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# Research Questions, Specific Aims and Hypothesis, and Outcomes

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## U.S. GOVERNMENT PARTNERS





1. Scientific evidence underpins professional practice (not just in health care)
2. The focus of science often led by funding interests
3. Because something not yet been proven, doesn't mean that what *has been* is the only possible conclusion



## Doctors and nutrition

SOPHIYA UPRETY AND DR. RAMESH KANT ADHIKARI

Modern medical science relies on scientific evidence as the gold standard. The past research focus was disproportionately tilted towards the curative side. More evidence was generated on treatment rather than on the cause of diseases. This seems to have happened more after the boom of pharmaceutical companies during the first half of the 20th century. Preventive aspects on the role of wholesome and nutritious diet were thus missed from the research purview. This led to the paucity in evidence proving the protective and promotive role of nutrition. Furthermore, the impacts of nutrition on health are often gradual with cumulative effect. This is another reason why the value of good nutrition gets overlooked. Consequently, nutrition science was unable to fit within the realm of medical science leading to an unfortunate disconnect between the two. However, the evidence base for nutrition has been gradually accumulating. — [blog.embracegoodnutrition.com/blogs](http://blog.embracegoodnutrition.com/blogs)



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## SESSION OBJECTIVES

- Define scientific research
- Describe the process of identifying research questions
- How to come up with hypotheses and clear and specific aims





## WHAT IS SCIENTIFIC RESEARCH?





## DEFINITIONS OF SCIENCE

“The intellectual and practical activity encompassing the systematic study of the structure and behaviour of the physical and natural world through observation and experiment.”

“A systematic enterprise that builds and organizes knowledge in the form of testable explanations and predictions about the universe.”





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## DEFINITION OF RESEARCH

“Systematic work undertaken to increase the stock of knowledge ... used to establish or confirm facts, reaffirm the results of previous work, solve new or existing problems, support theorems, or develop new theories.”

OECD. 2015. Guidelines for Collecting and Reporting Data on Research and Experimental Development, Paris





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Trial record 1 of 1 for: mycotoxins | Linear Growth Failure

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#### Aflatoxin Birth Cohort Study Nepal (AflaCohort) (AflaCohort)



The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

ClinicalTrials.gov Identifier: NCT03312049

Recruitment Status: Active, not recruiting

First Posted: October 17, 2017

Last Update Posted: October 18, 2017

#### Sponsor:

Tufts University

#### Collaborators:

Helen Keller International  
Patan Academy of Health Sciences  
Purdue University  
Government of Nepal  
Nepalgunj Medical College

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aflatoxin exposure: the AFB<sub>1</sub>-lysine adduct. The aflatoxin exposures in the study each time period (length-for-age [LAZ], weight-for-age [WAZ], and weight-for-length-for-age, and breastfeeding status. Results demonstrated chronic aflatoxin exposure 3.62 pg AFB<sub>1</sub>-lysine/mg albumin. However, the chronic aflatoxin exposure in this anthropometric z-scores, growth trajectories, age, or feeding status, based on the exposure. Low mean levels of aflatoxin exposure and infrequent occurrence of s this cohort are possible contributing factors to a lack of evidence for an associat a threshold dose of aflatoxin exists that could induce child growth impairment.

**Citation:** Mitchell NJ, Hsu H-H, Chandyo RK, Shrestha B, Bodhidatta L, Tu Y first 36 months of life was not associated with impaired growth in Nepalese c ONE 12(2): e0172124. <https://doi.org/10.1371/journal.pone.0172124>

Dietary exposure  
Biomarkers  
Child growth

B<sub>1</sub>-lysine (AFB<sub>1</sub>-lys) adducts, and urine samples collected between 24 and 36 months of age (n = 94) were analyzed for urinary fumonisin B<sub>1</sub> (UFB<sub>1</sub>). Anthropometric, socioeconomic, and nutritional parameters were measured and growth parameter z-scores were calculated for each child. Seventy-two percent of the children had detectable levels of AFB<sub>1</sub>-lys, with a mean level of 5.1 (95% CI: 3.5, 6.6) pg/mg albumin; and 80% had detectable levels of UFB<sub>1</sub>, with a mean of 1.3 (95% CI: 0.8, 1.8) ng/ml. This cohort had a 75% stunting rate [height-for-age z-scores (HAZ) < -2] for children at 36 months. No associations were found between aflatoxin exposures and growth impairment as measured by stunting, underweight [weight-for-age z-scores (WAZ) < -2], or wasting [weight-for-height z-scores (WHZ) < -2]. However, fumonisin exposure was negatively associated with underweight (with non-detectable samples included, p = 0.0285; non-detectable samples excluded, p = 0.005) in this cohort of children. Relatively low aflatoxin exposure at 24 months was not linked with growth impairment, while fumonisin exposure at 24-36 months based on the UFB<sub>1</sub> biomarkers may contribute to the high growth impairment rate among children of Haydom, Tanzania; which may be associated with their breast feeding and weaning practices.

