practice and policies?

Is Smoking Bad For Your Health?





CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

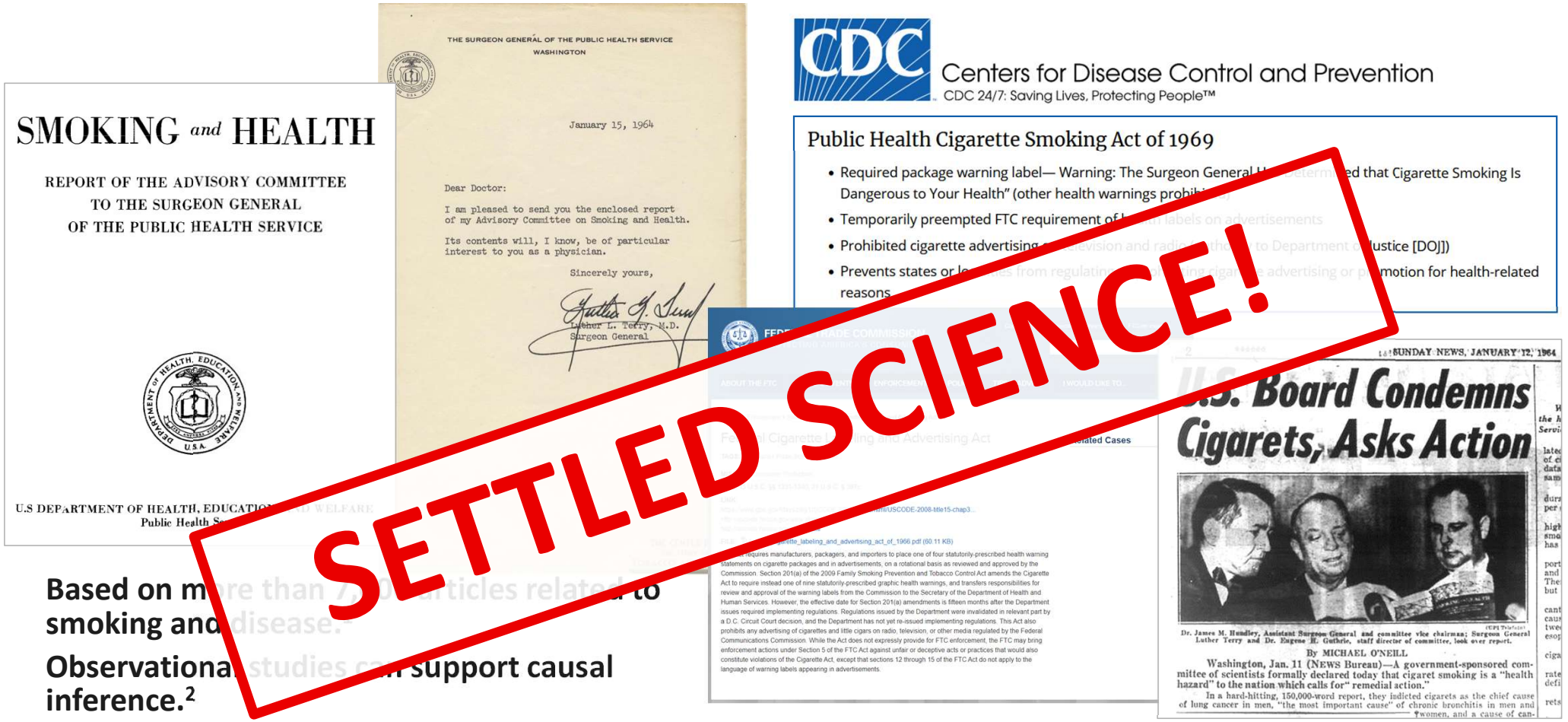
Public Health Cigarette Smoking Act of 1969

- Required package warning label— Warning: The Surgeon General Has Determined that Cigarette Smoking Is Dangerous to Your Health" (other health warnings prohibited)
- Temporarily preempted FTC requirement of health labels on advertisements
- Prohibited cigarette advertising on television and radio (authority to Department of Justice [DOJ])
- Prevents states or localities from regulating or prohibiting cigarette advertising or promotion for health-related reasons

Based on more than 7,000 observational studies related to smoking and disease.[1]

Observational studies can support causal inference.[2]

1. Centers for Disease Control and Prevention. *History of the Surgeon General's Reports on Smoking and Health*. Updated November 15, 2019. Accessed October 1, 2021. https://www.cdc.gov/tobacco/data_statistics/sgr/history/index.htm
2. Samet JM. *Epidemiology and the tobacco epidemic: how research on tobacco and health shaped epidemiology*. Am J Epidemiol. 2016;183:394-402.



1. Centers for Disease Control and Prevention. *History of the Surgeon General's Reports on Smoking and Health*. Updated November 15, 2019. Accessed October 1, 2021. https://www.cdc.gov/tobacco/data_statistics/sgr/history/index.htm
2. Samet JM. *Epidemiology and the tobacco epidemic: how research on tobacco and health shaped epidemiology*. Am J Epidemiol. 2016;183:394-402.

OBSERVATIONAL AND QUASI-EXPERIMENTAL STUDIES CAN SUPPORT CAUSAL INFERENCE

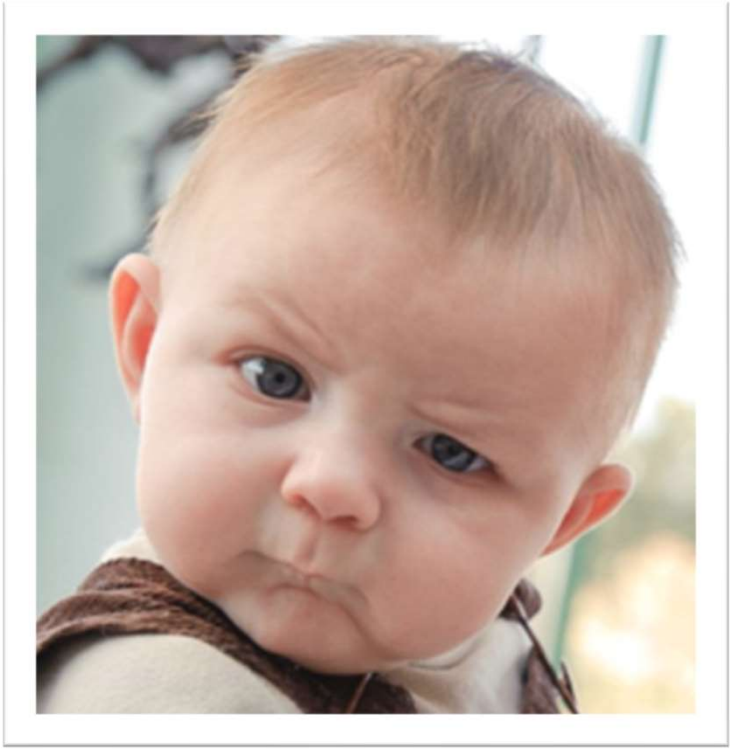
As evidence is amassed → the strength of the association increases → multiple study designs are used → and the results are replicated across different countries by multiple investigators

