Cochrane-WHO collaborative experiences

Systematic reviews to inform complex interventions, the importance of good reporting and context in guideline development processes.

Geraldine Macdonald

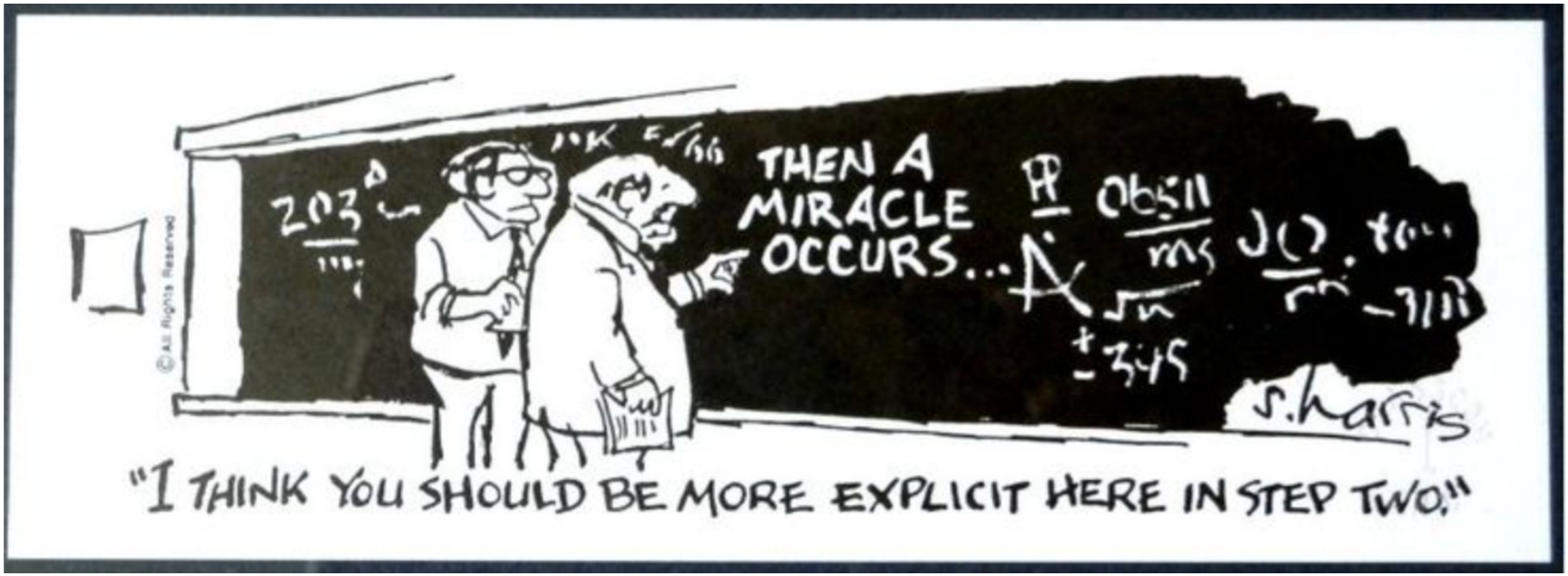
Juan Pablo Peña-Rosas

You're right, after thinking it through,
I'm not sure how the one leads to the other

Cochrane Reviews - Background

- Have always asked review authors to say ‘How the intervention might work’
- Extremely important for social interventions, or any complex intervention that might ‘work’ differently in different contexts
- BUT - least well done
- Impacts on a number of steps in the conduct of a review, including making sense of the results in terms of implications for practice and future research.

Black box evaluations



A theory of change

- Guideline developers need to know not only **whether** an intervention works, but
- **How** and **why** and **under what circumstances**

'A theory of change is a description of **how** and **why** a set of activities – be they part of a highly focused program or a comprehensive initiative – are expected to lead to early, intermediate, and long-term outcomes over a specified period.'

