Weight of Evidence Applied to Food Safety Interventions

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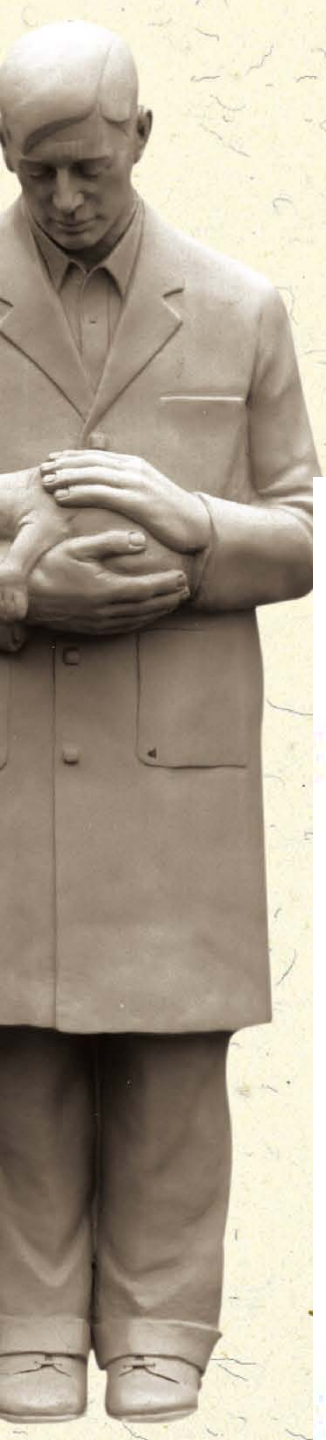
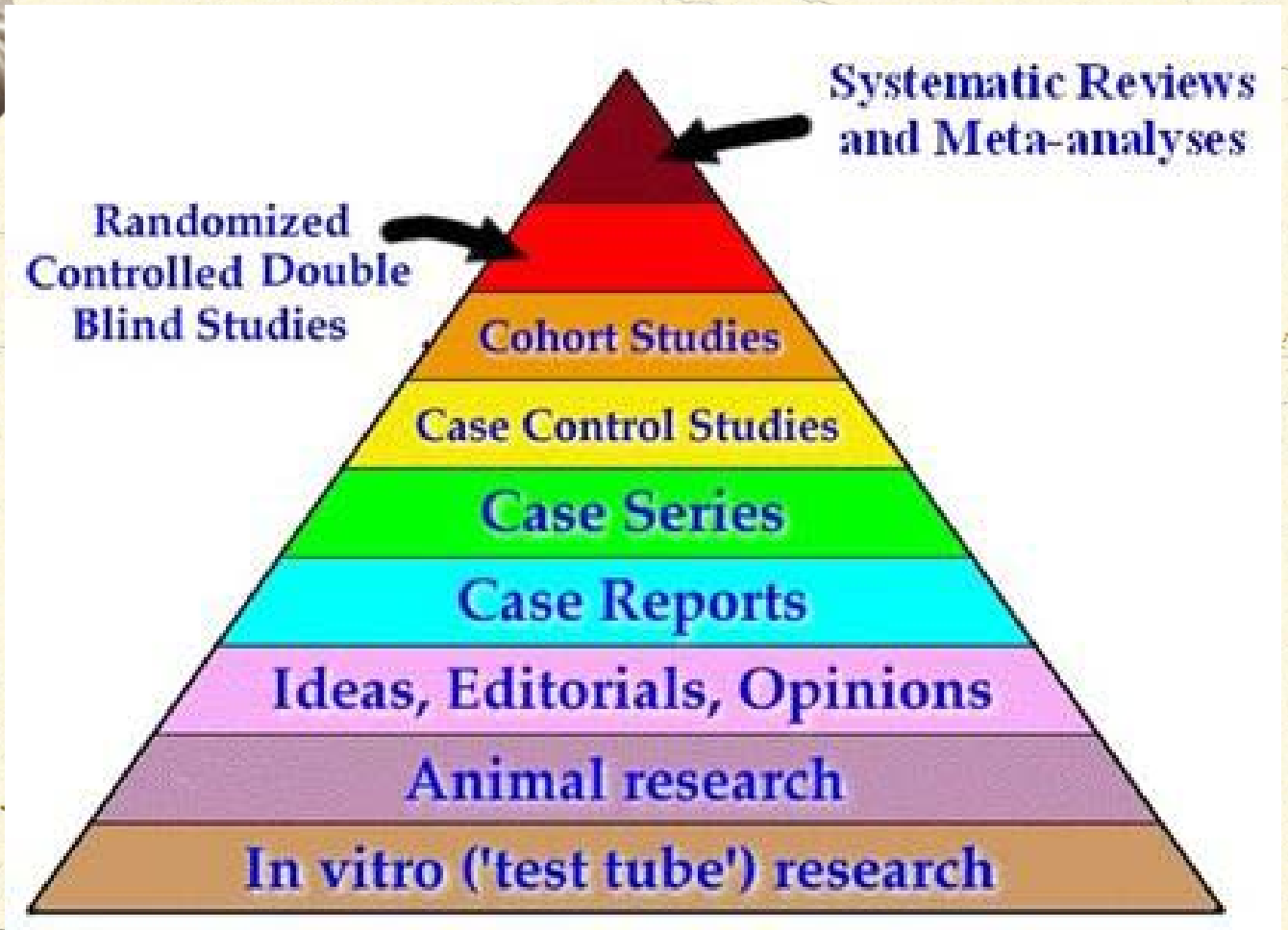
Evidence for