By a preponderance of the evidence, we can use the information to guide professional practice and policies in healthcare.

Samet JM. *Epidemiology and the tobacco epidemic: how research on tobacco and health shaped epidemiology.* Am J Epidemiol. 2016;183:394-402.

WHERE DO WE BEGIN?

SCHOLARLY CRITIQUE – BE A SKEPTIC



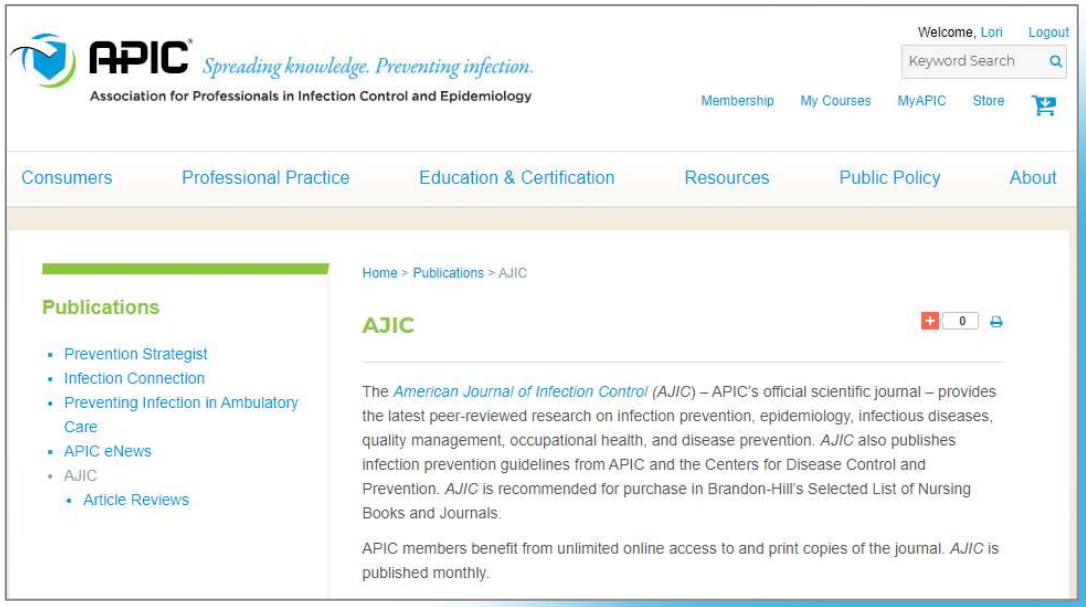
WHAT ARE YOU LOOKING FOR?

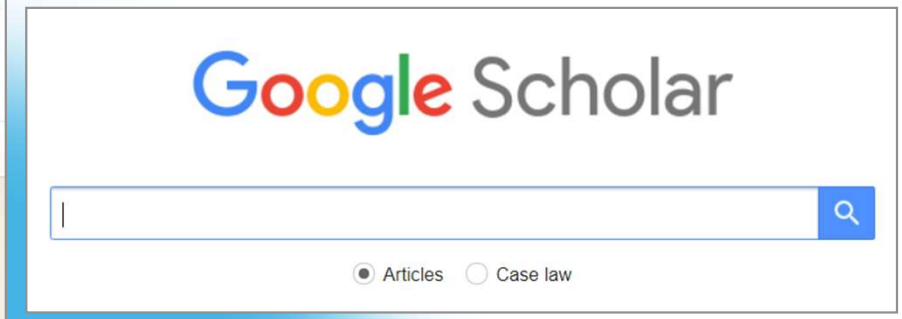
Three broad purposes for reading scientific studies

- Informal browsing to keep current and to satisfy intrinsic curiosity
- Focused, looking for answers, perhaps related to questions or solutions to problems
- Survey existing literature, perhaps before embarking on a research project

Greenhalgh T. *How to read a paper*. 6th ed. John Wiley & Sons Ltd; 2019.

FIND YOUR JOURNAL ARTICLE





PEER REVIEW

The process of subjecting an author's scholarly work, research or ideas to the scrutiny of others who are experts in the same field*

- Acts as a filter to ensure that only high-quality research is published

How to determine if a journal is peer-reviewed:

- Most journals in PubMed and Medline are peer-reviewed
- Hospital library Databases A-Z > Ulrich's Periodicals Directory > Enter name of journal
- Hospital library database > Journal Finder > Enter name of journal
- Go to Journal website > Home page

*Kelly J, Sadeghieh T, Adeli, K. *Peer review in scientific publications: benefits, critiques, & a survival guide.* Clin Chem Lab Med. 2014;25:227-243.

CONFLICT OF INTEREST DISCLOSURES

Interest: A commitment, goal, or value held by an individual or an institution[1]

Conflict of Interest: When two or more contradictory interests relate to an activity by an individual or an institution. The conflict lies in the situation, not in any behavior or lack of behavior of the individual. That means that a conflict of interest is not intrinsically a bad thing[1]

- Do not discount the findings if there is a financial disclosure or if the research is sponsored by a company that has an interest in the findings.[2]
  - Be aware of the relationship and carefully examine the methods and results.[2]

1. Korenman SG. *Teaching the Responsible Conduct of Research in Humans (RCHRH), Ch 4 Conflicts of Interest.* Accessed 11/8/2021 https://ori.hhs.gov/education/products/ucla/chapter4/default.htm
2. Step M. *Conflicts of Interest in Academics and Industry*. Lecture.

