



慢性病綜合防控試點培訓班

實施性研究理論和方法 以及在慢性病預防控制中的應用

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概要

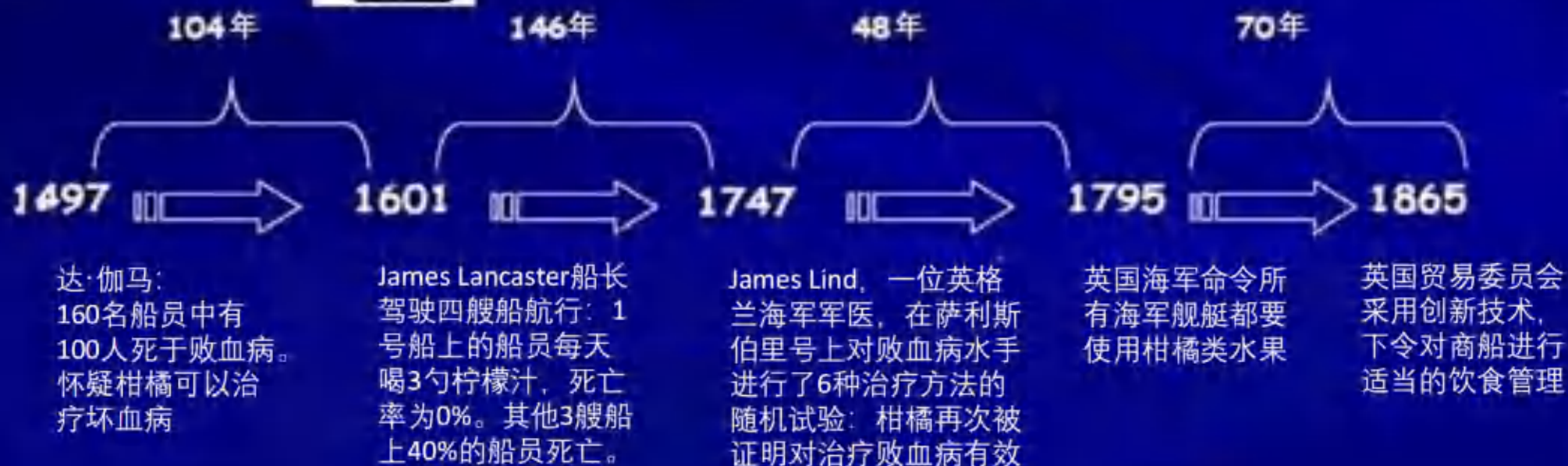
- 一. 背景 (background)
- 二. 核心概念 (core concepts)
- 三. 研究目的和科学问题 (Research aim & question)
- 四. 理论、框架和模型 (Theory, Framework and Model)
- 五. 实施研究逻辑框架 (Logic framework of ImpRes)
- 六. 选择干预措施与实施策略 (Mapping intervention and imp-strategy)
- 七. 实施研究设计和方法 (Study design and method in ImpRes)
- 八. 干预结果与实施效应评估 (Evaluation of the intervention and IR)

一、背景

实施科学发展的背景

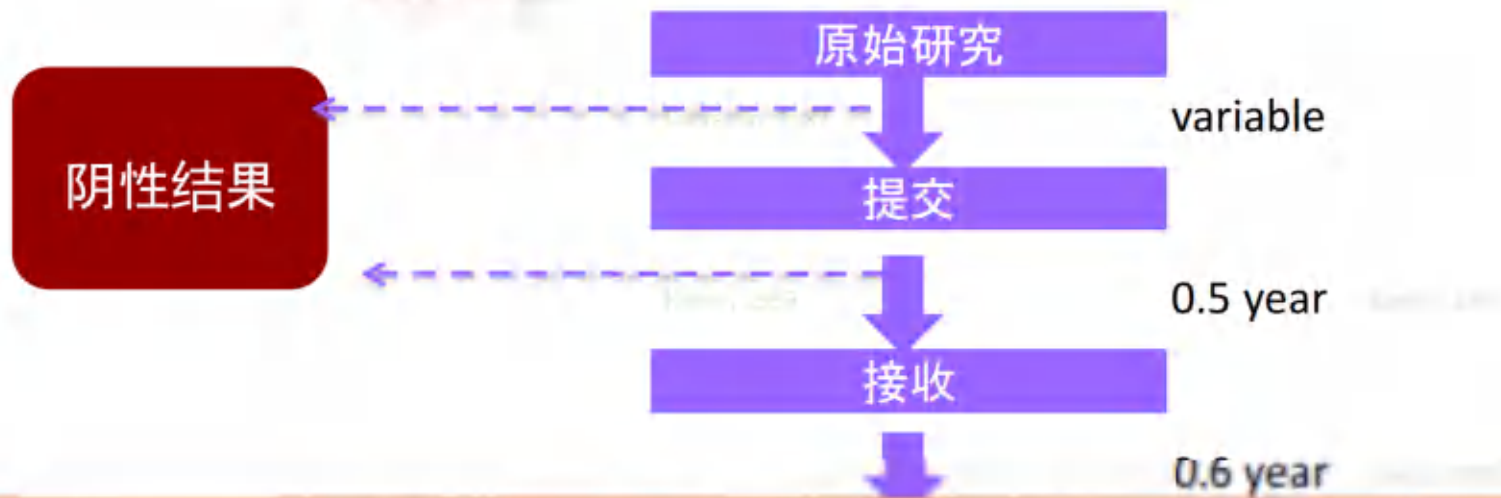
历史经验的启示

从Lancaster首次认知柠檬汁可防治败血症
到真正被纳入规定使用总共花费的时间：
264年



<http://greas.ca/publication/pdf/melaniebarwickenglish.pdf>

出版路径



将14%的原始研究成果转化为对患者有益的治疗需要17年的时间

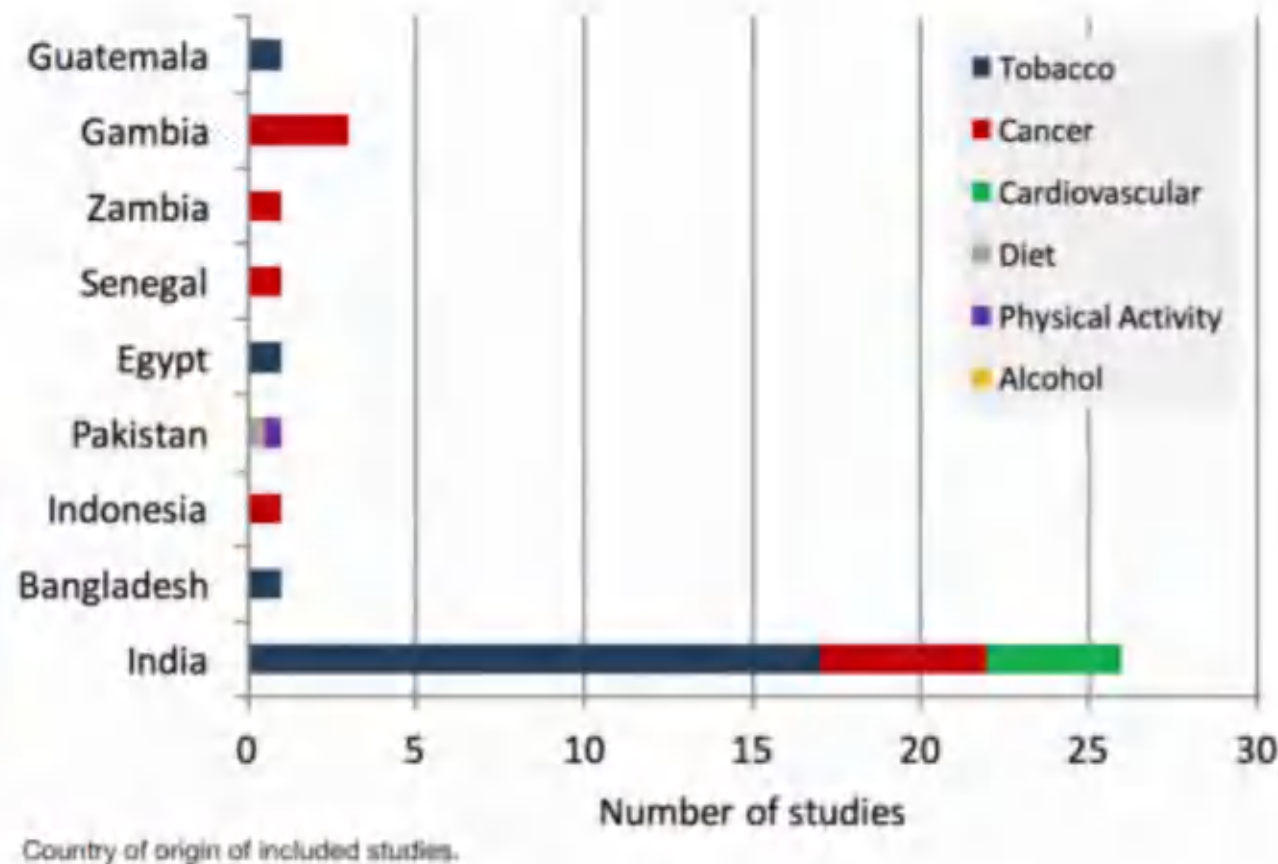
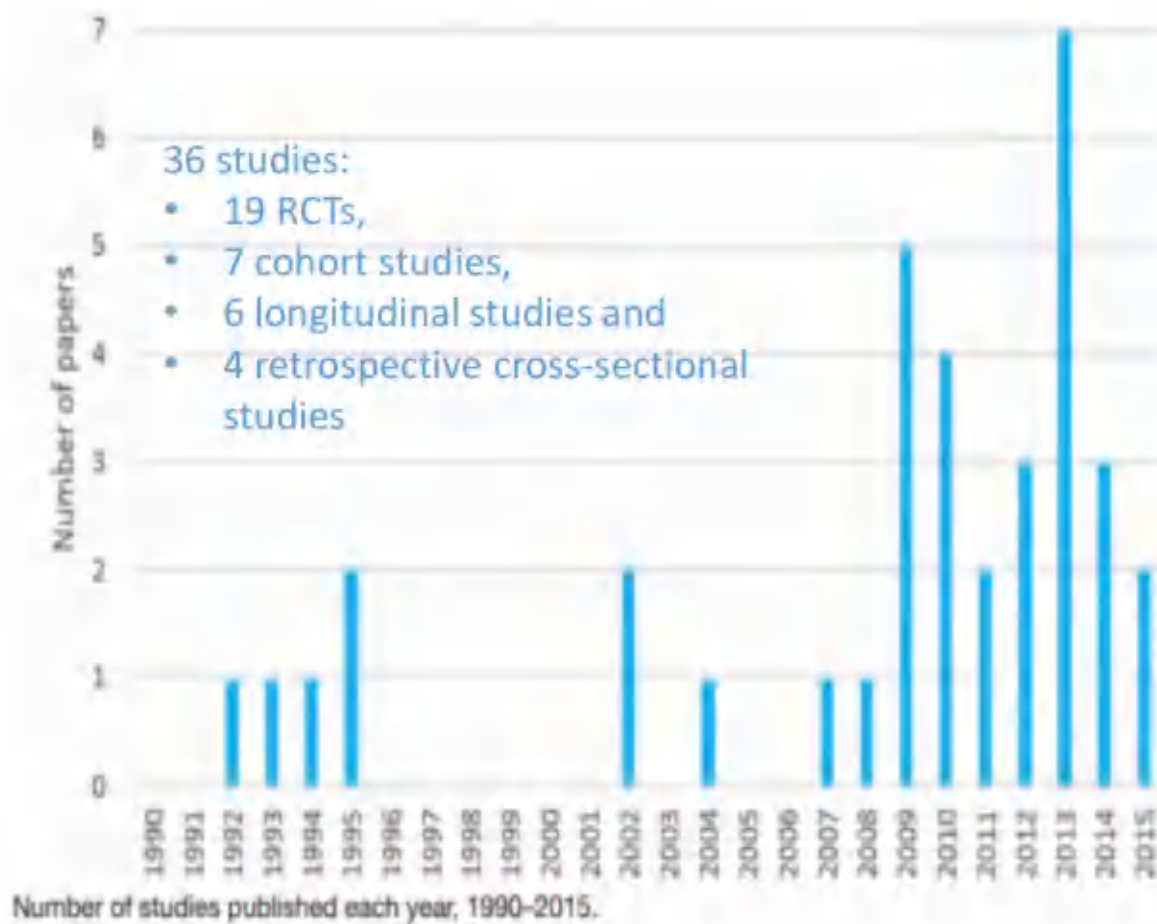
不一致的索引