Anderson, 2000

‘White box’ or theory driven evaluations

- Explore the internal/inherent ‘logic’ of an intervention
- Social science origins - Suchman (1967), Weiss (1972*ff*), Chen (1989)
- Beginning to appear in systematic reviews, and in broader discussions about the evaluation of complex health interventions e.g. Rohwer et al 2016; De Silva et al. 2014

Survey results: 9 out of 10 angels feel that dancing on the head of a pin is demeaning and potentially quite hazardous.

THEORIES of CHANGE

or

LOGIC MODELS

Building blocks of a theory of change

1. A clearly articulated **problem definition**
2. Specification of the **essential components** of the intervention; *f, d, 'dose'* and how this can be delivered;
3. The **means whereby** the intervention brings about change, including

   any important sequencing of events or

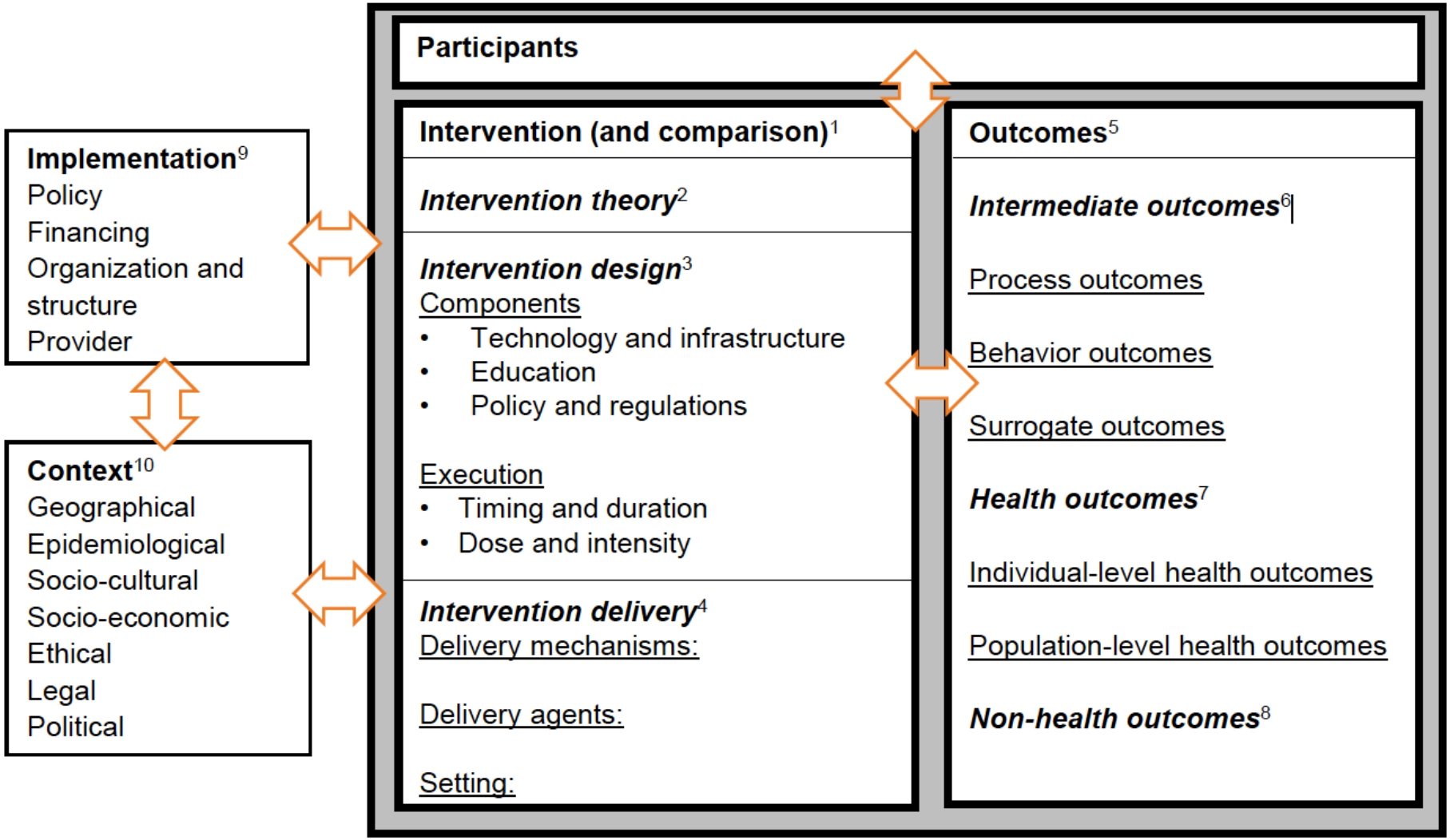
   relationships between component parts,