INITIAL QUICK APPRAISAL FOR ARTICLE SELECTION

JAMA Network Open. 2021;4(2):e2035331. doi:10.1001/jamanetworkopen.2020.35331 February 8, 2021 1/13

JAMA Network Open

Date of Publication

Original Investigation | Infectious Diseases

Effect of Wearing a Novel Electronic Wearable Device on Hand Hygiene Compliance Among Health Care Workers
A Stepped-Wedge Cluster Randomized Clinical Trial

Daniela Pires, MD, PhD; Angele Gayet-Ageron, MD, PhD; Chloe Guitart, PharmD; Yves-Alain Robert, MS; Carolina Fankhauser, MSc; Ermira Tartari, PhD; Alexandra Peters, MS; Funda Tymurkaynak, MD; Simon Fourquier, MS; Herve Soule, PharmD; Rene Beuchat, MS; Fernando Bellissimo-Rodrigues, MD, PhD; Yves Martin, MS; Walter Zingg, MD; Didier Pittet, MD, MS

Article title and study design

Authors

Author credentials, affiliations, disclosures

ARTICLE INFORMATION

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Author Affiliations: Infection Control Programme and World Health Organization Collaborating Centre on Patient Safety—Infection Control & Improving Practices, University of Geneva Hospitals and Faculty of Medicine, Geneva, Switzerland (Pires, Gayet-Ageron, Guitart, Fankhauser, Tartari, Peters, Tymurkaynak, Soule, Bellissimo-Rodrigues, Martin, Zingg, Pittet); Faculty of Health Sciences, University of Malta, Msida, Malta (Tartari); iQati, Sion, Switzerland (Robert, Martin); Haute école du paysage, d'ingénierie et d'architecture de Genève (HEPIA), Geneva, Switzerland (Fourquier, Beuchat); Social Medicine Department, Ribeirão Preto Medical School, University of São Paulo, Ribeirão Preto, São Paulo, Brazil (Bellissimo-Rodrigues).

Author Contributions: Drs Pire, Gayet-Ageron, and Pittet had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Concept and design: Pires, Gayet-Ageron, Soule, Bellissimo-Rodrigues, Martin, Zingg, Pittet.

Acquisition, analysis, or interpretation of data: Pires, Gayet-Ageron, Guitart, Robert, Fankhauser, Tartari, Peters, Tymurkaynak, Fourquier, Beuchat, Bellissimo-Rodrigues, Martin, Zingg, Pittet.

Drafting of the manuscript: Pires, Gayet-Ageron, Tymurkaynak, Fourquier, Zingg.

Critical revision of the manuscript for important intellectual content: Pires, Gayet-Ageron, Guitart, Robert, Fankhauser, Tartari, Peters, Soule, Beuchat, Bellissimo-Rodrigues, Martin, Zingg, Pittet.

Statistical analysis: Pires, Gayet-Ageron.

Obtained funding: Gayet-Ageron, Bellissimo-Rodrigues, Martin, Pittet.

Administrative, technical, or material support: Pires, Guitart, Robert, Fankhauser, Tartari, Peters, Tymurkaynak, Fourquier, Soule, Beuchat, Bellissimo-Rodrigues, Martin, Zingg, Pittet.

Supervision: Pires, Guitart, Fankhauser, Bellissimo-Rodrigues, Zingg, Pittet.

Pires D., et al. *Effect of wearing a novel electronic wearable device on hand hygiene compliance among health care workers: a stepped-wedge cluster randomized clinical trial.* JAMA Netw Open. 2021;4:e20335331

ABSTRACT

Summarizes the content of publications

Headings mirror the publication

Structured or unstructured

Abstract

IMPORTANCE Hand hygiene (HH) is essential to prevent hospital-acquired infections.

OBJECTIVE To determine whether providing real-time feedback on a simplified HH action improves compliance with the World Health Organization's "5 Moments" and the quality of the HH action.

DESIGN, SETTING, AND PARTICIPANTS This open-label, cluster randomized, stepped-wedge clinical trial was conducted between June 1, 2017, and January 6, 2018 (with a follow-up in March 2018), in a geriatric hospital of the University of Geneva Hospitals, Switzerland. All 12 wards and 97 of 306 eligible health care workers (HCWs) volunteered to wear a novel electronic wearable device that delivered real-time feedback on duration of hand rubbing and application of a hand-sized customized volume of alcohol-based handrub (ABHR).

INTERVENTIONS This study had 3 sequential periods: baseline (no device), transition (device monitoring without feedback), and intervention (device monitoring and feedback). The start of the transition period was randomly allocated based on a computer-generated block randomization.

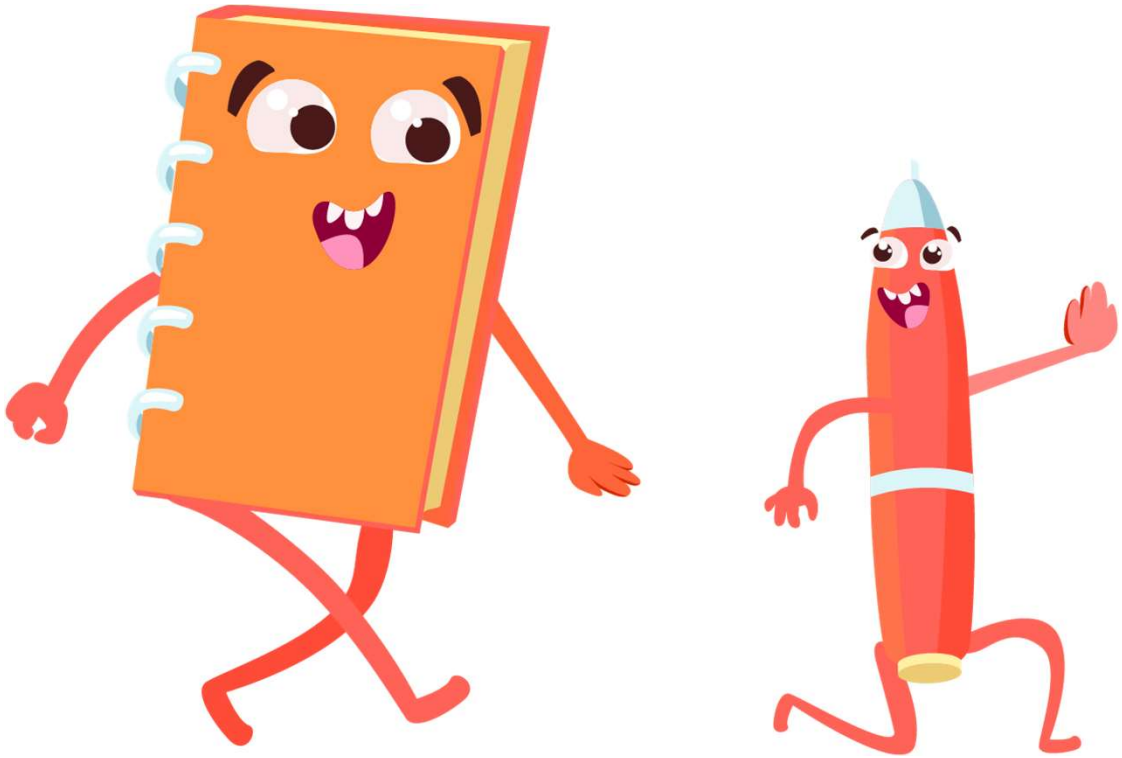
MAIN OUTCOMES AND MEASURES The primary outcome was HH compliance, according to the direct observation method during intervention as compared with baseline. Secondary outcomes included the volume of ABHR and duration of hand rubbing measured by the device during intervention as compared with transition.