whether  
to dietary  
Haydom,  
aflatoxin





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## IMPACT EVALUATION, M&E

“Monitoring is conducted after a programme has begun and continues throughout the programme implementation period. Monitoring is sometimes referred to as process, performance or formative evaluation.”

1. [www.endvawnow.org/en/articles/330-what-is-monitoring-and-evaluation-.html](http://www.endvawnow.org/en/articles/330-what-is-monitoring-and-evaluation-.html)

“Impact evaluation is an assessment of how the intervention being evaluated affects outcomes; whether these effects are intended or unintended.”

[www.oecd.org/dac/evaluation/dcdndep/37671602.pdf](http://www.oecd.org/dac/evaluation/dcdndep/37671602.pdf)





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## DESCRIPTIVE HYPOTHESES

Determine what is going on:

- Children in open-defecation villages are likely to have high rates of diarrhea.
- School children from high SES homes are likely to spend more on snacks than if from low SES homes.





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## OBSERVATIONAL/RELATIONAL

Do several things work together?

- Children with EED are more likely to have more diarrhoea and be stunted than non-EED children.
- Mothers of low stature who also have high levels of aflatoxin in the blood are more likely to have LBW babies.





## CAUSAL HYPOTHESES

Does one thing cause another?

- Does higher maternal literacy correlate with lower rates of maternal anemia?
- What impact does improved sanitation have on EED?
- Does sunspot activity correlate with outbreaks of famine?





## FORMULATING HYPOTHESES

- Viable (a question formulated in a meaningful way that can realistically be answered using current technology, resources, standards)
- “Not all questions can be transformed into research problems”
- Testable (a carefully articulated hypothesis that can be verified or disproved using data) Kumar (2014) p.63
  - Falsifiable (Karl Popper’s tenet that an hypothesis must be capable of being rejected via proof)





## Most accessed Cochrane Systematic Reviews of 2016 (i)

- What is the effect of dietary educational interventions versus control on changes in BMI, prevalence of obesity, and rate of weight gain among children <18y.
- What are the effects of honey compared with alternative wound dressings and topical treatments on the healing of acute (e.g. burns, lacerations) and/or chronic (e.g. venous ulcers) wounds.





## Most accessed Cochrane Systematic Reviews of 2016 (ii)

- What are the effects of early skin-to-skin contact for healthy newborn infants compared to standard contact (infants held swaddled or dressed in their mothers arms, placed in open cribs or under radiant warmers)?
- What is the effectiveness of exercise compared with no treatment (no intervention or control) for depression in adults?





## OBJECTIVES AND HYPOTHESES

### Research checklist

STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

	Item No	Recommendation
<b>Title and abstract</b>	1 ✓	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found
<b>Introduction</b>		
Background/rationale	2 ✓	Explain the scientific background and rationale for the investigation being reported
Objectives	3 ✓	State specific objectives, including any prespecified hypotheses
<b>Methods</b>		
Study design	4 ✓	Present key elements of study design early in the paper
Setting	5 ✓	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6 ✓	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (b) For matched studies, give matching criteria and number of exposed and unexposed







## FINER criteria for a good research question

- F** Feasible
  - Adequate number of subjects
  - Adequate technical expertise
  - Affordable in time and money
  - Manageable in scope
- I** Interesting
  - Getting the answer intrigues investigator, peers and community
- N** Novel
  - Confirms, refutes or extends previous findings
- E** Ethical
  - Amenable to a study that institutional review board will approve
- R** Relevant
  - To scientific knowledge
  - To clinical and health policy
  - To future research