   any mechanisms that might explain differential responses to the intervention, such as individual differences, timing, method of delivery;
4. Specification of expected outputs and outcomes, and the interrelationships between them.

Lipsey 1993

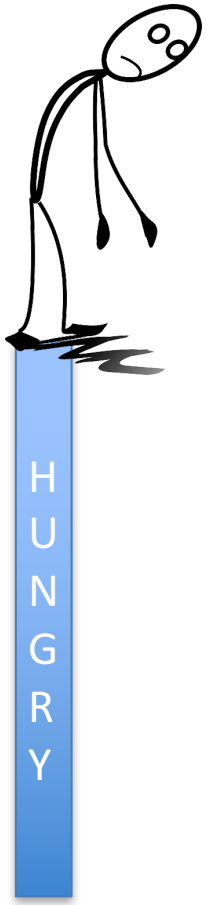
Component Parts

- Inputs
  - The resource that go into the programme, e.g:
    - Staff time, materials, money, equipment, training
- Outputs
  - What is ‘done’ and who ‘takes part’ e.g:
    - Parenting programme for parents of preschool children
- Outcomes
  - Changes or results from the programme:
    - short-, medium- or long-term
- PICO–friendly, but needs to articulate relationships and mechanisms of change



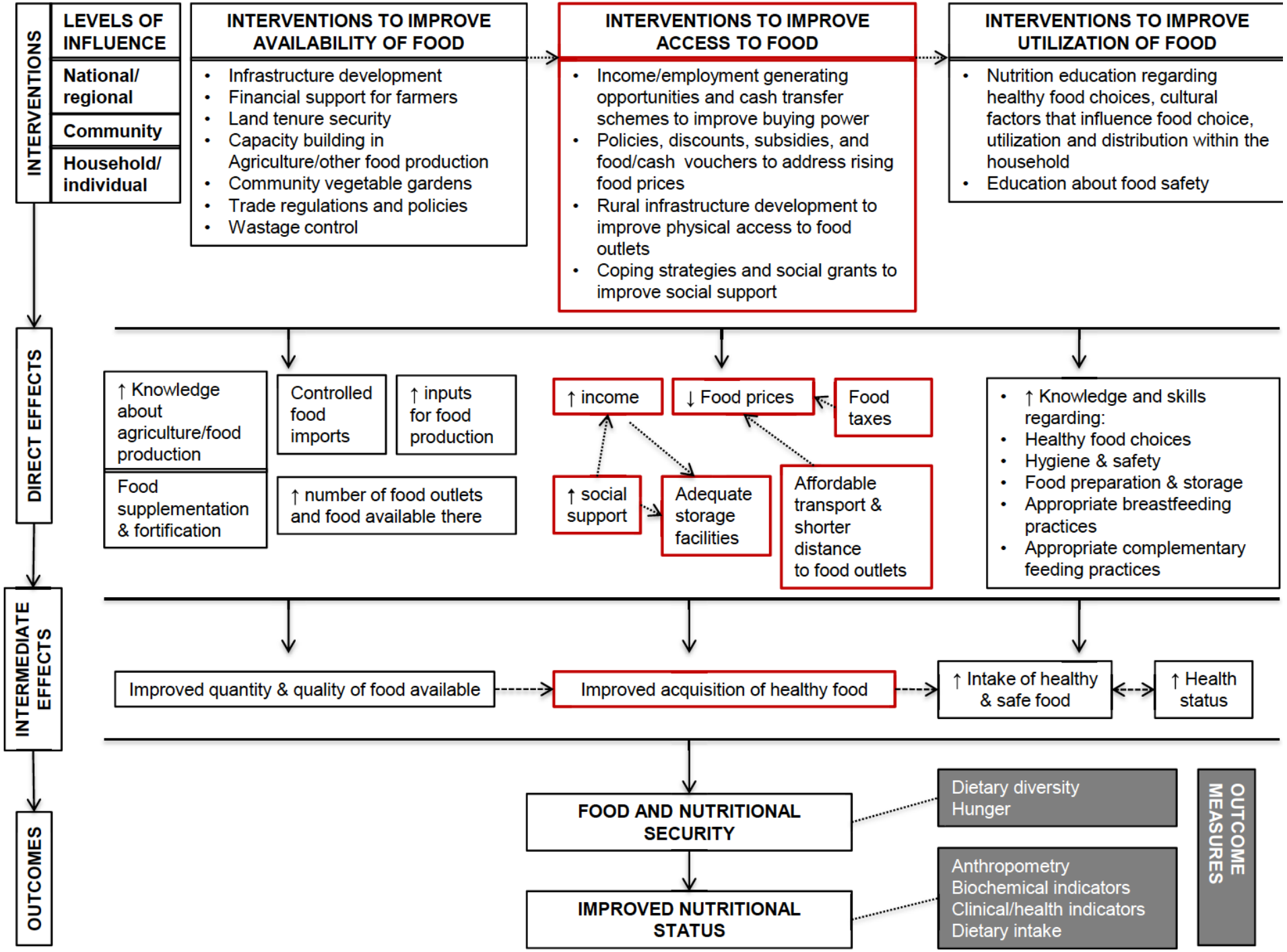
FROM: Rohwer et al. 2016 – their example of a ‘system-based logic model’