RESULTS All wards and respective HCWs were evenly assigned to group 1 (26 participants), 2 (22 participants), 3 (25 participants), or 4 (24 participants). Twelve HCWs did not fully complete the intervention but were included in the analysis. During 759 observation sessions, 6878 HH opportunities were observed. HH compliance at intervention (62.9%; 95% CI, 61.1%-64.7%) was lower than at baseline (66.6%; 95% CI, 64.8%-68.4%). After adjusting for covariates, HH compliance was not different between periods (odds ratio, 1.03; 95% CI, 0.75-1.42; $P = .85$). Days since study onset (OR, 0.997; 95% CI, 0.994-0.998; $P < .001$), older age (OR, 0.97; 95% CI, 0.95-0.99; $P = .015$), and workload (OR, 0.29; 95% CI, 0.20-0.41; $P < .001$) were independently associated with reduced HH compliance. The median (interquartile range) volume of ABHR and duration of hand rubbing in transition and intervention increased from 1.12 (0.76-1.68) mL to 1.71 (1.01-2.76) mL and from 6.5 (4.5-10.5) seconds to 8 (4.5-15.5) seconds, respectively. There were no serious adverse events.

CONCLUSIONS AND RELEVANCE The use of this device did not change HH compliance, but increased the duration of hand rubbing and volume of ABHR used by HCWs.

Pires D., et al. *Effect of wearing a novel electronic wearable device on hand hygiene compliance among health care workers: a stepped-wedge cluster randomized clinical trial.* JAMA Netw Open. 2021;4:e20335331

NOW THE HARD WORK BEGINS!



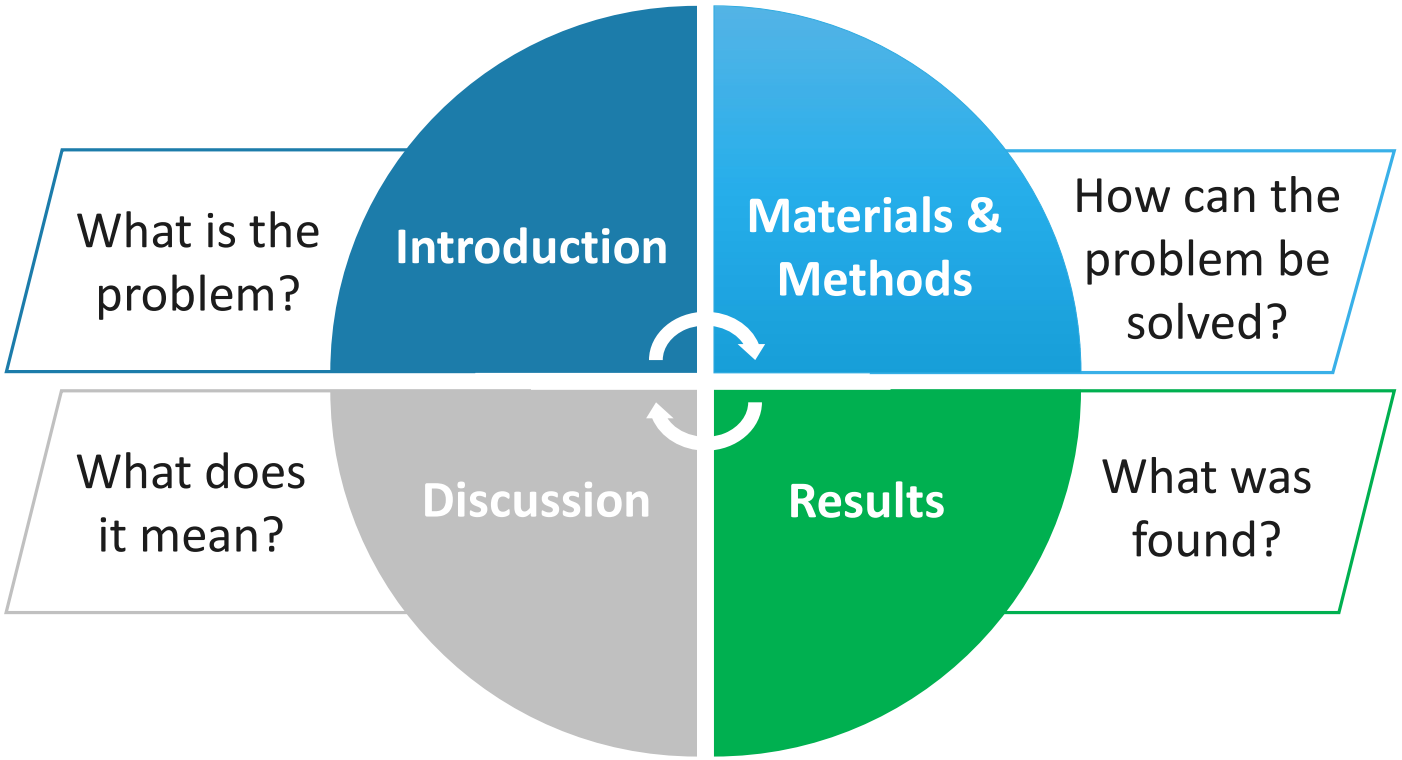
PRINT THE JOURNAL ARTICLE!
PEN TO PAPER

ELEMENTS OF A PUBLICATION

IMRAD

- **I**ntroduction
- **M**ethods
- **R**esults
- **a**nd
- **D**iscussion

Notes, references, and acknowledgements



Sollaci LB, Pereira MG. *The introduction, methods, results and discussion (IMRAD) structure: a fifty-year survey.* J Med Lib Assoc. 2004;92:365:371