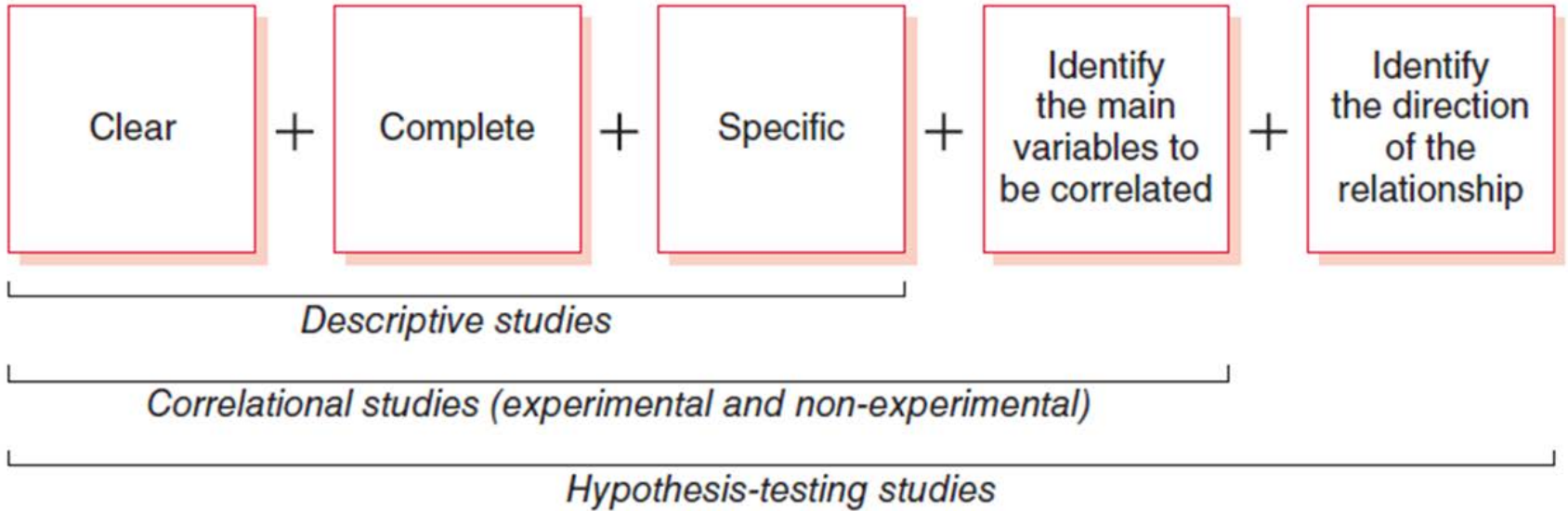
Farrugia et al. 2010.





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**Figure 4.5** Characteristics of objectives





## EXAMPLES OF NUTRITION RESEARCH OBJECTIVES

- Does breastfeeding prevent stunting?
- Are home gardens more sustainable than supplements to address vitamin A deficiency?
- Does iron supplementation beginning in mid-pregnancy reduce the risk of low birth weight?
- Are locally-produced RUFs as effective in treating MAM as imported RUFs?