Simple Logic Model



Get food → Eat food → Feel better

From: DEVELOPING A LOGIC MODEL: TEACHING AND TRAINING GUIDE 2/29/2008


INTERVENTIONS
LEVELS OF INFLUENCE
National/ regional
Community
Household/ individual
INTERVENTIONS TO IMPROVE AVAILABILITY OF FOOD
Infrastructure development
Financial support for farmers
Land tenure security
Capacity building in Agriculture/other food production
Community vegetable gardens
Trade regulations and policies
Wastage control
INTERVENTIONS TO IMPROVE ACCESS TO FOOD
Income/employment generating opportunities and cash transfer schemes to improve buying power
Policies, discounts, subsidies, and food/cash vouchers to address rising food prices
Rural infrastructure development to improve physical access to food outlets
Coping strategies and social grants to improve social support
INTERVENTIONS TO IMPROVE UTILIZATION OF FOOD
Nutrition education regarding healthy food choices, cultural factors that influence food choice, utilization and distribution within the household
Education about food safety
DIRECT EFFECTS
↑ Knowledge about agriculture/food production
Food supplementation & fortification
Controlled food imports
↑ inputs for food production
↑ number of food outlets and food available there
↑ income
↓ Food prices
Food taxes
↑ social support
Adequate storage facilities
Affordable transport & shorter distance to food outlets
↑ Knowledge and skills regarding:
Healthy food choices
Hygiene & safety
Food preparation & storage
Appropriate breastfeeding practices
Appropriate complementary feeding practices
INTERMEDIATE EFFECTS
Improved quantity & quality of food available
Improved acquisition of healthy food
↑ Intake of healthy & safe food
↑ Health status
OUTCOMES
FOOD AND NUTRITIONAL SECURITY
IMPROVED NUTRITIONAL STATUS
OUTCOME MEASURES
Dietary diversity
Hunger
Anthropometry
Biochemical indicators
Clinical/health indicators
Dietary intake

How ToC and Logic Models Help

- Improve ‘upstream’ development of interventions (feasibility and acceptability)
- For systematic reviews:
  - Improve review coherence
  - Improve choice of outcomes
  - Improve attention to ‘context’ and other indicators of the underlying mechanisms of change
  - Improve interpretation of results
  - Improve articulation of implications for future research and practice