- Interventions
- Causation
- Burden of disease (prevalence)
- Diagnostics



Evidence for

- Interventions



Evidence for

- Interventions
  - Hierarchy of evidence
- Randomized trials in
  - Natural exposure in “real setting”
  - Artificial exposure in “artificial setting”
- Cohort studies
- Case control studies

Evidence for

- Food safety studies susceptible to bias like other studies
  - Confounding
  - Misinformation bias
  - Selection bias
- Poor reporting
- Poor execution
- Publication bias

Illustrative Example

- Evidence for vaccination for pre-harvest *Salmonella spp.* in Swine

Illustrative Example

- What is the effect of vaccination for Salmonella on prevalence of *Salmonella spp*. at slaughter on the carcass?

- Randomized controlled trials as the highest standard of evidence
- Natural versus artificial

Body of Evidence

- 18 trials in artificial settings
- 5 Barn/building randomized studies
- Good evidence based on p values and author inference that vaccines effective
- High confidence in intervention

Body of Evidence

- 18 trials in artificial settings
  - Individual animal housing
  - Small groups
  - Few randomized
  - Even few blinded

- 5 Barn/building randomized studies
  - None studied the outcome of interest
  - Non discussed blinding

Artificial setting

TABLE 2. THE COUNTRY, ANIMAL TYPE, AND AGE OF ANIMALS IN THE CHALLENGE STUDIES REPORTING VACCINATION OF SWINE AGAINST *SALMONELLA* ASSOCIATED WITH FOODBORNE OUTCOMES

uthor	*Country*	*Type of pig*	*Age at enrollmen*
aum *et al.*, 1997	USA	Commercial	3 weeks
harles *et al.*, 1999	USA	Commercial	3–4 weeks
roninga *et al.*, 2000	USA	Commercial	3 weeks
olb *et al.*, 2003	USA	Commercial	2 weeks
ramer *et al.*, 1992	USA	Commercial	Nursery pigs
ramer *et al.*, 1987	USA	Commercial	Weaned
eubauer *et al.*, 2005	USA	Commercial	3 weeks
oof and Doitchinoff, 1995	USA	Commercial	3–4 weeks
harles *et al.*, 2000a	USA	Experimental	3–4 weeks
harles *et al.*, 2000b	USA	Experimental	3–4 weeks
ennedy *et al.*, 1999	USA	Experimental	7 weeks
u *et al.*, 2005	USA	Experimental	5–8 weeks
oringer *et al.*, 2001	Germany	Experimental	3–4 weeks
oe *et al.*, 1992	USA	SPF	8 weeks
anna *et al.*, 1979	Ireland	SPF	7 weeks
umsden *et al.*, 1991	Canada	SPF	5–6 weeks
oesler *et al.*, 2004	Germany	SPF	4 weeks
oster *et al.*, 2003	UK	Gnotobiotic	5 days
raayer 1986	USA	Not defined	5 weeks
ibson *et al.*, 1999	USA	Not defined	3–4 weeks
usa *et al.*, 2006	USA	Not defined	3 weeks
ern *et al.*, 1994	USA	Not defined	3–4 weeks
etellier *et al.*, 2000	Canada	Not defined	12 days