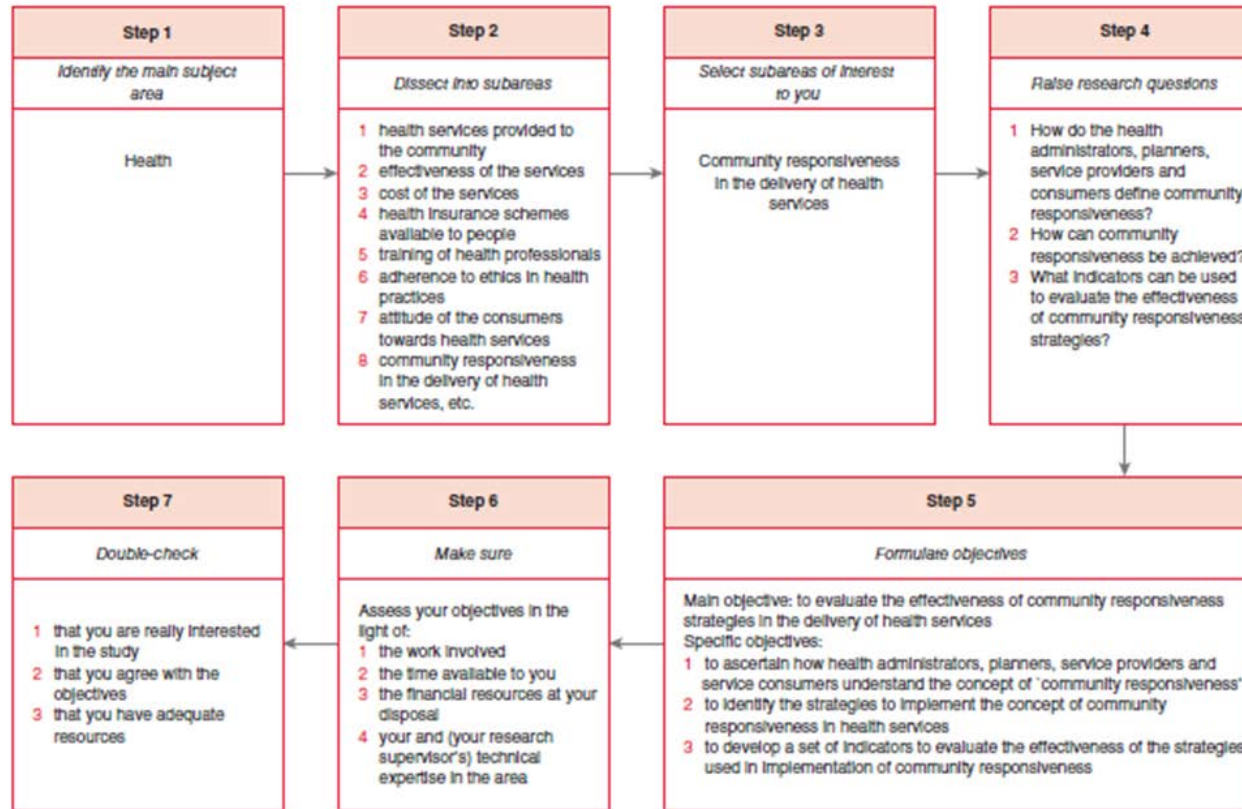




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