综述, 指南, 教科书

实施

缺乏对于那些已经证明有效的干预措施的应用研究

Evaluation of research on interventions aligned to WHO 'best buys' in LMICs: a systematic review 1990-2015 in 115 countries



Allen LN, Pullar J, Wickramasinghe KK, et al. Evaluation of research on interventions aligned to WHO 'Best Buys' for NCDs in low-income and lowermiddle-income countries: a systematic review from 1990 to 2015. *BMJ Glob Health* 2018;3:e000535. doi:10.1136/bmjgh-2017-000535

循证干预措施的现实证据挑战

- 89%的“best buy”在低收入和低中收入国家不存在循证证据
- 24项世卫推荐的“best buy”中：
 - 仅有4项内容有超过两个不同的研究提供证据支持：小组戒烟、公众场所禁烟、宫颈癌筛查、乙肝疫苗接种
- 而这些国家是最需要实施慢病预防的国家

Are WHO “best buys” for non-communicable diseases effective in low-income and lower-middle-income countries? A systematic review

Background The leading cause of the global burden of disease, non-communicable diseases (NCDs) is a cluster of highly preventable interventions that WHO has dubbed “best buys”. These 24 interventions recommended by WHO include tobacco taxation, salt reduction, alcohol taxation, and aspirin. Although the greatest burden of NCDs is in low-income and lower-middle-income countries, evidence for most of the best buys comes from high-income countries. We did a systematic review to assess evidence for the effectiveness of best buys in high-income and lower-middle-income countries (LMICs) across the world for selected NCDs outcomes (17 points).

Methods Using a registered protocol (PROSPERO: 2018020652) and following PRISMA guidelines, we searched at least two databases for studies that quantified the effectiveness of the 24 interventions as defined in the 2013–15 Global Action Plan on NCDs. We included studies that were undertaken in 19 countries defined by the World Bank as LMICs, published between Jan 1, 1990, and Feb 5, 2015. We assessed and rated the quality of evidence for each best buy that compared interventions with usual health care, over treatment independently assessed papers using a protocol form. We used guidelines for Newcastle-Ottawa and Cochrane tools to assess risk of bias and adopted a narrative approach to data synthesis. Primary outcomes were all-cause mortality, cardiovascular mortality, and disability-adjusted life expectancy.

Results Our search returned 1677 records after duplicate removal and we included 59 studies in the final review, of which 26 had been done in LMICs. 49 of the 59 studies reported mortality outcomes, 40 reported morbidity and physical quality of life outcomes, 40 reported cardiovascular mortality, and 11 on cancer interventions. Only four “best buys” had been in LMICs studies that showed that the intervention was effective: group smoking cessation programmes, smoking bans in public places, tobacco taxation, and aspirin for cardiovascular. There was no evidence for the effectiveness of any food/dietary interventions or 14 of the 14 LMICs (86%).

Conclusions There is an urgent need to achieve a more established evidence base for NCDs interventions from high-income countries and effective in LMICs settings. Our work following the wording of the WHO best buys definitions could have helped with relevant studies. However, our review was comprehensive in scope and had a very robust search strategy.

Keywords World Health Organization

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Background (continued)

Background (continued)

Background (continued)

Background (continued)

Background (continued)

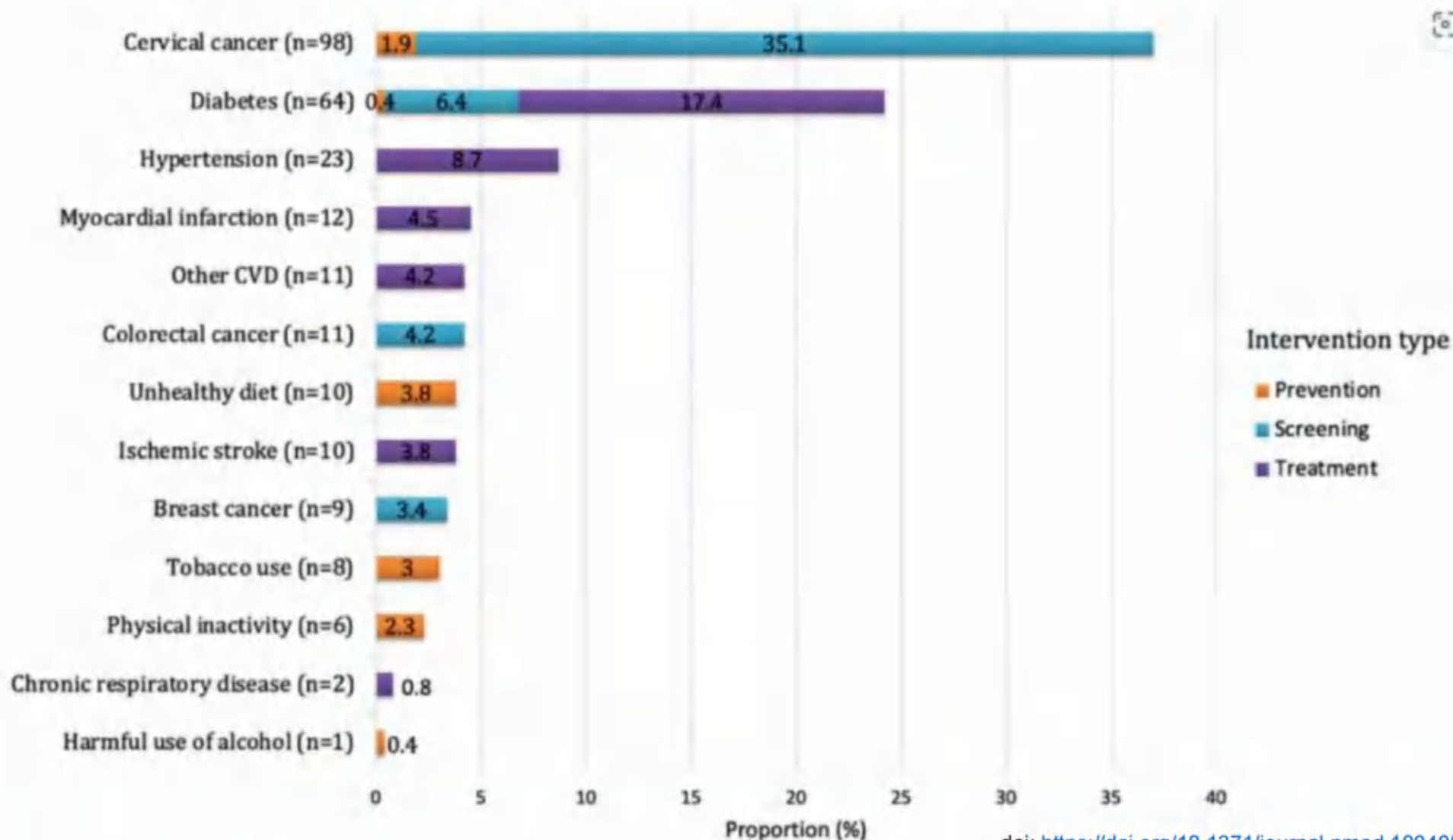
Background (continued)

Background (continued)

Background (continued)

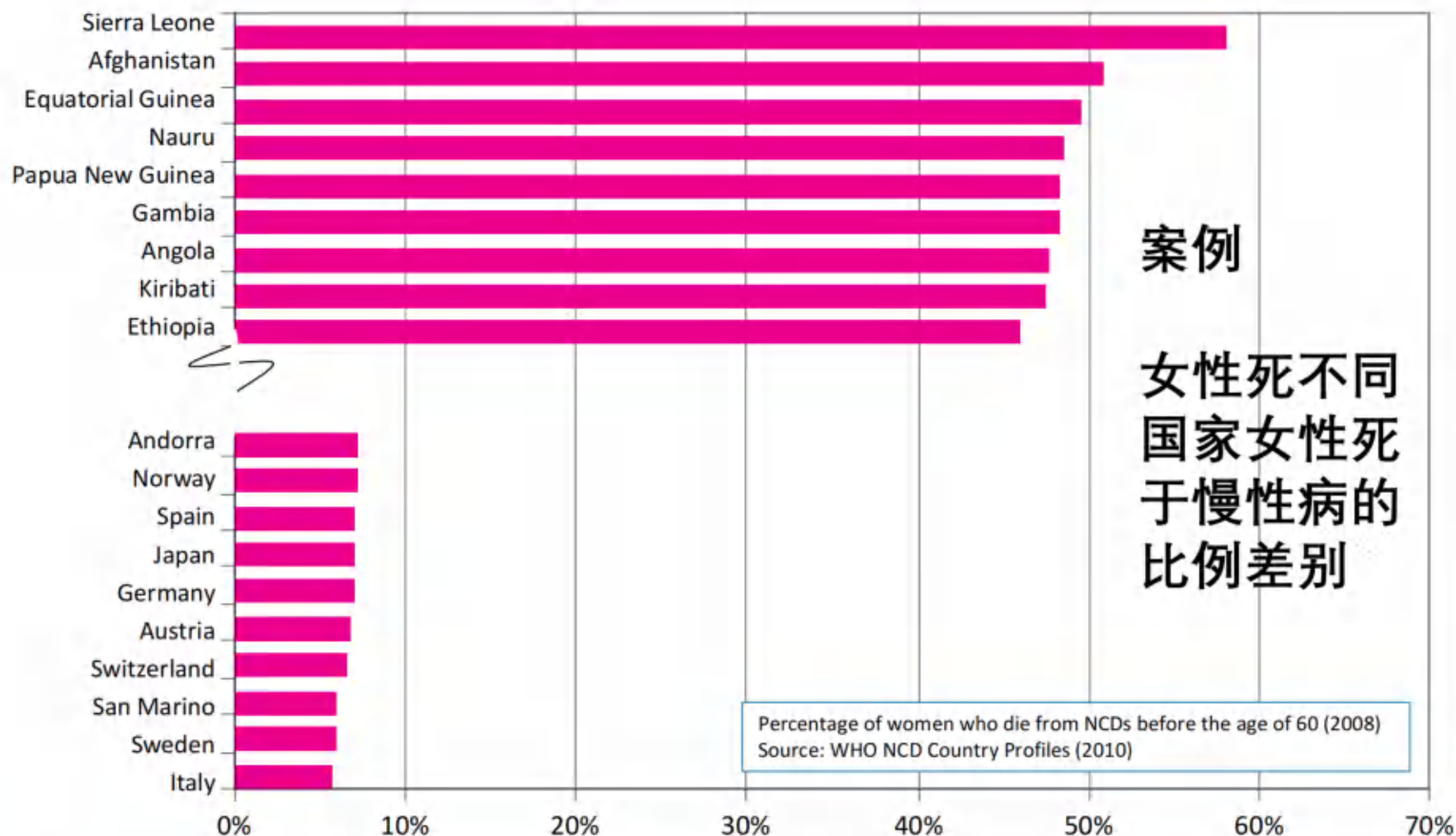
Background (continued)