Body of Evidence

- Natural Setting
- 5 Barn/building randomized studies
- None studied the outcome of interest
- Non discussed blinding

Bias in Evidence

- Randomized 8 barns of 500 pigs each to 2 treatments

- Analyzed the data as if 2000 animals in each treatment rather than 4 barns

Body of Evidence

- 18 trials in artificial settings
- 5 Barn/building randomized studies
- Little confidence this is effective

Bias due to poor methodology

Sargeant et al , 2009a, b, c

Body of Evidence

- 100 on-farm food safety (1998 – 2008)
  - Randomization- 46%
  - Double blinding- 0%
  - Lost to follow-up - 43%
  - Inclusion criteria -16%
  - # of animals housed together- 52%

  - Sargeant et al, 2009 Foodborne Pathog Dis. 2009 Oct;6(8):989-99.

Evidence for

- Interventions
- Causation
- Burden of disease (prevalence)
- Diagnostics

Body of Evidence

- Cause of Salmonella spp. in swine
- High quality evidence would be studies evaluating feed type at farm during the finishing phase and carcass outcomes

Causation

- feed characteristics, including
  - acidified feed,
  - heat-treated versus untreated feed,
  - pelleted feed versus non-pelleted,
  - course versus fine-ground feed, and
  - wet versus dry feed.

Causation

- Studies were
  - Cross-sectional
  - Challenge studies
- Measured Salmonella serology

Standard of Evidence

- Very similar concepts/ topics as human medicine
- More similar to public health topics with group level outcomes

Evidence Standards

- Risk assessment
  - The basis for much food safety policy
  - No standards for reporting evidence included in risk assessments in the USA
  - Few risk assessments are clear and why particular parameters are chosen and if they are rationale

EFSA JOURNAL

Application of systematic review methodology to food and feed safety assessments to support decision making

EFSA Journal 2010; 8(6):1637 [90 pp.].
doi:10.2903/j.efsa.2010.1637

European Food Safety Authority

Acknowledgment
Contact

Type: Guidance of EFSA

Systematic Reviews

- Only just starting in food safety
- Meta-analysis is currently very difficult

Validation of HACCP

- Section 417.4 of the meat and poultry regulations requires “Every establishment shall validate the HACCP plan’s adequacy in controlling the food safety hazards identified during the hazard analysis….”

Two Parts of Validation

1. The scientific or technical justification or documented basis for the system.

2. The initial practical demonstration proving the system will perform as expected.

- Focus on the scientific or technical justification or documented basis for the system.

Scientific or Technical Justification

- What types of documents can be used for scientific or technical justification?

Scientific or Technical Basis

- The supporting documentation can consist of an article from:
  - Peer-reviewed scientific journal
  - Documented challenge study
  - Data underlying published guidelines
  - In-house data
  - Regulatory Guidance
  - Risk Assessments
  - University extension articles

Evidence in Food Safety

- Interventions and risks assessed data single point but the system may be effective

System-wide Evidence

- Where should the effort be put to reduce the *Salmonella* prevalence in the slaughtered swine carcass effectively?
- **Alban and Stark, Preventive Veterinary Medicine** Volume 68, Issue 1, April 2005, Pages 63-79

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Citations

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- Sub-iliac lymph nodes at slaughter lack ability to predict Salmonella enterica prevalence for swine farms. Wang B, Wesley IV, McKean JD, O'Connor AM. Foodborne Pathog Dis. 2010 Jul;7(7):795-800. 3.
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