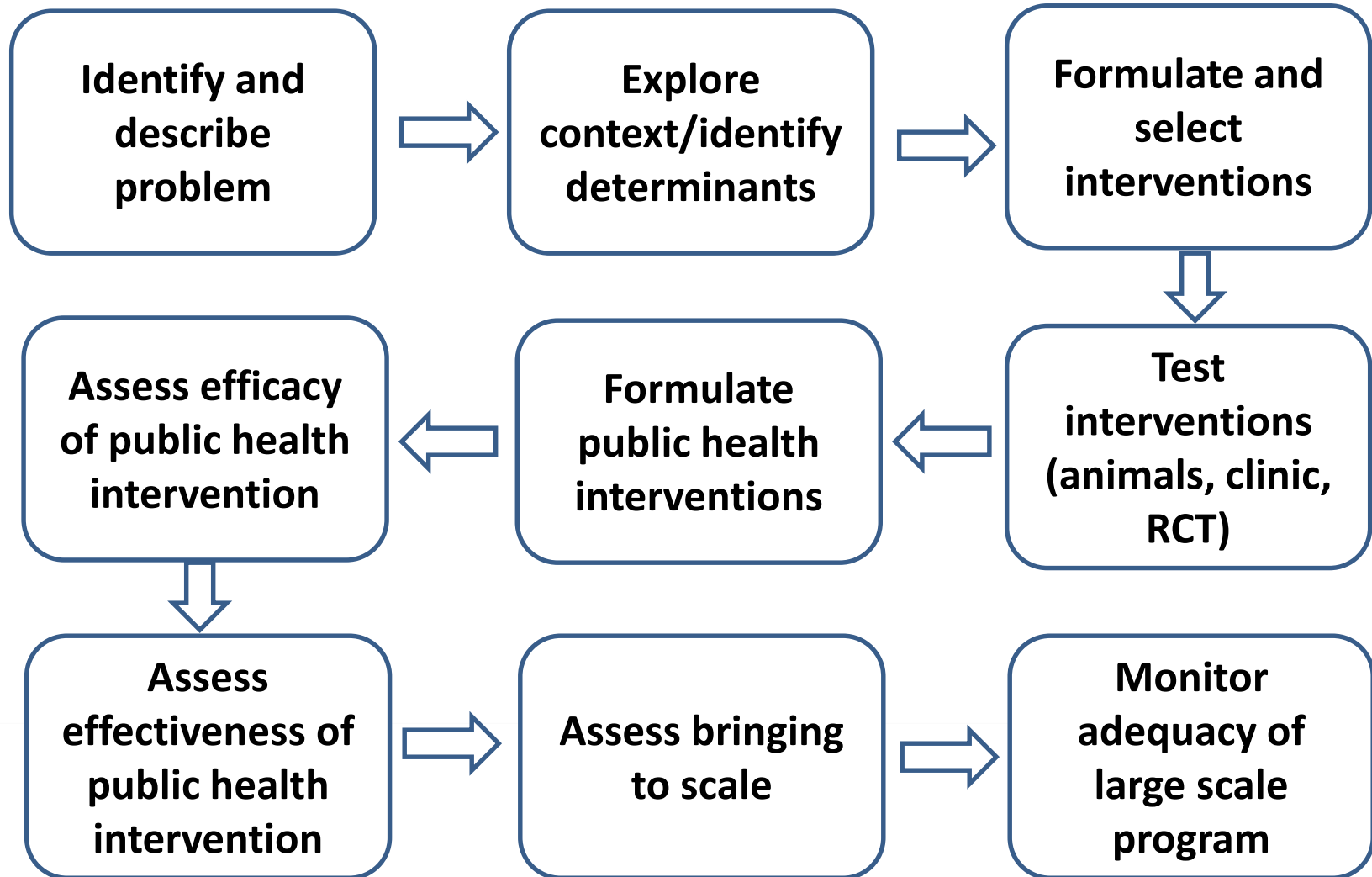
**Example 3:** Suppose you want to conduct a study in the area of health. Follow these steps.