INTRODUCTION

Provides the context for the study

- Justification and purpose of the study – Clear statement of the problem
- Short review of the background information to understand the significance of the problem
- Relevant scientific literature cited
  - What is known and unknown about the topic or problem
  - How the study fills the gap
- The study question, hypothesis, or aim clearly stated

Cooper D. *How to write an original research paper (and get it published).* J Med Lib Assoc. 2015;103:67-68

INTRODUCTION

Purpose / Problem

Literature review

Aim of the study, hypotheses, study population

Introduction

Health care–associated infections (HAI) and the spread of antimicrobial resistance are major public health concerns[1,2] that are largely avoidable in health care by effective implementation of infection prevention and control best practices.[3,4] The World Health Organization (WHO) recommends that performing hand hygiene (HH) correctly ("How to Handrub") at the correct time ("5 Moments") is the most effective measure to prevent HAI.[5,6] The appropriate HH action is crucial to assure proper antimicrobial efficacy.[7-9] Unfortunately, HH compliance remains suboptimal,[10] and new strategies are needed to improve its implementation.

A number of studies suggest that the HH action, as endorsed by the WHO, could be simplified without compromising efficacy. Proposed changes include shortening duration of hand rubbing to 15 seconds (instead of 30 seconds)[11-14] and changing the number or order of steps ("3 steps" or "fingertips-first" instead of the "6 step" technique).[15-17] Additionally, standardization of the hand-size ("palm full") concept recommended by the WHO has been proposed.[18,19] It is hypothesized that these changes could lead to an increase in the quality of the HH action performed by health care workers (HCWs).[13,16] In addition, some small-sized studies have suggested that a simplified HH action could also improve compliance with the "5 Moments."[13,16]

Monitoring and feedback are essential parts of the WHO multimodal strategy to improve HH.[6] However, direct observation and timely feedback are time-consuming, costly, and prone to bias.[20,21] There has been a growing interest in the use of electronic monitoring, which can increase the number of monitored actions and remove the observation bias.[21]

We developed a novel wearable electronic device that monitors and provides real-time, personalized feedback to HCWs based on a simplified and customized HH action. This device is the result of an investigator-initiated partnership between 3 Swiss institutions: the University of Geneva Hospitals (HUG) and Faculty of Medicine, the Haute école du paysage, d'ingénierie et d'architecture de Genève (HEPIA), and iQati, a start-up medical device company.

We aimed to test the impact of the electronic device on compliance with the WHO "5 Moments" for HH and on the quality of hand rubbing in daily patient-care activities. We hypothesized that the use of the device would create a permanent sense of being observed on the HCWs, the so-called positive Hawthorne effect,[22] that is known to influence compliance with HH. We also hypothesized that the use of the device would directly increase the quality of HH action reflected by the volume of ABHR used and the duration of HH.

Quasi-Experimental Study

Intervention

Testing impact of wearable electronic device on:

- Hand hygiene compliance ★
- Quality of hand rubbing
- Volume of ABHR
- Duration of hand rubbing

Pires D., et al. *Effect of wearing a novel electronic wearable device on hand hygiene compliance among health care workers: a stepped-wedge cluster randomized clinical trial.* JAMA Netw Open. 2021;4:e20335331

INTRODUCTION – PEN TO PAPER

- What is the problem and purpose of the study?
- Does the literature review offer a balanced appraisal of the literature; can you detect any biases?
  - Does the content in the literature review directly relate to the research problem?
  - Are the references current and from reputable journals?
- Do the stated aims and objectives of the study reflect the information presented in the literature review?

Manning ML & Davis J. *Journal club: a venue to advance evidence-based infection prevention practices*. Am J Infect Control. 2012;40:667-669

METHODS – CORE OF THE PAPER

Roadmap to how the study was carried out – many say most important section

Provides readers with enough information that will help them either repeat the study or elaborate and extend the study

- Describes the setting in which the study took place
- Conveys study design, population (participants/subjects), sample size and interventions
- Describes how the data were collected (measurement devices) and validation procedures
- Presents a brief description of data analysis methodology

Cooper D. *How to write an original research paper (and get it published).* J Med Lib Assoc. 2015;103:67-68

METHODS

Methods

Study Design

This study was a Swiss National Research Foundation–funded, investigator-initiated, single-center (ie, HUG) project. We conducted a stepped-wedge, cluster randomized, and controlled open-label trial. This study design was preferred to a classic parallel cluster randomized trial because the device was assumed to be a quality improvement tool to which all participating HCWs should have access.

The trial was approved by the Regional Research Ethics Committee, and all participating HCWs provided written informed consent. This study followed Consolidated Standards of Reporting Trials (CONSORT) reporting guideline. A full trial protocol is available in Supplement 1.

Participants

All wards of the geriatric hospital at HUG, including outpatient clinics and the emergency department, were eligible to participate if at least 5 permanent HCWs volunteered. HCWs were not eligible if, during the study period, they: (1) planned to leave the ward; (2) worked in more than 1 ward (risk of contamination bias); (3) had more than 3 consecutive weeks of vacations scheduled for the study period; or (4) used an ABHR agent other than the standard at HUG due to skin allergy. HCWs were recruited over the course of 26 10-minute information sessions at clinical nursing and medical staff meetings, as well as by posters and leaflets (eFigure 1 in Supplement 2).

Settings

HUG is a 1900-bed, tertiary care university hospital with approximately 50 000 admissions per year. The geriatric hospital is a 300-bed, freestanding building, located at a separate site in Geneva, with approximately 10 000 admissions per year.