Distribution of priority NCD prevention and control interventions by type of NCD and their risk factors



doi: <https://doi.org/10.1371/journal.pmed.1004055.g002>

为什么需要实施研究？



医疗卫生领域各类转化研究

从疾病控制角度关于医学研究分类



	研究的主要科学问题	案例	应用
观察性研究 Observational study	疾病的病因或者影响因素? 疾病对人群健康的影响?	Seven country study, Framingham study, 英国医生吸烟队列, Interheart, Intersalt, Whitehall study, PURE study	疾病病因或危险因素调查与评估; 评估人群与环境健康; 社会与舆论动员、
干预性研究 Interventional study	有无干预措施? 干预措施的效果如何?	MRFIT, North Karelia project(芬兰), Stanford three community study/five community study, IHHP(伊朗)、大庆糖尿病预防项目、首钢高血压研究, HOPE4	评估干预与结果之间的关系; 用于循证公共卫生和疾病控制实践
实施性研究 Implementation Research	干预措施是否在不同的环境下实施并达到预期效果? 什么策略可促进循证基础的干预措施的实施?	SAHELITrial, ACTIVATE, PACE study, EIRA study	促进循证实践和研究的方法和策略在真实世界应用: 调查干预措施、规范、指南在实际应用中的差距以及影响因素; 制定策略促进干预措施与指南实施; 促进实施策略与干预措施效果评估

卫生系统和政策研究

生物医学研究

基础研究：
物理和生物科学，包括
化学，药理学，毒理学，
遗传学等。

药品、疫苗、诊断、器具等的研
究和开发。

了解疾病的生物学性质。创造预防或
治疗疾病状态的产品

卫生政策和系统研究

政策制定、证据关系，优先
排序等研究。

研究卫生系统管理、功能
、效率、效力、影响获取
的系统因素、扩大规模、
监测和评价等。

了解如何测试、扩大和跟踪干预措施的引入，以优化其效益

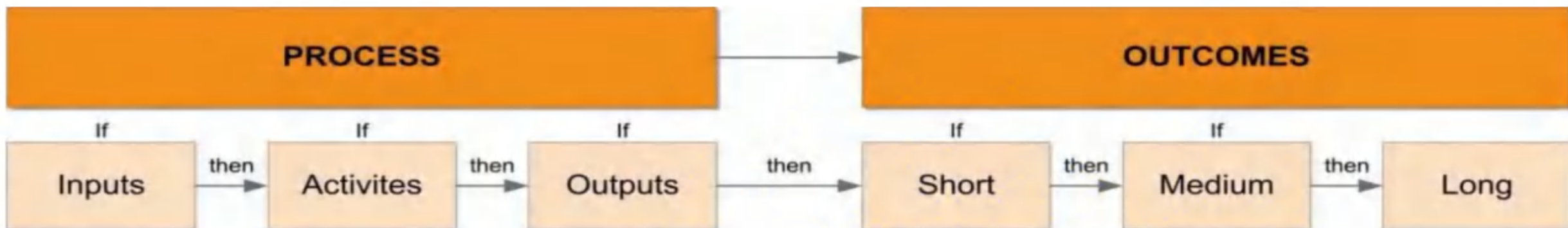
社会科学和行为研究

研究影响健康的社会和行为
因素及其与公平、获得、生
活方式和健康寻求行为等的
关系。

影响

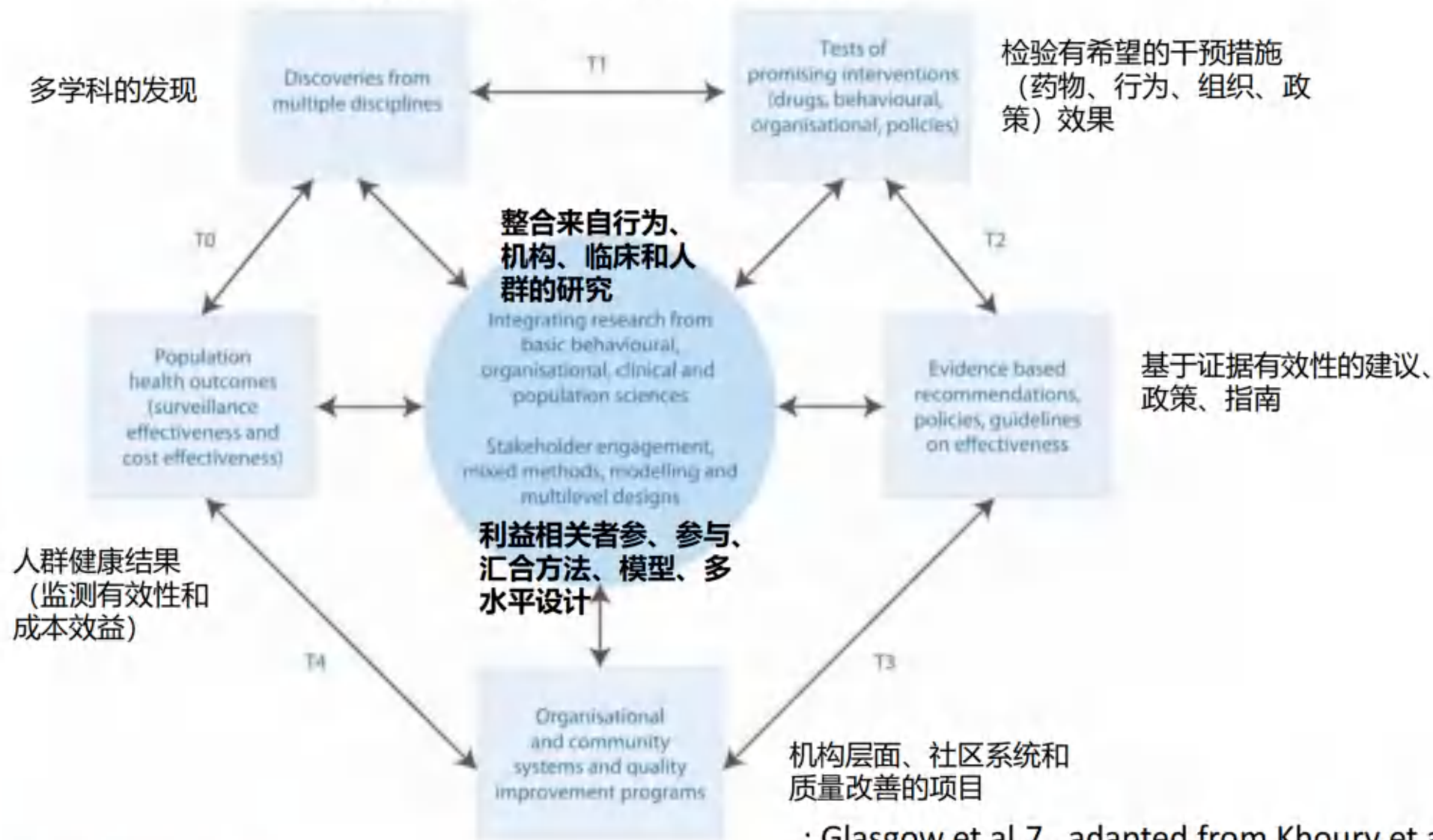
传统卫生项目的实施过程与结果

- A logic model is a graphic “snapshot” of how a program works (its theory of change); it communicates the intended relationships among program components.



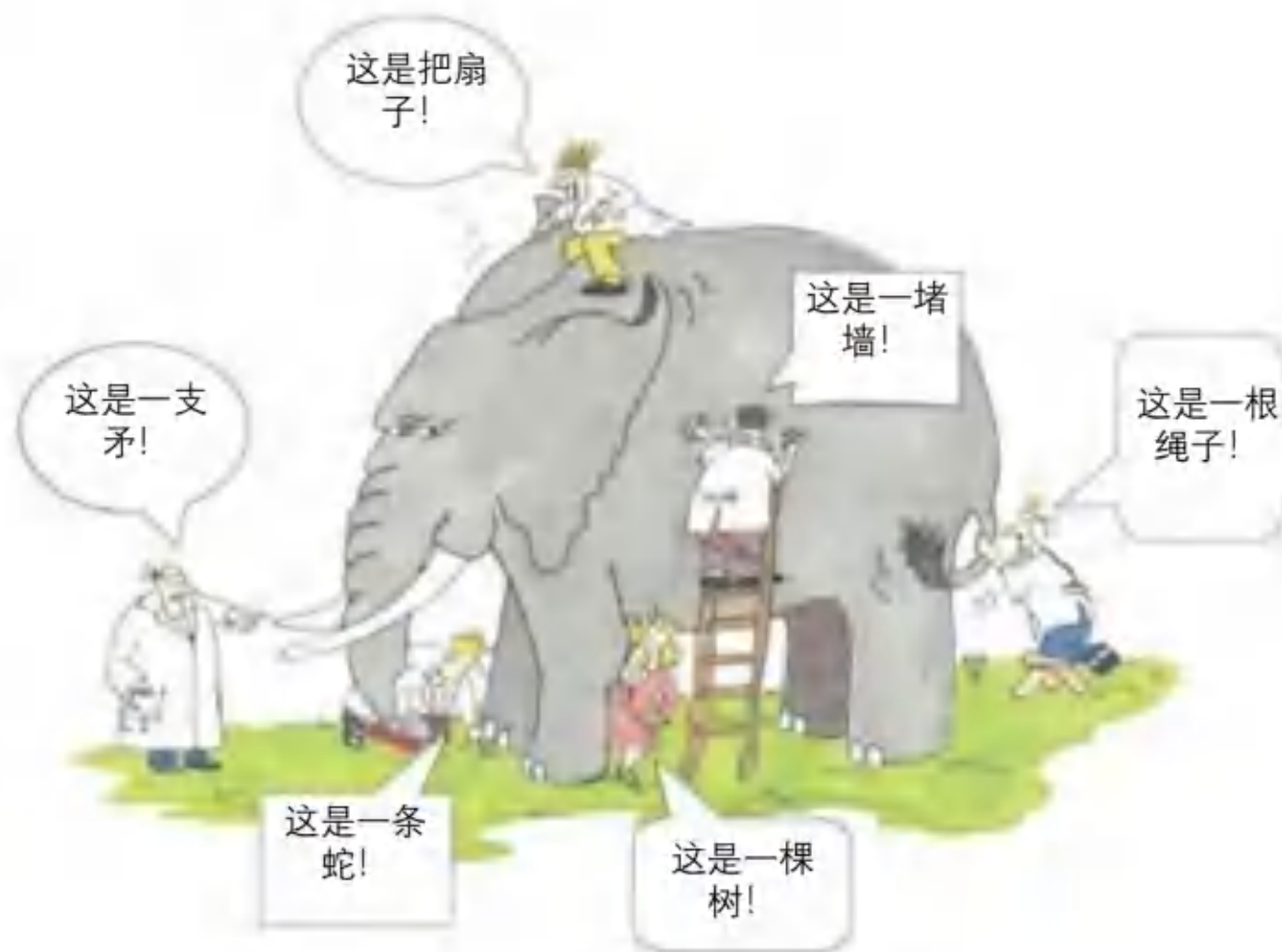
转化研究的T0-T4阶段

T0-T4 phases of translational research



如何促进循证干预策略和措施的实施？

- ❑ 流行病学研究
(Epidemiological study?)
- ❑ 运筹 (Operational research
(OR)?)
- ❑ 评估研究 (Evaluation
study? (Process evaluation?
Impact evaluation)
- ❑ 加强卫生系统研究 (Health
systems strengthening) ?
- ❑ 实施科学研究
(Improvement science?)