HOLE IN YOUR
LOGIC

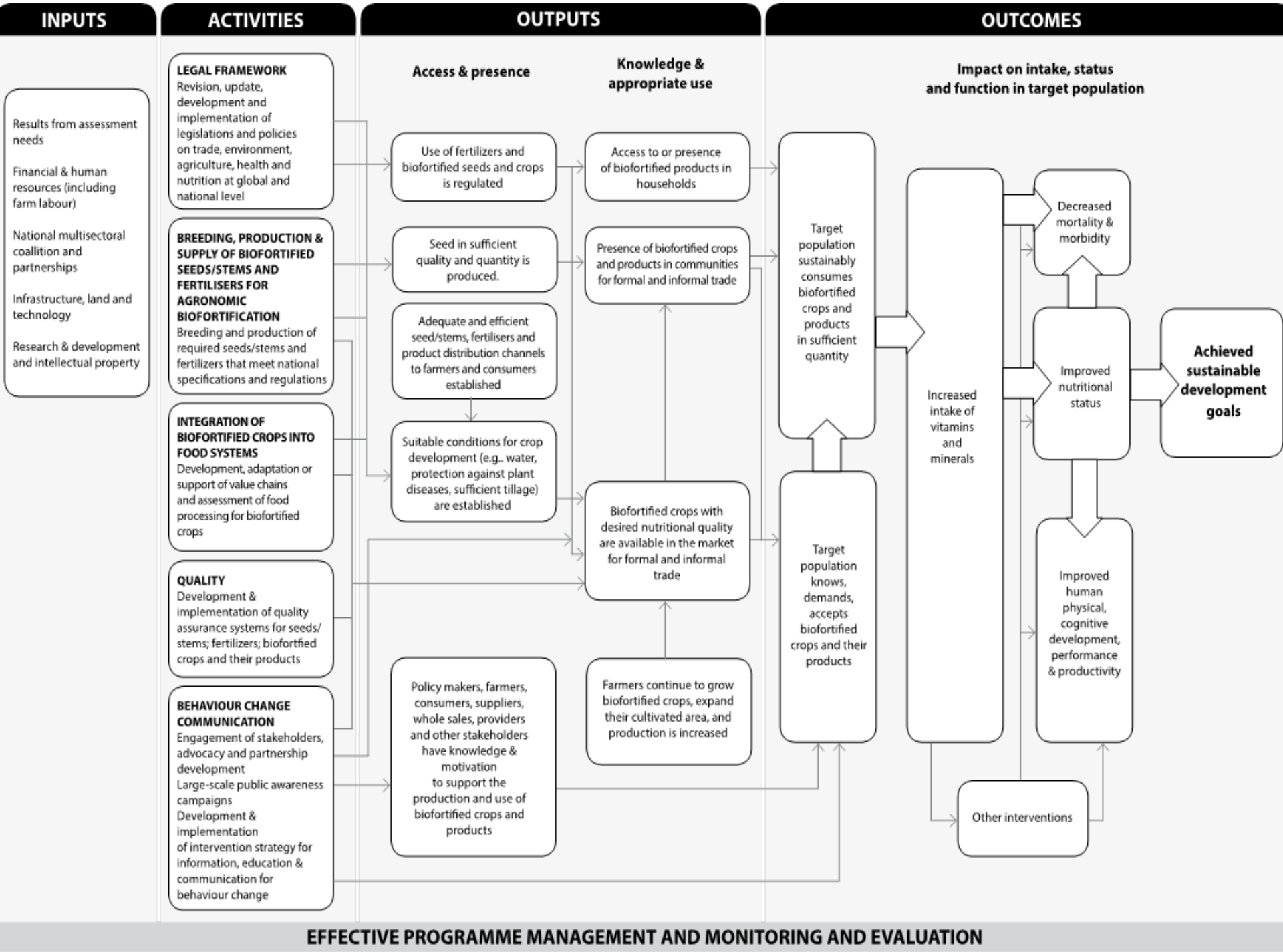
SOME REFERENCES

- Chen, H-T. and Rossi, P. H. (1983) 'Evaluating with Sense: The Theory driven approach' *Evaluation Review*, **7 ¸3,** 283-302**.**
- De Silva et al. (2014) Theory of Change: a theory-driven approach to enhance the Medical Research Council's framework for complex interventions, *Trials*, **15**, 267
- *Evaluation and Program Planning – 2013 - Special Issue on logic modelling and evaluation theory Vol **38.***
- Lipsey, M. W. (1993) 'Theory as Method: Small Theories of Treatments' *New Directions for Program Evaluation*, **57**, 5-38.
- Rohwer et al. (2016) Logic models help make sense of complexity in systematic reviews and health technology assessments. J. Clin Epidem, http://dx.doi.org/10.1016/j.jclinepi.2016.06.012
- White, H. (2009) Theory-Based Impact Evaluation: Principles and Practice. International Initiative for Impact Evaluation. Working Paper 3 3ie

The Black Box

"the way scientific and technical work is made invisible by its own success. When a machine runs efficiently, when a matter of fact is settled, one need focus only on its inputs and outputs and not on its internal complexity. Thus, paradoxically, the more science and technology succeed, the more opaque and obscure they become.“

Bruno Latour, *Pandora's hope: essays on the reality of science studies, 1999*


INPUTS
ACTIVITIES
OUTPUTS
OUTCOMES
Results from assessment needs
Financial & human resources (including farm labour)
National multisectoral coallition and partnerships
Infrastructure, land and technology
Research & development and intellectual property
LEGAL FRAMEWORK
Revision, update, development and implementation of legislations and policies on trade, environment, agriculture, health and nutrition at global and national level
BREEDING, PRODUCTION & SUPPLY OF BIOFORTIFIED SEEDS/STEMS AND FERTILISERS FOR AGRONOMIC BIOFORTIFICATION
Breeding and production of required seeds/stems and fertilizers that meet national specifications and regulations