**Figure 4.4** Narrowing down a research problem – health



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Barrett C. 2006. *Food Aid's Intended and Unintended Consequences*. Working Papers 06-05, FAO.

“Before proceeding, let me emphasize that readers should exercise caution when assessing claims made in the literature. Some data sets and empirical methods are better suited than others to exploring complex questions of food aid’s behavioral and welfare effects.

Many of the alleged negative effects of food aid or negative dependency triggers are supported only by unverified anecdotes rather than by detailed ethnographic or econometric research.

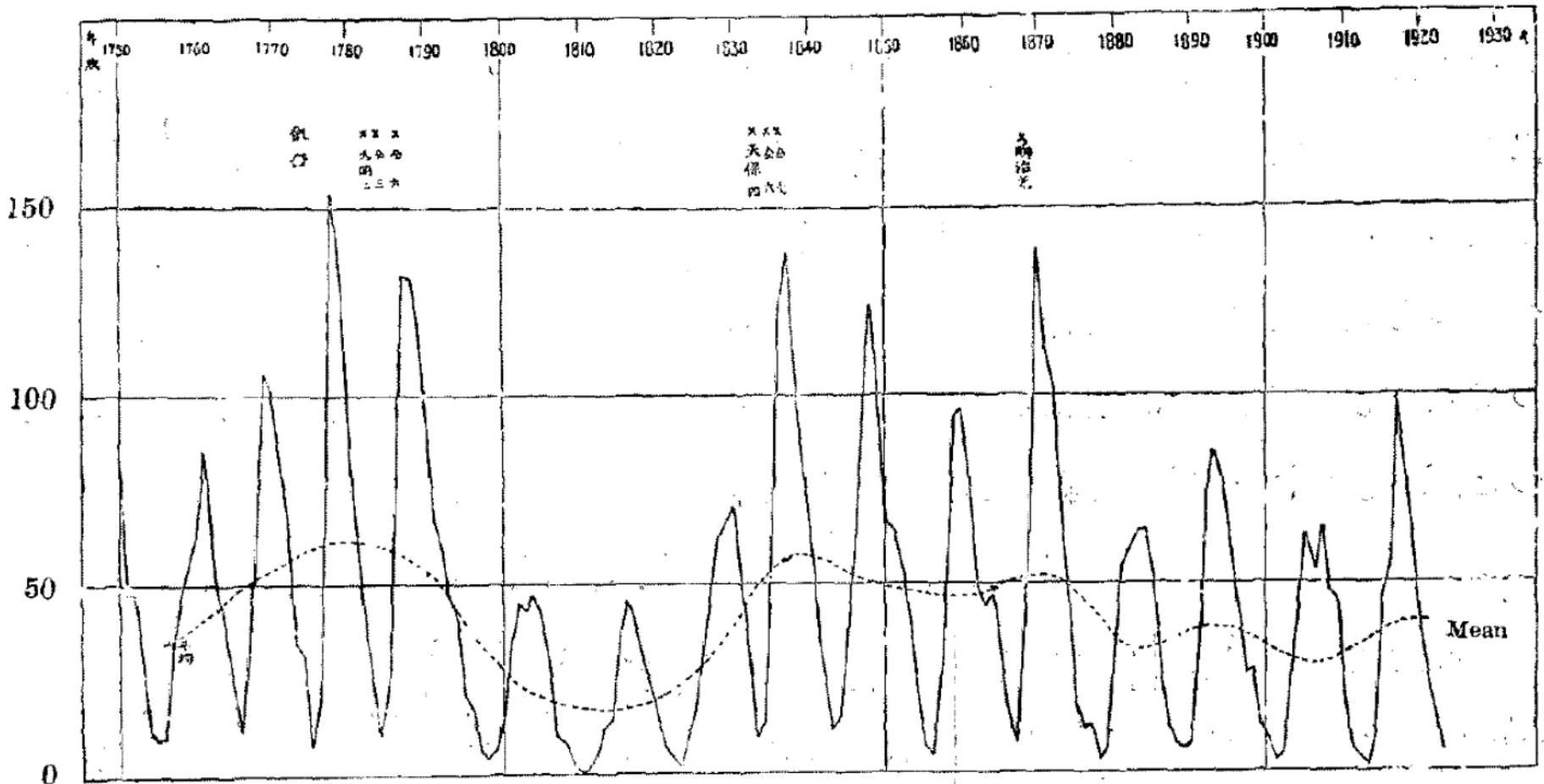
Reports of food aid causing negative dependency are [not] based on a demonstrable causality. **This distinction between causality and correlation is critical.**”





## CORRELATION OR CAUSALITY?

Sunspot number (× the year of the dreadful famine)



Taguti K. 1925. Relation between the Famine and the Sunspot Number. *Jou. Meteorological Society of Japan*, 3 (5): 128-130



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Published online 22 December 2003 | Nature | doi:10.1038/news031215-12

News

## Sun set food prices in the Middle Ages

### Changes in solar activity sent wheat prices soaring in medieval England.

Philip Ball



Low solar activity equals cloudy skies and poor crops. *P. Brueghel (1565)*

The belief in the Middle Ages that the heavens govern fate and fortune might not have been as ludicrous as it sounds.

Two researchers in Israel have found a statistical link between the activity of the Sun and the price of wheat in seventeenth-century England. At the point in the solar cycle when sunspots were least likely, wheat prices tended to be high, report Lev Pustilnik of Tel Aviv University and Gregory Yom Din of the Golan Research Institute in Kazrin<sup>1</sup>.

For a medieval peasant, this could mean the difference between life and death: bad harvests and famine were common; high grain prices sometimes triggered riots in Europe.