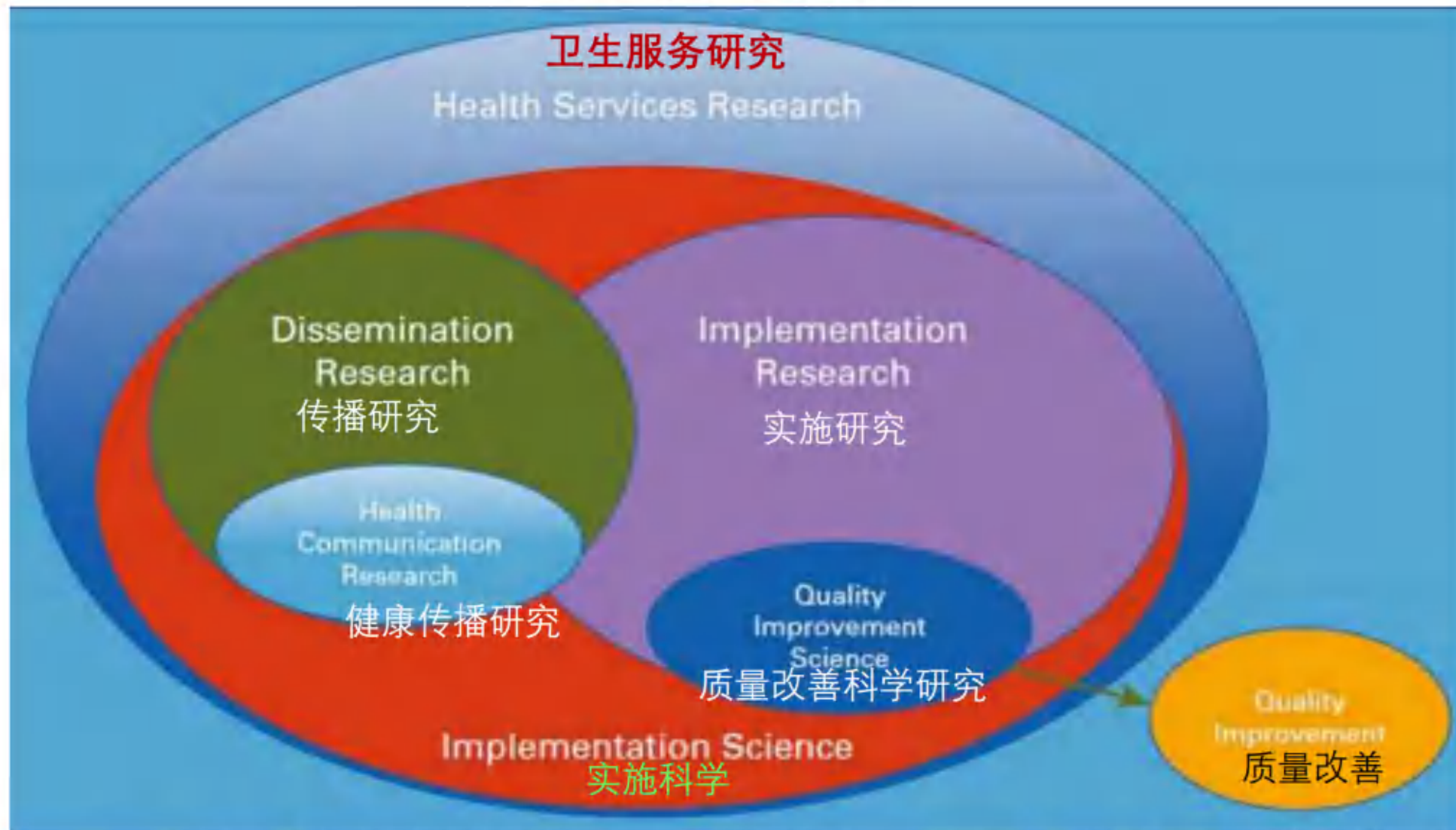
二、核心概念 (core concepts)

背景和概念

什么是实施科学？

实施科学

Implementation science



Mitchell SA, Chambers D. Leveraging Implementation Science to Improve Cancer Care Delivery and Patient Outcomes. JOP 2017; 13(8):523-529

实施科学



解决循证干预向实践应用推广过程中
面临的问题而提出的交叉学科

■ Science 科学

■ Systematic knowledge building
系统性的产生科学证据、完善科学体系

■ Implementation 实施

■ Promote the translation from evidence into
practice
促进循证证据和循证实践向真实世界实施转变



什么是实施科学？

definition

source

Implementation science is commonly defined as the study of methods and strategies to promote the uptake of interventions that have proven effective into routine practice, with the aim of improving population health. (实施科学通常被定义为针对实施有关的方法和策略研究，以促进循证干预措施纳入常规实践系统，缩小已有知识和实际采纳使用之间的差距，从而改善人群健康。)

[Eccles/Mittman](#) 2006

Implementation Research has the basic intent to understand what is and isn't working, how and why implementation is going right or wrong and to test approaches to improve implementation (实施研究的基本目的是了解什么是有效的，什么是无效的，实施如何以及为什么是正确的或错误的，并研究改进实施的方法。)

Implementation Research in Health, a practical guide; AHPSR WHO, 2013

Implementation Research is the application and creation of knowledge to improve the implementation of health policies, programmes, practices, intervention or guideline (实施研究是通过创造和应用知识，以促进卫生政策、方案、实践、干预措施或指导方针的实施。)

Theobald S et al. Lancet, 2018; forthcoming

实施科学

从科学发现到常规卫生项目的路径

Pathway from basic discovery to regular health program



为什么实施的场境很重要？

如何理解实施科学中的场景?

What is **context** in IR?

A

Evidence-based intervention or best practice
循证干预或者最佳实践

- 干预或者卫生服务研究运用各种科学研究的方法, Intervention research or Health system research using RCT or other research methods
- Best practice from other environment 来源于其他环境的最佳实践

B

Complicate context in real world
现实世界的复杂性

- 文化决定因素 (**Culture determinants**)
- 社会关系和支持 (**Social relations and support**)
- 组织支持 (**Organizational support**)
- 组织文化和气氛 (**Organizational culture and climate**)
- 组织准备好变革 (**Organizational readiness to change**)
- 物理环境 (**Physical environment**)
- 病人 (**Patients**)
- 其他地方上的特殊因素 (**Others specific factors in local society**)

如何理解实施研究中的场境?

What is **context** in IR?

A

Evidence-based intervention or best practice

循证干预或者最佳实践

- 干预或者卫生服务研究运用随机对照或者其他科学研究的方法, Intervention research or Health system research using RCT or other research methods
- 来源于其他环境的最佳实践 Best practice from other environment

B

Complicate context in real world

现实世界的复杂性

- 文化决定因素 (Culture determinants)
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- 组织准备好变革 (Organizational readiness to change)
- 物理环境 (Physical environment)
- 病人 (Patients)
- 其他地方上的特殊因素 (Others specific factors in local society)

实施研究的场景因素

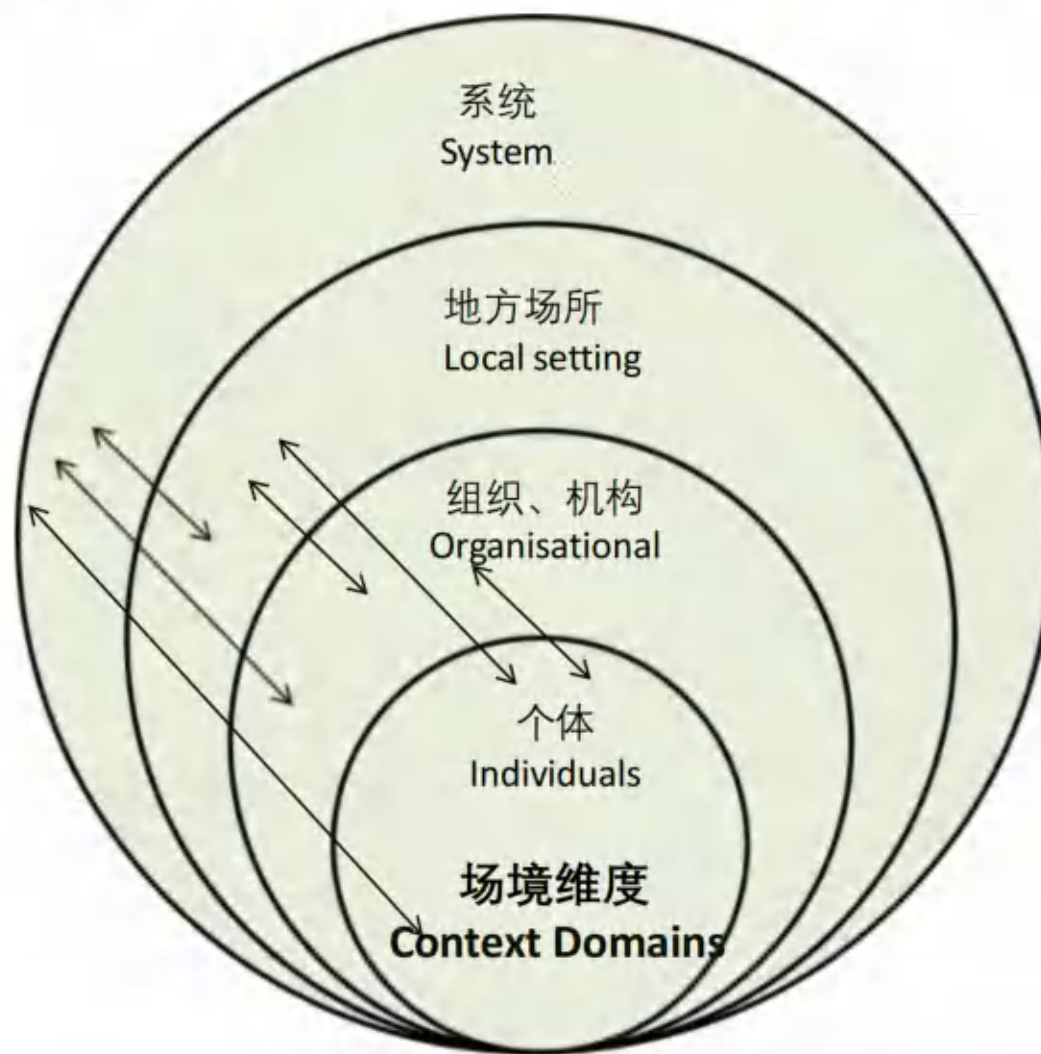
Contextual factors for implementation research



创新/干预措施在哪里实施，为谁实施

WHERE AND FOR WHOM IS THE INNOVATION TO BE IMPLEMENTED

场境生态模型
Ecological model of
context



实施“什么”？ The thing

来源于干预研究的“the Thing”

循证干预措施

以GRADE为代表的证据质量和推荐强度分级方法

Levels of Evidence



GRADE



Journal of Clinical Epidemiology

Volume 126, July 2024, Pages 42-53



Editorial Board

Challenges in applying the GRADE approach in public health guidelines and systematic reviews: a concept article from the GRADE Public Health Group

Michele Hilton-Boon^{a,*}, Hilary Thomson^a, Beth Shaw^b, Elie A. Akl^{c,d}, Stefan K. Linchinski^{e,f}, Jesús López-Alcalde^g, Miloslav Klugar^h, Leslie Choiⁱ, Zuleika Say-Parkinson^j, Reem A. Mustafa^{k,l}, Miranda W. Lingsdalen^m, Olivia Changⁿ, Rebecca L. Morgan^o, Eva Behrhuus^p, Bradley C. Johnston^q, Lee Yee Chong^r, Gordon H. Guyatt^s, Holger J. Schünemann^t, Srinivasa Vital Katikireddi^u, GRADE Working Group

SUNY Downstate Medical Research Library of Brooklyn: Evidence-Based Medicine Course. Evidence Based Pyramid[EB/OL]. [2022-11-05]. <https://guides.downstate.edu/c.php?g=856794&p=6831536>.

什么是循证干预措施？

What is an Evidence-Based Intervention?