INTEGRATION OF BIOFORTIFIED CROPS INTO FOOD SYSTEMS
Development, adaptation or support of value chains and assessment of food processing for biofortified crops
QUALITY
Development & implementation of quality assurance systems for seeds/ stems; fertilizers; biofortfied crops and their products
BEHAVIOUR CHANGE COMMUNICATION
Engagement of stakeholders, advocacy and partnership development
Large-scale public awareness campaigns
Development & implementation of intervention strategy for information, education & communication for behaviour change
Access & presence
Knowledge & appropriate use
Use of fertilizers and biofortified seeds and crops is regulated
Seed in sufficient quality and quantity is produced.
Adequate and efficient seed/stems, fertilisers and product distribution channels to farmers and consumers established
Suitable conditions for crop development (e.g.. water, protection against plant diseases, sufficient tillage) are established
Access to or presence of biofortified products in households
Presence of biofortified crops and products in communities for formal and informal trade
Biofortified crops with desired nutritional quality are available in the market for formal and informal trade
Policy makers, farmers, consumers, suppliers, whole sales, providers and other stakeholders have knowledge & motivation to support the production and use of biofortified crops and products
Farmers continue to grow biofortified crops, expand their cultivated area, and production is increased
Impact on intake, status and function in target population
Target population sustainably consumes biofortified crops and products in sufficient quantity
Target population knows, demands, accepts biofortified crops and their products
Increased intake of vitamins and minerals
Decreased mortality & morbidity
Improved nutritional status
Improved human physical, cognitive development, performance & productivity
Other interventions
Achieved sustainable development goals
EFFECTIVE PROGRAMME MANAGEMENT AND MONITORING AND EVALUATION