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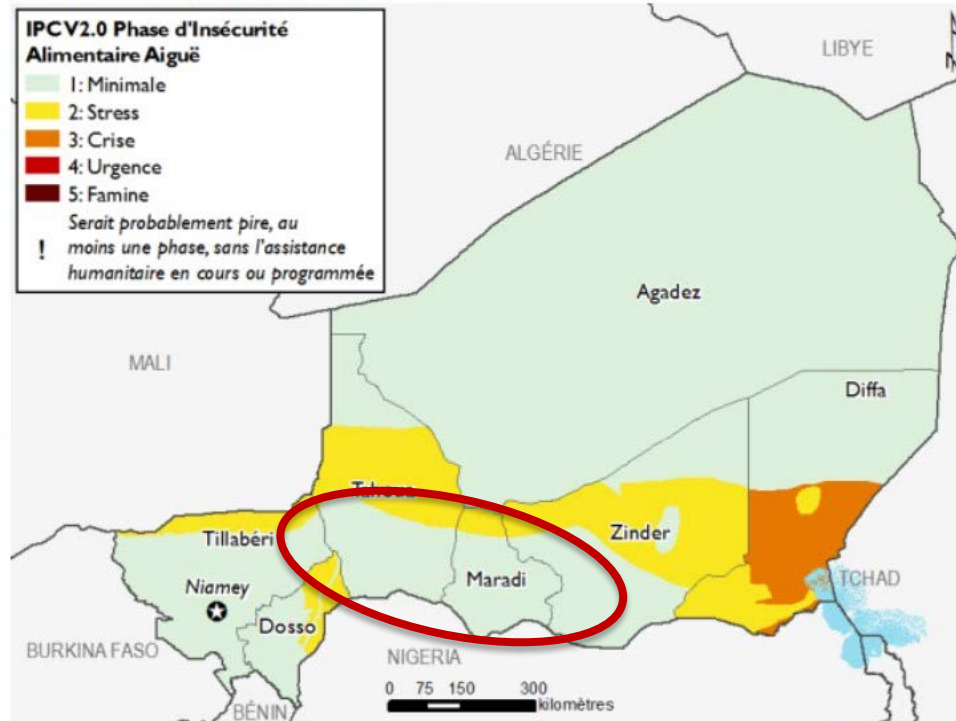




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## Carte des résultats estimés plus probables de la sécurité alimentaire, février-mai 2018



Source : FEWS NET

## Rural Labor-Intensive Public Works: Impacts of Participation on Preschooler Nutrition: Evidence from Niger

rown, Yisehac Yohannes, and Patrick Webb

ence of preschool malnutrition ated in many areas of the world. and 1990 the number of under- polers rose from 164 million to the percentage of preschool child- o standard deviations of NCHS ht for age in 1990 ranged from Asia and 31% in South East Asia, Saharan Africa. A concern is the ase in Sub-Saharan Africa during nistrative Committee on Coord- Committee on Nutrition (ACC/ While the incidence of poverty on are highly correlated, income is not sufficient to reverse the utrition. In Pakistan, despite a owth rate in GDP per capita bend 1990 (World Bank), and a ion in poverty (Malik), the im- the prevalence rate of under- of children was less than 1% per N 1993).

es between income and improved omes have led to a growing fod inputs to nutrition. These in- education and social service in terms of health care, safe lequate sanitation (Thomas, Henriques; Strauss; Alderman However an input that has rely little attention is time in- are.

Yisehac Yohannes are research analysts, and search fellow, all at the International Food ate.  
I also like to acknowledge the unfailling sup- plied, and contributions from Harold Alder- Jane Hopkins, Shabh Kumar, Carol Levin

### Time Use, Income Generation, and Child Nutrition

Time is a direct input to child nutrition in terms of child care as well as a complementary input to both food and nonfood nutrition inputs. Generation of income, particularly for the poor, involves allocation of time to labor activities. Low household income requires more household members, particularly women, to be engaged in income-generating activities. This exacerbates already tight female time constraints. Lipton and Ravallion note that "The burden of the 'double day'—market labor and domestic labor—is more severe for women. Female age-specific participation rates increase sharply as income falls toward severe poverty; yet so do the ratios of children to adult women."

In the current economic climate of structural adjustment, the use of social services such as health and education often entails both user fees and a complementary time input for service use. Thus, the time demands of female child caretakers may conflict with good child nutritional outcomes. Time in income generation activities (translated into higher food expenditures) and time in utilizing health and education facilities improve child nutrition outcomes, but the loss of direct time spent in child care may worsen nutritional outcomes. The net effects, therefore, of female employment outside the home are complex, involving a reallocation of time and changing expenditure patterns.

A further potential consequence of female employment is a change in internal household decision-making processes. The resultant higher share of female income relative to male income can tilt the power base inside the household toward women. Evidence indicates

Amer. J. Agr. Econ. 76 (December 1994): 1213-1218  
Copyright 1994 American Agricultural Economics Association



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## CONCLUDING THOUGHTS

- Research is about Mindset and Mastery:
  - **Mindset** =
    - systematic, structured enquiry
    - using evidence to inform practice and new enquiry
  - **Mastery** =
    - careful formulation of testable hypotheses to answer appropriate questions
    - use of appropriate methods
    - careful interpretation of findings (causality vs correlation, credible pathways)



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