- **经过验证的、能够改善健康行为、健康结果或与健康相关的环境的有效干预措施** (Interventions with proven efficacy and effectiveness at improving health behaviors, health outcomes, or health-related environments)
- **干预可能包括计划、实践、政策和指导方针** (Intervention could include programs, practices, policies & guidelines)

Rabin, B. A., Brownson, R. C., Haire-Joshu, D., Kreuter, M. W., & Weaver, N. L. (2008). A glossary for dissemination and implementation research in health, *Journal of Public Health Management and Practice*, 14(2), 117-123.; Brown CH, Curran G, Palinkas LA, Aarons GA, Wells KB, Jones L, et al. An overview of research and evaluation designs for dissemination and implementation. *Annu Rev Public Health*.. 2017; 38:1-22

可以实施和推广的循证干预措施 (EBIs) 类型

Types of Evidence-Based Interventions (EBIs) that can be implemented and disseminated

- **临床实践指南** Clinical Practice Guidelines
- **临床创新** Clinical Innovations (e.g. new screening technology)
- **健康促进项目** Health Promotion Programs (Packaged programs)
- **政策** Policies
- **策略** Strategies (USPSTF Community Guide Recommendation; e.g. mass media, one on one, provider reminders)

Fernández ME, Mullen PD, Leeman J, Walker TJ. Evidence-Based Cancer Practices, Programs, and Interventions. In: *Advancing the Science of Implementation across the Cancer Continuum*. 2018, Oxford Press.

WHO推荐的最佳干预措施和服务包

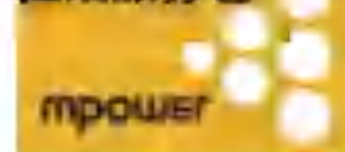
WHO best buys interventions

慢性病最佳干预措施

减少烟草使用	● 提高烟草制品消费税和价格 ● 实施平装/标准化包装及/或在所有烟草包装上使用大幅图片健康警告 ● 制定并实施法律, 全面禁止烟草广告、促销和赞助 ● 消除所有室内工作场所、公共场所、公共交通的二手烟暴露 ● 实施有效的大众媒体宣传行动, 向公众讲解吸烟/使用烟草和二手烟的危害
减少有害使用酒精	● 提高对酒精饮料征收的消费税 ● 制定并执行针对酒类广告的禁令或全面限制令(跨多种媒体类型) ● 立法(通过缩短销售时间)限制零售酒类的实际可获得性并执行这些限制措施
控制不健康饮食	● 调整食品配方降低含盐量并确定食品和餐饭含盐量目标, 减少盐摄入量12 ● 在医院、学校、工作场所、疗养院和公共机构中建立支持性环境, 促进提供低钠饮食, 减少盐摄入量 ● 开展促进行为变化的宣传和大众媒体行动, 减少盐摄入量 ● 落实包装正面标签规定, 减少盐摄入量
减少身体不足活动	● 在整个社区开展鼓励身体活动的公共教育和宣传运动, 包括开展大众媒体运动, 并实行基于社区的其它教育、激励和环境规划, 以促进行为变化, 增加身体活动*
管理心血管疾病和糖尿病	● 为曾发生过心脏病发作或脑卒中的个人以及在今后10年内有致命和非致命心血管事件高风险($\geq 30\%$)的人提供药物治疗(包括从控制总风险*角度进行糖尿病血糖控制和高血压控制)和咨询 ● 为曾发生过心脏病发作或脑卒中的个人以及在今后10年内有致命和非致命心血管事件的中高风险($\geq 20\%$)的人提供药物治疗(包括从控制总风险角度进行糖尿病血糖控制和高血压控制)和咨询
管理癌症	● 9-13岁少女接种(2剂)人乳头状瘤病毒疫苗 筛查 30-49岁妇女, 预防宫颈癌, 可选用如下技术: ➢ 醋酸试验肉眼观察法, 并结合及时治疗癌前病变22 ➢ 每三五年进行一次巴氏涂片(宫颈细胞学)检查, 并结合及时治疗癌前病变 ➢ 每五年进行一次人乳头状瘤病毒检测, 并结合及时治疗癌前病变

慢性病相关的技术服务包

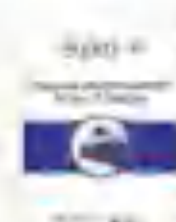
控烟服务包



Package of Essential NCD Interventions



Hearts Technical Package



Diabetes Management Module



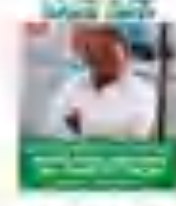
Maintaining services during COVID-19



Digital health for NCDs



Strategic fund for essential NCD medicines



Clinical cancer guidelines



NCD survey: Steps Survey instrument

什么因素影响干预措施的落实？

什么因素影响干预措施的落实?

中华预防医学杂志 2024 年 5 月第 58 卷第 5 期 Chin J Prev Med, May 2024, Vol. 58, No. 5

· 615 ·

表1 高血压、糖尿病照护级联效应的促进与阻碍因素

高血 因素	患者层面		卫生服务提供者层面		系统层面		
	促进因素	阻碍因素	促进因素	阻碍因素	促进因素	阻碍因素	
	意识	1.家族病史 2.身边患者案例 3.定期体检	教育文化水平低	良好的医生居 民关系	卫生服务提供者人 力缺乏	对医生下乡宣教、义诊 有相关的考核激励 制度	1.健康教育考核缺乏 量化细则 2.缺乏针对性适宜的 干预措施
王振中 ¹ 井瑞 ² 邵 “中国医学 预防控制” 疾病预防 262699; ** 通信作者:	筛查	1.筛查可及与便 利性 2.良好健康意识	1.无症状,自觉健康 2.心理因素,害怕被诊 断及污名化问题 3.社会负担重	良好的医生居 民关系	1.卫生服务提供者人 力缺乏 2.初筛精度较差	1.基层领导支持筛查 活动 2.正在开展多个慢病 项目	筛查耗材成本无专项 资金支持
	诊断	1.诊断的可及性 与便利性 2.良好健康意识	1.无症状,自觉健康 2.患者自主用药 3.不信任基层医疗机 构能力 4.认为诊断项目复杂 产生的抗拒 5.就诊时患者健康问 题等需求未被满足	1.良好的医生 居民关系 2.医生能力与 口碑好	诊断时间紧张所导 致的诊断迅速但 不全面	1.对诊疗行为的监督 规范与培训 2.良好的医疗环境 3.医疗机构人文建设	

【摘要】
高血压、糖尿病
广东省佛山市
各提供者以
析。结果
理者、卫生
断、治疗、
结论 本研
括证的实施

三、研究目的和科学问题

(Research aim & question)

你的研究目的是什么？

1. 了解与实施有关的障碍和有利因素 (understand barriers and facilitators to implementation)
2. 调整基于证据的干预措施 (adapt an Evidence-based intervention (EBI))
3. 选择、开发和调整实施策略 (select/develop/adapt implementation strategies)
4. 评估实施策略的可行和可接受性 (evaluate the feasibility/acceptability of strategies)
5. 评估调整的干预措施效果 (evaluate the impact of an adapted EBI)
6. 评估实施策略的效果 (evaluate the performance of a strategy)
7. 评估实施的效果 (assess the impact of implementation)

如何提出“实施研究”关心的 “科学问题”

- 主要的实施挑战是什么？针对哪些利益相关方（比如目标人群、医疗保健服务人员、管理人员、政策制定者）？
- 可能影响实施的干预措施的关键场景因素是什么？
- 影响干预措施实施的主要组织有哪些？
- 它们如何促进或阻碍实施？
- 实施是我们预期或期望的吗？
- 为什么会这样？哪些因素（阻碍或促进因素）可能影响实施和应用？
- 何种政策或干预措施最适合新的环境？实施它的最佳方式是什么？
- 如何将实施成本降到最低？
- 如何扩大和维持干预措施，使健康效益最大化？

实施科学研究的科学问题

How? Objectives, implementation questions, methods

目标 Objectives	实施问题 Implementation question	研究方法和资料收集 Research method and data collection
探索 Explore	哪些因素可能影响健康干预措施的实施、加强或扩大?	- 定性研究—关键人员访谈、焦点小组、案例研究、叙事法…… - 定量研究—网络分析、横断面调查…… - 混合方法—Q+Q
描述 Describe	实施环境是什么?影响实施的主要因素是什么?	- 定性研究—关键人员访谈、焦点小组、案例研究、叙事法…… - 定量研究—网络分析、横断面调查…… - 混合方法—Q+Q
适度 Adequacy	干预措施的覆盖面是否在改变?	- 前-后对比、干预范围的时间序列 - 参与式行动研究
合理性 Plausibility	健康状况是否因干预措施而改变?	- 前-后对比、干预对象和非干预对象的横断面研究 - 典型的质量改善研究
解释 Explain	实施干预措施如何以及为什么会对健康行为、服务或健康状况产生影响?	- 定性研究—关键人员访谈、焦点小组、案例研究、叙事法…… - 定量研究—效果-实施(评估实施策略和结果) - 混合方法—Q+Q - 参与式行动研究(研究对象本身)
预期 Predict	未来实施干预措施的可能过程是什么?	- 定性研究—情景构建、德尔菲 - 定量研究—建模、灵敏度分析

Peters DH, Peters MA, Wickramasinghe K, Osewe PL, Davidson PM. Asking the right question: implementation research to accelerate national non-communicable disease responses. BMJ. 2019 May 20;365:l1868. doi: 10.1136/bmj.l1868. PMID: 31110030; PMCID: PMC6526393.

案例—实施研究问题：实施结果

可接受度
Acceptability

实施者(例如管理人员和服务人员)和目标人群对干预措施的认同度？
健康问题或干预措施对目标人群的重要性？

采用
Adoption

关键利益相关方(如管理人员、医疗保健服务人员、目标人群)将在多大程度上决定尝试新的干预措施？

适应 (Adaptation)

在多大程度上实施干预措施以及如何实施会根据实施过程中的学习而改变？

相关性 (Relevance)

实施者或目标人群在多大程度上相信干预措施与他们的现实条件相关？

可行性 (Feasibility)

实施组织或目标人群能在多大程度上实施非传染性疾病的干预措施？

忠实度 (Fidelity)

干预措施能按照原本设计实施到什么程度(例如合适的工作人员、培训、强度和实施的一致性)？

成本 (Cost)

干预措施成本是多少？不同环境下的成本差异？能否在不影响实施效果的情况下降低成本？

覆盖面 (Coverage)

干预措施的目标人群是否真的进行了干预措施？为什么没有呢？如何扩大项目规模？

可持续 (Sustainability)

干预措施的可持续性(例如组织、社会、经济、政治、技术等方面)？

四、实施研究产生的理论、框架和模型

2.

改变的理论

Theory of Change

它解释了（活动）对（投入）的使用如何产生一组（产出和结果），从而为产生（影响）奠定了基础。 It is an explanation of how the use of (inputs) by (activities) produce a group of (outputs and outcomes) that sets the stage for producing (impact).