Quasi-Experimental Study

Study design

IRB information

Inclusion criteria

Population sample

Exclusion criteria

The setting in which the study took place

Pires D., et al. *Effect of wearing a novel electronic wearable device on hand hygiene compliance among health care workers: a stepped-wedge cluster randomized clinical trial.* JAMA Netw Open. 2021;4:e20335331

METHODS

Intervention components

Data collection

Quasi-Experimental Study

Intervention

The intervention consisted of providing real-time individual feedback to HCWs after 15 seconds of hand rubbing and the application of a hand-sized volume of ABHR. Feedback was provided by the novel electronic wearable device (SmartRub), which consists of 2 elements—a bottle and a wristband (eFigure 2 in Supplement 2). Each individual ABHR bottle that is widely used at HUG was equipped, during the transition and intervention periods, with a volumetric flow meter. The flow meter measured the volume of ABHR poured onto hands and during the intervention period it also provided feedback by vibrating as soon as the predefined volume had been applied. The volume was determined for each HCW by taking into account the surface area of each individual's hands,[23] as described in previous studies.[9,12,18] The wristband, made from silicone, was worn during the transition and intervention periods. It measured the duration of each HH action, and during the intervention period it also vibrated after 15 seconds independently of the hand rubbing duration performed by the HCW.[11,12]

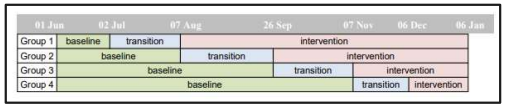
Instructions regarding the duration of hand rubbing and the volume of ABHR were solely delivered by the vibration of the electronic device during the intervention period. No additional educational sessions were organized during the study.

HCWs were asked to place the device into a charging station at the end of each shift and to collect it upon starting the subsequent shift. The device recorded the date and time of use, volume of applied ABHR, duration of hand rubbing, and whether feedback was provided to the HCW or not for all of the HH actions. Overall sensitivity and specificity of this novel electronic wearable device (to correctly identify a HH action) were 94.1% (95% CI, 91.4%-96.2%) and 99.0% (95% CI, 97.5%-99.7%), respectively.[24]

Instrument validation

METHODS

Study timeline



Group start times were randomly assigned

Statistical analysis (we will not cover)

Study Periods and Randomization

Study duration, including baseline, transition, and intervention periods was approximately 6 months, followed by a 2-month washout and a 1-month follow-up period. HH observations were performed at least once a month throughout the baseline, transition, intervention, and follow-up periods.

At baseline period, HCWs did not wear the devices. During the transition period, the novel electronic wearable device was worn but the feedback mode (vibration) was not activated, although the device actively monitored the volume of ABHR and duration of hand friction for each HH action. During the intervention period, the feedback mode of the device was activated and the monitoring of practices by the device continued. At follow-up, HCWs did not use the device.

After an initial common 1-month baseline period, 3 wards per month were randomly assigned to start with the 1-month transition period, followed by the intervention period. The length of the baseline and intervention periods were thus inversely related and varied from 1 to 4 months according to the group of randomization (eFigure 3 in Supplement 2).

In total, 12 wards were randomized following a computer-generated block randomization (1:1:1:1) performed by an independent statistician. Numbered opaque envelopes allowed allocation concealment.

Wards were informed the day before shifting from baseline to transition period. Because of the nature of the study, it was not possible to mask study participants or observers after the baseline period.

Quasi-Experimental Study

Study procedures

No masking / blinding

Statistical Analysis

Sample size was estimated by hypothesizing that wearing the device would improve HH compliance by a relative 20%, going from 69% (the 2015 HH compliance at HUG) in baseline to 83% in the intervention period. This corresponds to a 0.35 standardized difference in proportions.[26] We used an

Pires D., et al. *Effect of wearing a novel electronic wearable device on hand hygiene compliance among health care workers: a stepped-wedge cluster randomized clinical trial.* JAMA Netw Open. 2021;4:e20335331

METHODS – PEN TO PAPER

- Is the study design clearly identified?
- Are the study steps/processes/procedures clearly identified?
- How were the data collected?
  - Was the measurement instrument validated?
- Was an intervention used? Is it clearly described?
- Is the sample population clearly defined? Who are they?
  - How were they selected? Is the sample size adequate? Are inclusion/exclusion criteria specified?
- Was institutional review board (IRB) approval obtained?
- How were the data analyzed?

A study cannot recover from bad data!

Manning ML & Davis J. *Journal club: a venue to advance evidence-based infection prevention practices*. Am J Infect Control. 2012;40:667-669

RESULTS

- Provides information about the final sample population enrolled in the study
- Key findings from statistical analyses are provided without comment or interpretation
- Statistical significance = *p*-value
- Data and statistics are summarized narratively and graphically
- Negative results should not be ignored

Cooper D. *How to write an original research paper (and get it published).* J Med Lib Assoc. 2015;103:67-68

STATISTICAL SIGNIFICANCE

p-value

- Determines whether there is a statistically significant relationship between the variables being studied? Refers to the probability that the results are due to chance?
- Does not “prove” that the research hypothesis is correct
- Provides “support for” or “evidence for” the hypothesis
- *p*-value <.05 (less than 1 in 20) = statistical significance
  - If p-value is <.05, we reject the null hypothesis
  - Null hypothesis states there is no difference; alternative hypothesis states there is a difference
    - e.g.: There is a difference in longevity between those who eat nuts and those who do not eat nuts

RESULTS

Quasi-Experimental Study

Final study participants

Results

All 12 wards of the geriatric hospital at HUG were eligible and were recruited from June 1 to 30, 2017. There were 4 medical wards, 6 geriatric wards, 1 ambulatory unit, and the emergency department included. Of the 306 eligible HCWs, 97 volunteered and were included in the study (**Figure 1**). There were 80 women participants, and the median (IQR) age was 42 years (33-53); 63 were nurses, 32 were assistant nurses, and 2 were physiotherapists. Baseline characteristics of wards and HCWs per group are presented in **Table 1**. See eFigure 3 in Supplement 2 for a summary of the dates of the study periods.