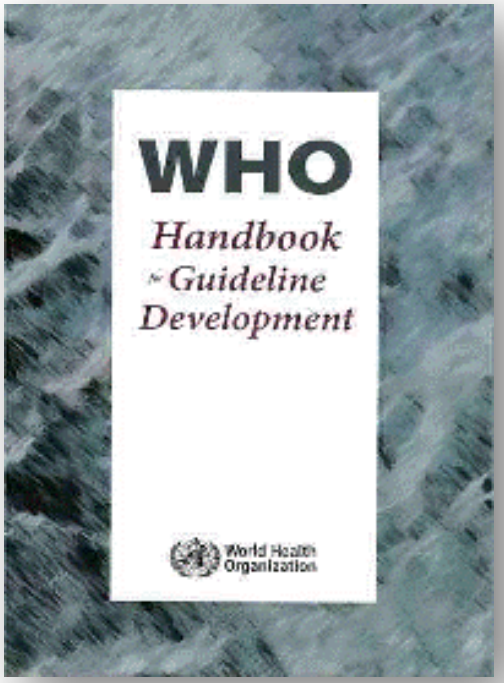
Complex interventions: our common ground

- Aspects of complexity
  - characteristics of the intervention, contextual factors, multiple outcomes, effect modifiers, package of interventions (integrated actions)
- Clarity in the question to be addressed
  - Outcomes, processes, mechanisms
- Outcomes of interest

Petticrew, M., Anderson, L., Elder, R., Grimshaw, J., Hopkins, D., Hahn, R., ... & Welch, V. (2013). Complex interventions and their implications for systematic reviews: a pragmatic approach. Journal of clinical epidemiology, 66(11), 1209-1214.

Global policies are not “based” on evidence

- Quality of the evidence
- Values and preferences
- Balance of benefits and harms
- Resource implications
- Priority of the problem
- Equity and human rights
- Acceptability
- Feasibility



WHO. Handbook for guideline development, 2nd edition. Geneva: World Health Organization

Beyond the effects of an intervention: biofortification example

- Biofortified crops: agronomic biofortification, conventional plant breeding, and bio-engineering
- Biofortified crops production, use and consumption
- Bioavailability of biofortified crops
- Models for estimating nutrient fortification levels in different biofortified crops
- Economic feasibility and impact of biofortified crops: from consumers to added productivity and economic development
- Legal framework for biofortified crops and seeds production
- Food safety and environmental considerations of biofortified crops
- Determinants of equity in access to biofortified crops
- Seed markets, trade and intellectual property
- Ethical considerations in biofortification of crops
- Country experiences and case studies

Cochrane Library

Cochrane Database of Systematic Reviews

Staple crops biofortified with increased micronutrient content: effects on vitamin and mineral status, as well as health and cognitive function in the general population (Protocol)

Garcia-Casal MN, Peña-Rosas JP, Pachón H, De-Regil LM, Centeno Tablante E, Flores-Urrutia MC

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Staple crops biofortified with increased micronutrient content: effects on vitamin and mineral status, as well as health and cognitive function in the general population.
Cochrane Database of Systematic Reviews 2016, Issue 8. Art. No.: CD012311.
DOI: 10.1002/14651858.CD012311.

www.cochranelibrary.com

Staple crops biofortified with increased micronutrient content: effects on vitamin and mineral status, as well as health and cognitive function in the general population (Protocol)
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WHO/CDC logic model for vitamin and mineral interventions in public health programmes

- developed by applying principles of programme evaluation, public health nutrition theory and programmatic expertise
- Available in all six WHO official languages and is adaptable through ppt version

De-Regil LM, Peña-Rosas JP, Flores-Ayala R, del Socorro Jefferds ME. Development and use of the generic WHO/CDC logic model for vitamin and mineral interventions in public health programmes. Public Health Nutr. 2014 Mar;17(3):634-9.

Challenges in the collaboration

- Need to ask for more explicit reporting of "excluded" studies – they are informative!!
- Alignment of search updates for guideline development group consensus, WHO ePublication clearance including GRC, and Cochrane publication requirements – be realistic!

Acknowledgements

- WHO thanks Cochrane for its support to our normative work in nutrition, especially
  - Developmental, Psychosocial and Learning Problems Group
  - Pregnancy and Childbirth Group
  - Public Health Group
  - Infectious Diseases Group
  - Metabolic and Endocrine Disorders Group
  - Editorial unit (London)
  - Tobacco Addiction Group