理论，模型和框架

Theory, model and framework

A theory is "a coherent and non-contradictory set of statements, concepts or ideas that organizes, predicts and explains phenomena, events, behaviour, etc.
理论是“一个连贯且矛盾的概念或思想体系，用于组织、预测和解释现象、事件、行为等。”

——Bem S and Looren-de-Jong H, 1997

Models are specific and attempts to objectify the concept they represent - has value even if not complete
模型是具体的，旨在客观呈现其所代表的概念。

——Frnkfort-Nachmias et al, 1996

A framework provides a frame of reference, assists in organizing thinking and guides the user on what to focus on.
框架提供了一个参考体系，帮助理清思路，并引导使用者关注关键点。

——Rycroft-Malone and Bucknall, 2010

理论、模型和框架的不同之处

Differences of theory, model and framework

理论 Theory



- “理论”为理解、解释和预测现象提供了一种系统的方法。在实施科学的情境下，“理论”通常解释了某些因素为什么以及如何影响实施结果。
- 例如：创新扩散理论，NPT

模型 Model



- 实施科学中的“模型”更具描述性，通常旨在表示实施中涉及的过程，而不是提供深入的解释，“模型”倾向于制定实施所需的步骤或阶段。
- 例如：COM-B，创新扩散理论

框架 Framework



- 框架对与实施相关的概念或因素进行分类和组织，而不一定指定它们之间的关系。框架通常用于指导对实施决定因素、策略或结果的识别和分析。
- 例如：CFIR、RE-AIM

改变理论

Theory of Change – 从传统项目管理路径出发

投入 (input)

- Materials
- Trainers
- Participants

活动 (Activity)

- Conduct training
- Followup

产出 (Output)

- # of Participants trained
- # of workshops

结果 (Outcome)

- Capable participants to apply M&E techniques

效果 (Impact)

- Better decisions

实施科学中所使用的理论，模型和框架

各种模型（框架）
的目标

I
描述或者指导
研究过程

II
理解或者解释什么
因素影响实施结果

各种模型（框架）
的主要特点

过程模型

- K2A（知识到行动模型）
- Dynamic Adaption Process
- Dynamic sustainability
- -----

决定因素框架

- CFIR
- TDF
- iPARiHS
- -----

经典理论

- Theory of Diffusion
- -----

实施科学理论

- Implementation Science
- -----

实施科学理论

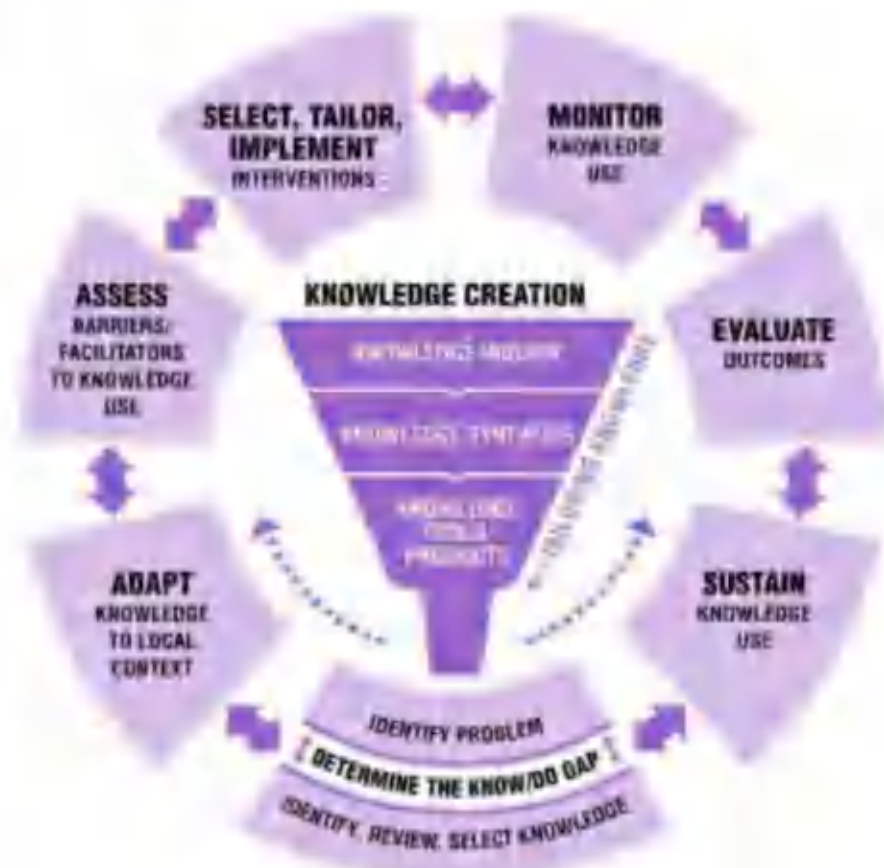
- Implementation Science
- -----

I- 过程模型 Process Model

■ 案例：Knowledge-to-action Framework

从知识到行动包括7个步骤

1. 确定问题/选择解决问题的知识
2. 将证据引入特定情境 (adapt)
3. 评估证据本身、潜在采纳者、实施环境的促进和阻碍因素
4. 执行干预措施
5. 监测知识应用
6. 知识应用后结果评价
7. 维持知识应用



Knowledge-to-action Framework (Graham et al., 2006). Used with permission.

• <https://rnap.ca/leading-change-toolkit/knowledge-to-action>

• **The Knowledge to Action Framework.** From Graham I, Logan J, Harrison M, Strauss S, Tetroe J, Caswell W, Robinson N: Lost in knowledge translation: time for a map? *The Journal of Continuing Education in the Health Professions* 2006, 26, p. 19. Reprinted with permission from John Wiley and Sons

Use of "The Knowledge-to-Action Framework" for the implementation of evidence-based nursing in child and family care: Study protocol

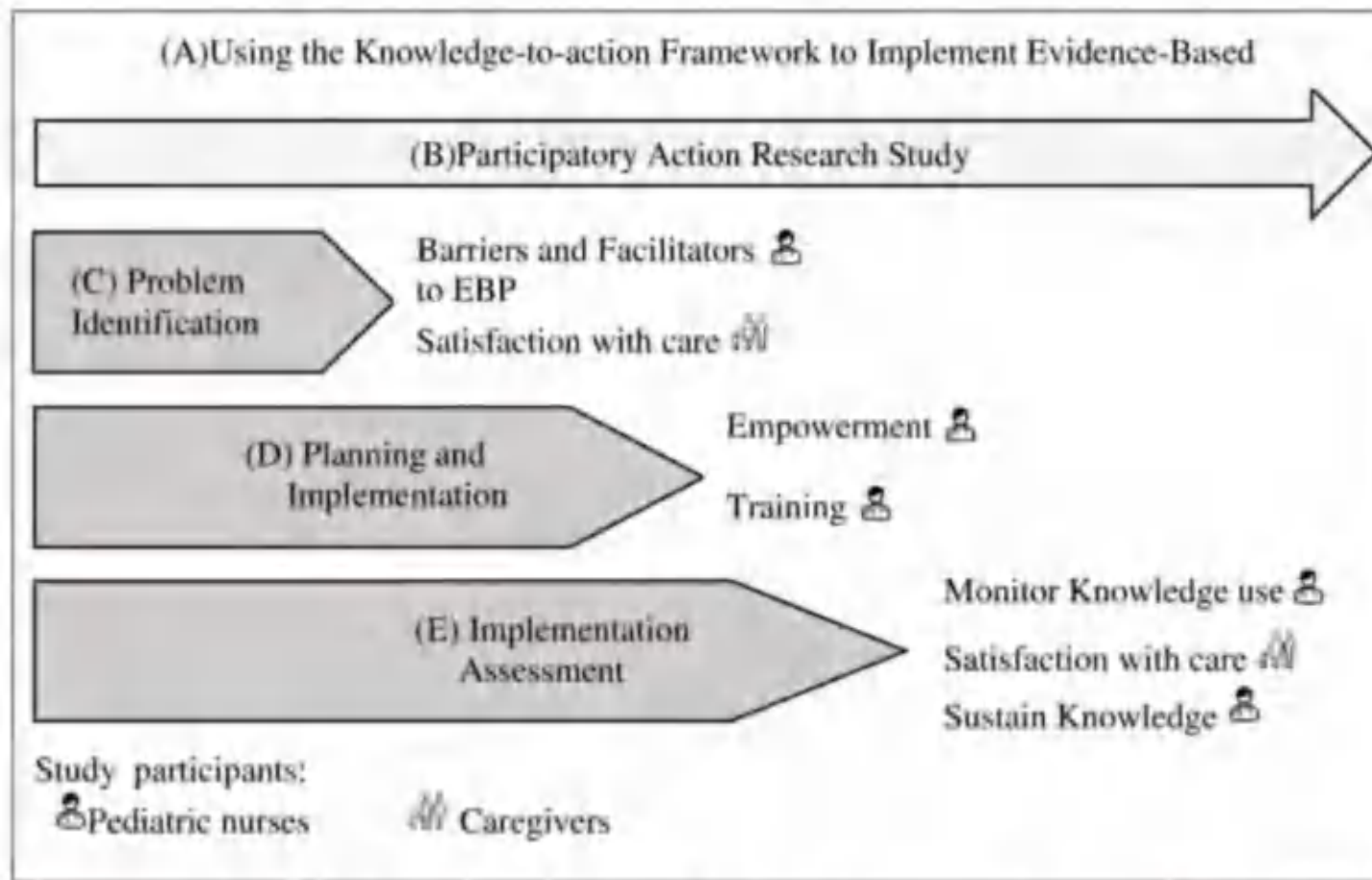


Fig 2. Research design [13, 23, 24]. (A) Research topic. (B) Methodology. (C) Phase 1 of the research. (D) Phase 2 of the research. (E) Phase 3 of the research. (F) Study I, Phase 1 of the research. (G) Study II, Phase 1 of the research. (H) Study III, Phase 2 of the research. (I) Study IV, Phase 3 of the research.

Torres CP, Mendes FJ, Barbieri-Figueiredo M (2023) Use of "The Knowledge-to-Action Framework" for the implementation of evidence-based nursing in child and family care: Study protocol. PLoS ONE 18(3): e0283656. <https://doi.org/10.1371/journal.pone.0283656>

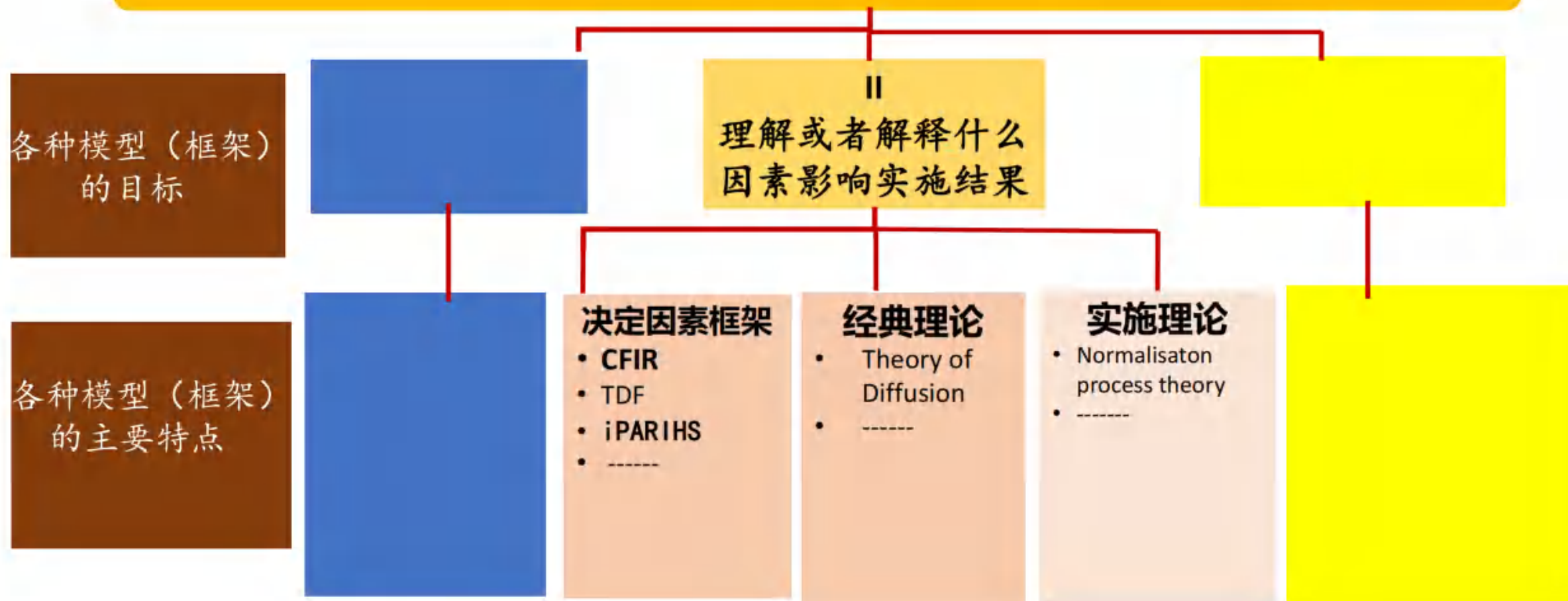
ion Framework"
evidence-based
e: Study

rbieri-Figueiredo^{1,2,5}

orto, Portugal, 2 Center for Health
CINTESIS@RISE), Porto, Portugal,
Porto, Portugal, 4 Nursing School of
University of Huelva, Huelva, Spain