Table 3. Effect of Real-Time Feedback Provided by SmartRub on Compliance With HH Across Calendar Time and Exposure to the Intervention[a]

Characteristic	OR (95% CI)	*P* value
Baseline	1 [Reference]	[Reference]
Intervention	1.03 (0.75-1.42)	.85

Statistically significant result if p-value = *<0.5*

Odds Ratio <1: Device associated with lower HHC
Odds Ratio 1: Device did not impact HHC
Odds Ratio >1: Device associated with higher HHC

Testing impact of wearable electronic device on:

- **Hand hygiene compliance** ★
- Quality of hand rubbing
- Volume of ABHR
- Duration of hand rubbing

Pires D., et al. *Effect of wearing a novel electronic wearable device on hand hygiene compliance among health care workers: a stepped-wedge cluster randomized clinical trial.* JAMA Netw Open. 2021;4:e20335331

RESULTS

Quasi-Experimental Study

Volume

The individually applied ABHR volume increased during the intervention period (feedback on) (median [IQR], 1.71 [1.01-2.76] mL) as compared with the transition period (feedback off) (1.12 [0.76-1.68] mL). Correct HH actions, as per correct application of volume of ABHR only, increased from 10.2% (95% CI, 9.8%-10.6%) during transition to 30.5% (95% CI, 30.0%-30.9%) during intervention (eTable in Supplement 2). After adjusting for covariates, the effect of the intervention on higher applied ABHR volume was significant in every group.

Quality

Duration

Notably, the duration of hand rubbing also increased during intervention (median [IQR], 8 [4.5-15.5] seconds as compared with the transition period, 6.5 [4.5-10.5] seconds). Correct HH actions, as per correct duration only, increased from 11.4% (95% CI, 10.6%-11.9%) in transition to 26.9% (95% CI, 26.4%-27.4%) (eTable in Supplement 2) during intervention. After adjusting for covariates, the effect of the device on the duration of hand rubbing was significant in every group.

Results:

Quality: Increased from 10.2% to 30.%
Volume: Increased from 1.12 to 1.71 ml
Duration: Increased from 6.5 to 8 seconds

Testing impact of wearable electronic device on:

- Hand hygiene compliance
- **Quality of hand rubbing**
- **Volume of ABHR**
- **Duration of hand rubbing**

Pires D., et al. *Effect of wearing a novel electronic wearable device on hand hygiene compliance among health care workers: a stepped-wedge cluster randomized clinical trial.* JAMA Netw Open. 2021;4:e20335331

RESULTS – PEN TO PAPER

- What were the findings of the study?
- Were the results statistically significant?
  - Remember: Results do not **"prove"** anything; they confirm or reject the hypothesis
- Are the results presented in a clear and understandable manner?
- Did the authors explain or interpret the results in this section?
  - This should not take place in the Results section
- Are the tables and/or figures easy to understand?
- Are the results clinically significant?

Manning ML & Davis J. *Journal club: a venue to advance evidence-based infection prevention practices*. Am J Infect Control. 2012;40:667-669

DISCUSSION / CONCLUSIONS

- Major findings of the study and whether the hypotheses were supported – or rejected
- Interpretation of the results, relevance and implications of the findings
- Discrepancy between anticipated and observed results are explained and elaborated upon
- Compare and contrast the findings of your study with those of similar research
- Contributions to the field of study
- Formal conclusions

Cooper D. *How to write an original research paper (and get it published).* J Med Lib Assoc. 2015;103:67-68

DISCUSSION

Quasi-Experimental Study

Discussion

This stepped-wedge cluster randomized clinical trial tested the effect of a novel electronic wearable device that provides feedback on appropriately applied ABHR volume and sufficient duration of hand rubbing, on both compliance and quality of HH practices. Our study showed that wearing the novel electronic wearable device did not improve HH compliance. However, wearing the device did improve the quality of the HH action, with a significant increase in both ABHR volume applied and in the duration of hand rubbing.

Restatement of key findings

Intriguingly, we observed a gradual decline in HH compliance throughout the study, from 73.5% (95% CI, 70.5%-76.5%) during the first month to 56.6% (95% CI, 53.2%-60.1%) during the last month. This time trend was unexpected and, likely, hampered the assessment of the effect of the device on HH compliance. We hypothesize there was a significant Hawthorne effect when HCWs were observed for the first time during the baseline period, which resulted in overestimated HH compliance. The same auditors performed repeated observations of the same HCWs, and HCWs may have become accustomed to them over time. Thus, the presence of the auditors may not have sparked immediate behavior change in subsequent observations. This would result in regression of an initial Hawthorne effect, resulting in HH compliance falling back to routine behavior. This phenomenon of habituation has been previously described in Chen et al.[31]

Explanation for deviation from expected

DISCUSSION

Link to previous literature

The most recent systematic review on the effect of monitoring technologies on HH adherence suggested that electronic devices have the potential to change HH behavior.[32] However, there is a lack of clinical trials with solid designs including system-independent, relevant outcomes.[22,32,34] We believe that the design of this stepped-wedge, cluster randomized clinical trial contributed to raise the standards of methodological quality of studies on this topic.

Our study is a proof of concept of the benefits of a wearable device on improving the quality of HH in clinical practice and it opens perspectives for new strategies on HH improvement. The great majority of HH monitoring devices focus on dispensing events or proxies for HH indications.[21] This electronic wearable device is unique in its potential to improve HH by interacting directly with the HCW during HH, in real time and during daily routine.

Quasi-Experimental Study

Contribution to field of study

Limitations

Limitations

Our study had several limitations. This was a novel device and, not surprisingly, we faced a series of technical challenges. Problems included random inactivation of the devices (more frequent with the wristband) and loss of data because of errors in data transfer. These prevented us from calculating predetermined secondary outcomes, such as the frequency of HH events, adherence to device use, and ward-level ABHR consumption. The lack of such data did not allow us to analyze if trends of observed HH compliance were different from trends of performed HH events. In addition, the implementation of the study revealed some difficulties. For example, we faced problems related to the production and delivery of the devices that induced delays in the pre-established dates of rollout from baseline to transition in some groups. However, we did manage to respect the stepped-wedge design of the study.

DISCUSSION: PEN TO PAPER

- Are the study findings linked back to the introduction/literature review?
- Does the study contribute to the body of knowledge?
- What are the study strengths and limitations? Were they identified?
  - Are there other strengths/limitations that were not called out by the authors?
- What is the clinical significance of the study to your practice or professional area?