scientific knowledge. However, it is

实施科学中所使用的理论，模型和框架

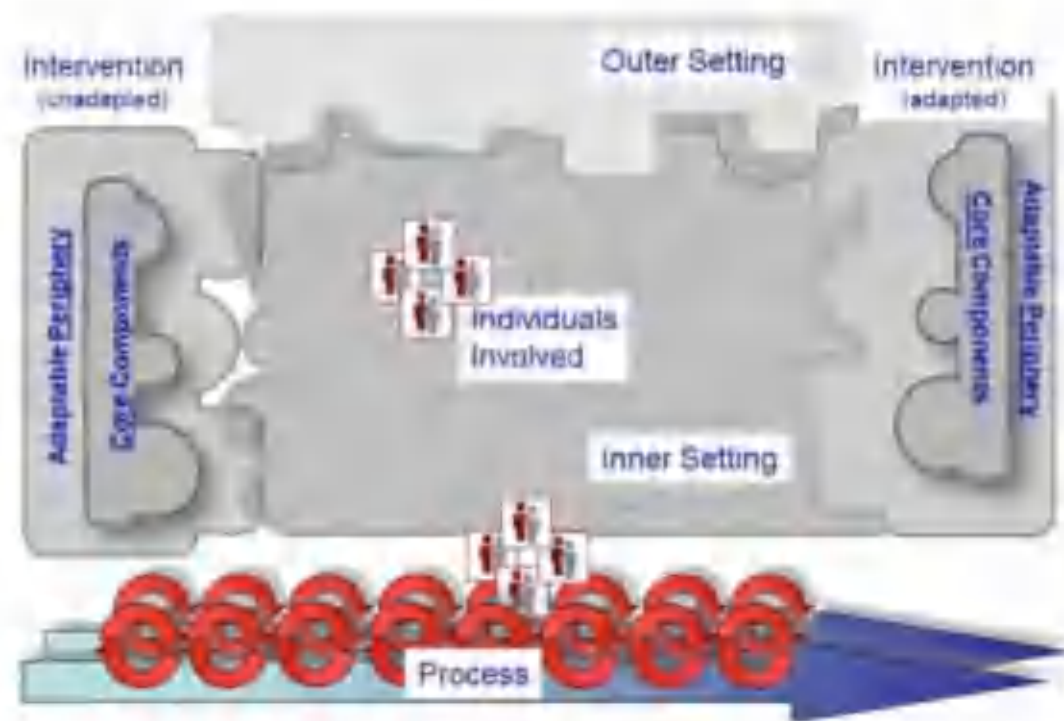


II-1 决定因素框架 (1)

(Determinant frameworks)

Consolidated Framework for Implementation Research (CFIR)

- 2009年Damschroder等人回顾了500余篇实施性研究文献，查找和筛选出设计传播、创新、组织变革、实施、知识转化和应用研究等方面的19个理论与模式，通过这些现存理论或模式中的结构进行提取和分析，整合出CFIR框架（meta-theoretical framework）
- CFIR框架包含5个主要维度及39个构成要素
 - 干预特征 (intervention characteristics)
 - 外部因素 (outer setting)
 - 内部因素 (inner setting)
 - 个体特征 (Characteristics of individuals)
 - 实施过程 (process)



CFIR应用：高血压、糖尿病级联效应项目研究

识别影响因素+构建实施策略

共同设计 (Co-design)：共创工作坊

基于CFIR
识别影响因素

使用CFIR-ERIC工具
识别潜在策略

策略匹配结果
本土化

实施策略共创
1 清单评估

实施策略共创
2 焦点小组共识构建

根据级联不同阶段：
意识、筛查、诊断、
治疗、长期管理等

对CFIR的五大维度
进行匹配：

- 干预特征
- 外部因素
- 内部因素
- 个人特征
- 过程



CFIR障碍

匹配

ERIC策略

构建

候选策略库

参与的利益相关者：

- 干预提供者9人
- 政策制定者3人
- 慢病专家6人
- 技术合作方6人

对候选策略库进行独立评估

双维度：重要性、可行性

5级Likert评分

农村本土化原则：

- 低成本
- 低技术依赖
- 文化适配

共创工作坊

河南舞钢

河南巩义

山东临朐

第一轮：使用优先级矩阵将实施策略
条目归类至四个象限

(重要性vs可行性)



第二轮：对争议策略进行加权评分

争议策略：跨象限 ≥ 2 组

权重：

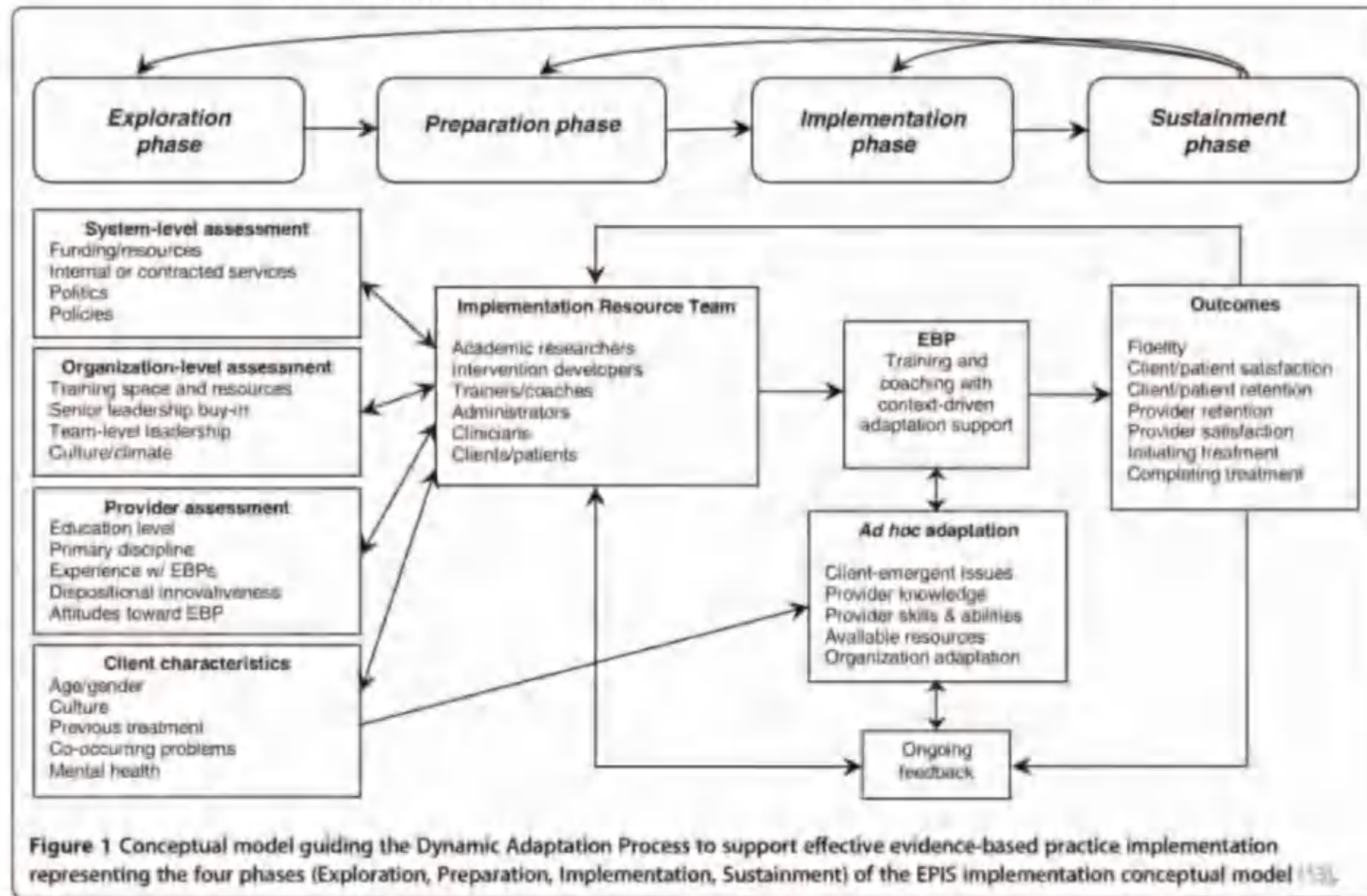
村医实践经验占40%

专家证据强度占30%

技术可行性占30%

[1] <https://cfirguide.org>

I-Process Model · 动态实施过程



Aarons, G.A., Green, A.E., Paolinkas, L.A. et al. Dynamic adaptation process to implement an evidence-based child maltreatment intervention. *Implementation Sci* 7, 32 (2012). <https://doi.org/10.1186/1748-5908-7-32>

II-1 決定因素框架 (2)

(Determinant frameworks)

Theoretical Domains Framework (TDF)

- Developed on the basis of a synthesis of 128 constructs related to behavior change found in 33 behavior change theories
- Sort into 14 theoretical domains

Social influences
Environmental context and resources
Social professional role and identity
Beliefs about capabilities
Optimism
Intentions
Goals
Beliefs about consequences
Reinforcement
Emotion
Knowledge
Cognitive and interpersonal skills
Memory, attention and decision processes
Behavioural regulation
Physical skills



实施因素框架——指导影响因素分析



Structure of Behaviour

TDF Domains

Cap - Skills, knowledge
 Eff - Effectiveness, Commit, and Resources
 Int - Social Norms, Social and Identity
 Soc Cap - Networks and Capabilities
 Gsk - Capabilities
 Int - Environment
 Know - Cognition
 Nat Eats - Beliefs about Environmental
 Health - Health-related
 Em - Emotions
 Norms - Norms
 Cog - Cognition and knowledge about
 Beh - Beliefs, Attitudes, and Decision Processes
 Soc Norm - Beliefs and Norms
 Phys - Physical ability

Diagram Labels:

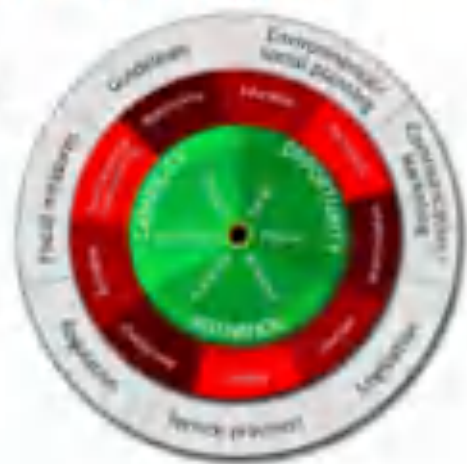
- Capability (Top Left)
- Opportunity (Top Right)
- Motivation (Bottom)
- PULL (Center)

实施模型——解释实施因素间的关系

COM-B为BCW核心

Source of behavior
Intervention functions
Policy categories

行为改变轮
(Behavior change wheel, BCW)