Manning ML & Davis J. *Journal club: a venue to advance evidence-based infection prevention practices*. Am J Infect Control. 2012;40:667-669.

SHOULD YOU CHANGE YOUR PRACTICE BASED ON ONE RESEARCH STUDY?

Advisable to use current best evidence in conjunction with clinical expertise

When a sufficient research base is not available, decisions may be made based on expert opinion and scientific principles

Results may be statistically significant but not clinically significant

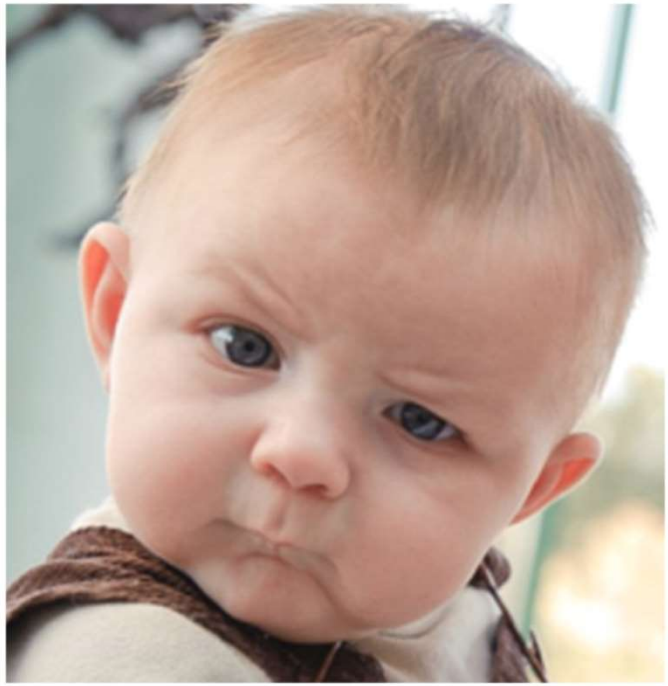
Titler MG. *The evidence for evidence-based practice implementation.* Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Rockville, MD: Agency for Healthcare Research and Quality, US Dept of Health and Human Services; April 2008. Publication No. 08-0043.

SCHOLARLY CRITIQUE – BE A SKEPTIC

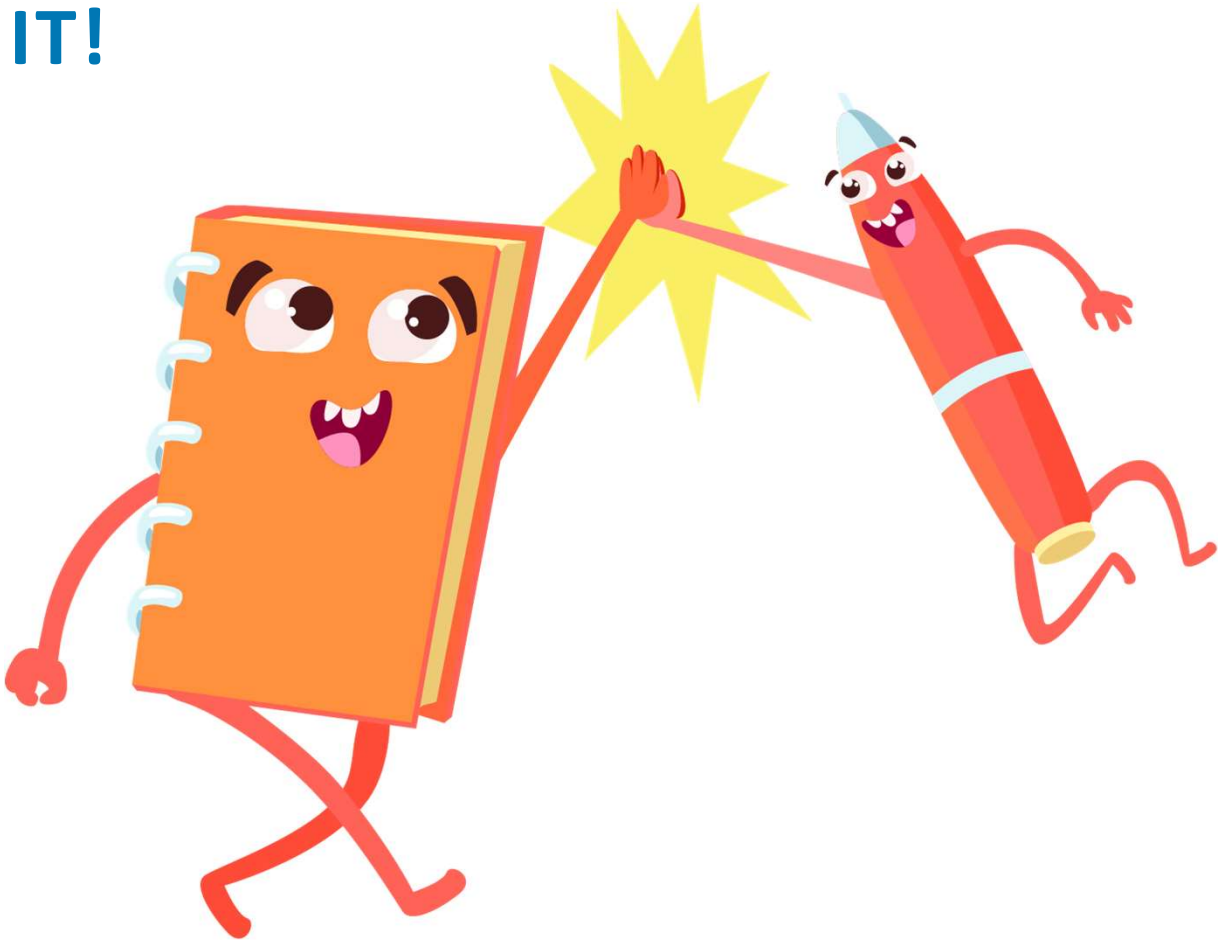
Never blindly accept findings as fact or “proof”

Examine the entire body of evidence, not just one study

Have studies been replicated and produced the same results?



YOU DID IT!



THANK YOU

Q&A