COM-B为BCW核心

行为改变轮
(Behavior change wheel, BCW)

COM-B 与Theoretical Domains Framework

综合应用案例

SHORT REPORT

Open Access

探索COM-B模型和理论领域框架（TDF）在定义助产护理循证实践的促进因素和障碍方面的应用

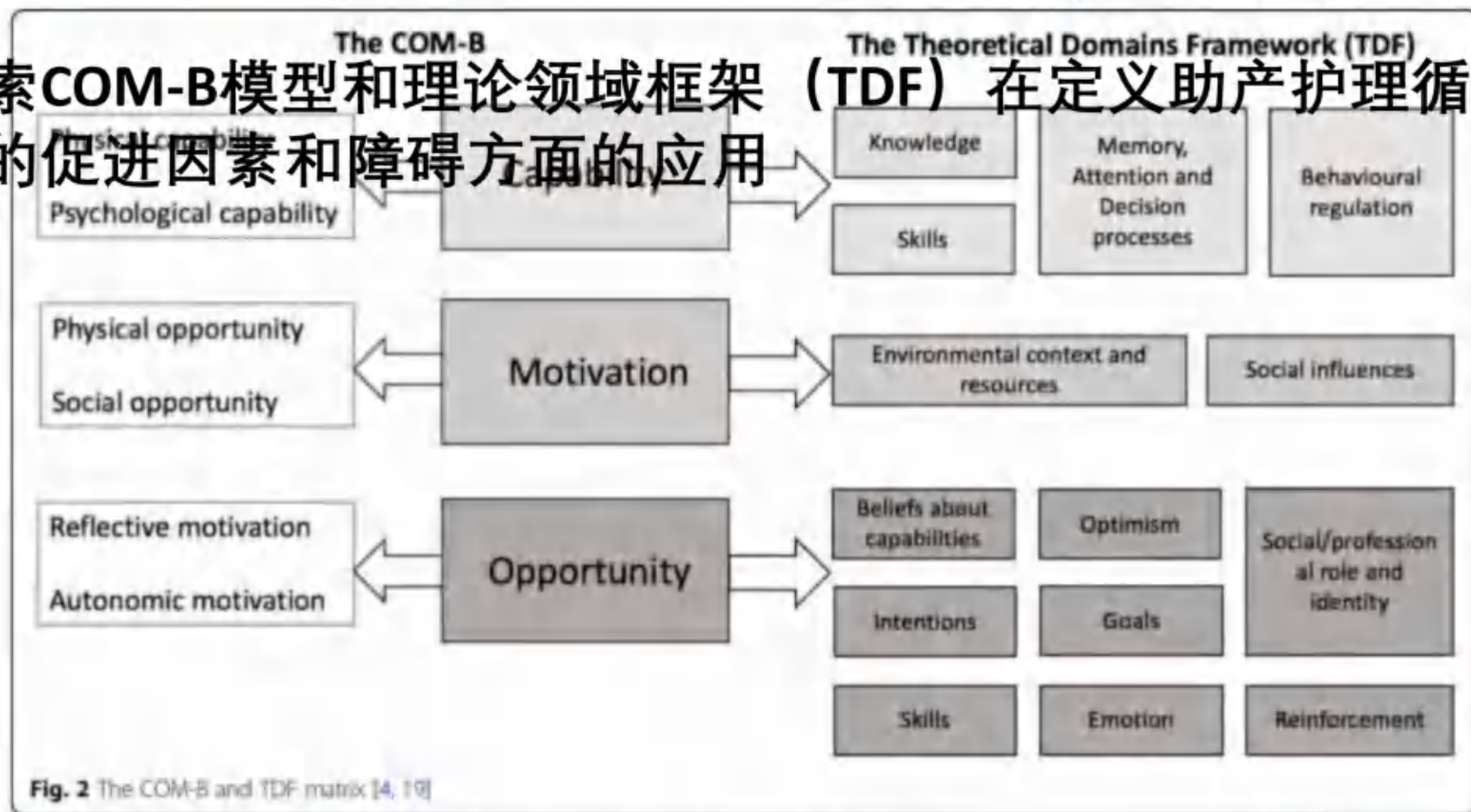


Fig. 2 The COM-B and TDF matrix [4, 19]

valuable insight into the barriers to and enablers to evidence-based practice in midwifery.

Conclusion: Midwives are motivated to integrate evidence-based change yet have limited knowledge of

.1186/s43058-020-00100-x

II-2、经典理论 Classic theories

参考心理学、社会学、组织学等传统学科的经典理论，通常用于解释而不指导变化的发生

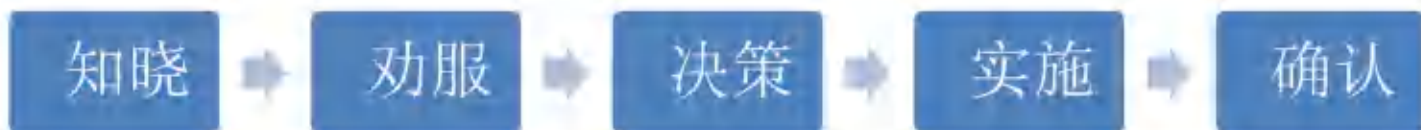
1. 心理行为改变理论 Psychological behavior change theories”
 - Theory of reasoned action
 - Social cognitive theory
 - Theory of planned behavior
2. 社会科学理论 Social science theories
 - Social network, social capital
3. 组织层面的理论 Organizational level theories
4. 扩散理论 Theory of Diffusion

II-2、经典理论

Theory of diffusion



Source: Diffusion of Innovation, Rogers 1995



当创新具有如下特征时，它们会被更快地采用：

1. 创新者(敢于冒险者，占比2.5%);
2. 早期采用者(adopters)(受人尊敬者，占比13.5%);
3. 早期大众(深思熟虑者，占比34%);
4. 后期大众(多疑者，占比34%);
5. 落后者(传统者，占比16%)

- (1) 相对优势性(和现有的方法相比有相对优势);
- (2) 相容性(与现有的价值观、过去的经验以及当前的需求相容);
- (3) 易懂性(简单易懂);
- (4) 可试性(可以被潜在采用者尝试或使用);
- (5) 可观察性(采用者可以看到结果)。

消费者电子健康创新

A consumer e-health innovation

RESEARCH ARTICLE

Open Access

Using diffusion of innovation theory to understand the factors impacting patient acceptance and use of consumer e-health innovations: a case study in a primary care clinic

Xiaoqin Zhang¹, Ping Yu^{1*}, Jun Yan¹ and Li Tong A-Mi Spil²

Abstract

Background: Consumer e-Health is a potential solution to the problem of accessibility, quality and time of receiving public healthcare services to patients. Although consumer e-health has proliferated in recent years, it remains unclear if patients are willing and able to accept and use this new and rapidly developing technology. Therefore, the aim of this research is to study the factors influencing patients' acceptance and usage of consumer e-health innovations.

Methods: A single but typical consumer e-health innovation – an E-symptom checker including decision tree – was developed and implemented in a primary health care clinic in a regional town in Australia. A longitudinal case study was undertaken for 24 months after system implementation. The major factors influencing patients' acceptance and use of the e-symptom checker were examined through the application of Rogers' innovation diffusion theory. Data were collected from the computer log records of 3341 patients who visited the medical centre of our urban study centre, and from a short questionnaire with 25 patients.

Zhang, X., Yu, P., Yan, J. et al. Using diffusion of innovation theory to understand the factors impacting patient acceptance and use of consumer e-health innovations: a case study in a primary care clinic. *BMC Health Serv Res* 15, 71 (2015). <https://doi.org/10.1186/s12913-015-0726-2>

研究表明，医疗保健提供者在实施更复杂的消费者电子健康创新之前需要考虑并解决已确定的因素

II-3 实施理论

Implementation theory

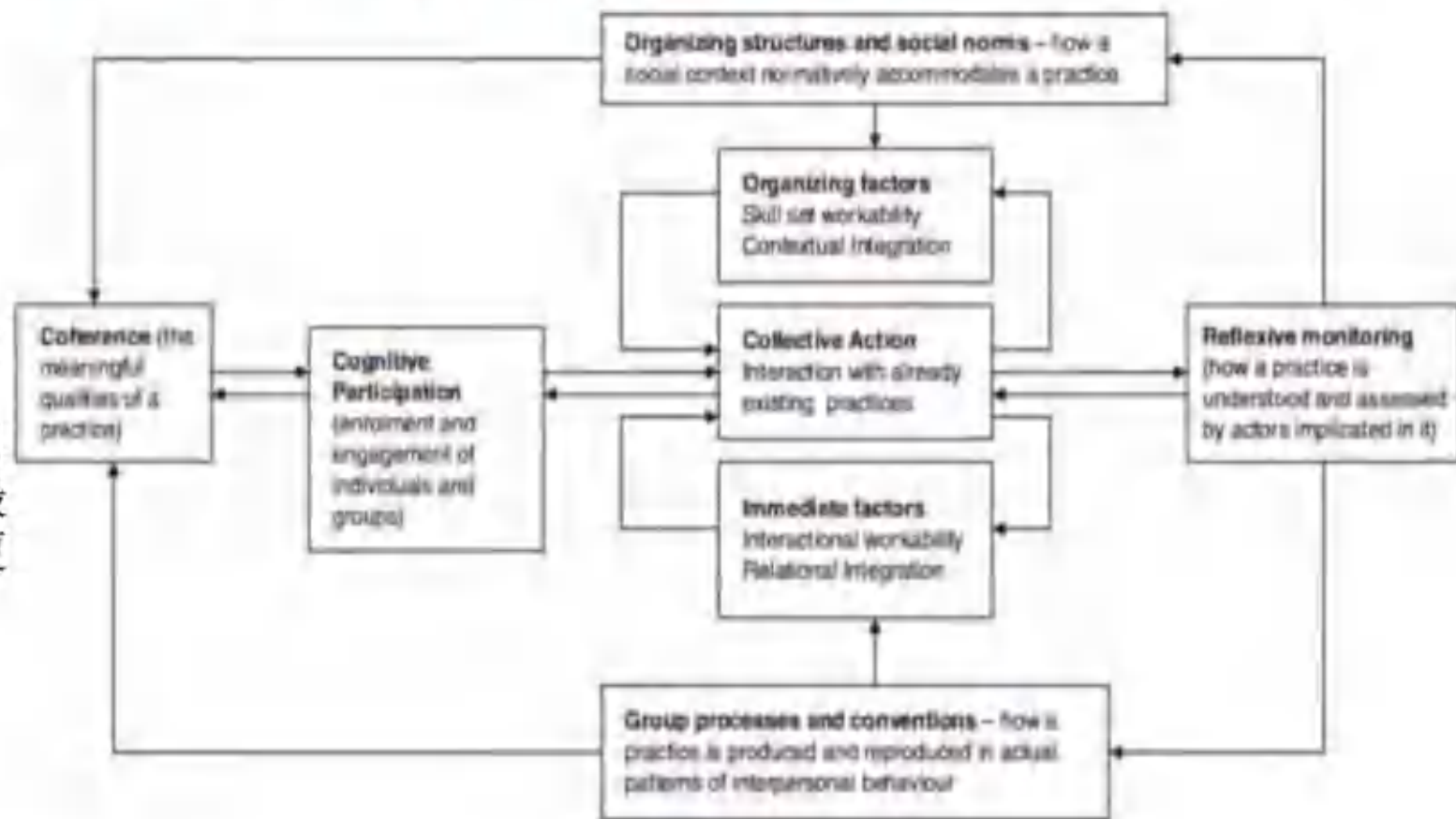
常态化理论 Normalisation process theory

实施临床实践指南的理论经历了三个发展阶段

- 认识到常态化（嵌入）过程的重要性
- 开发常态化过程模型
- 到2009年形成包含4个实施机制的理论

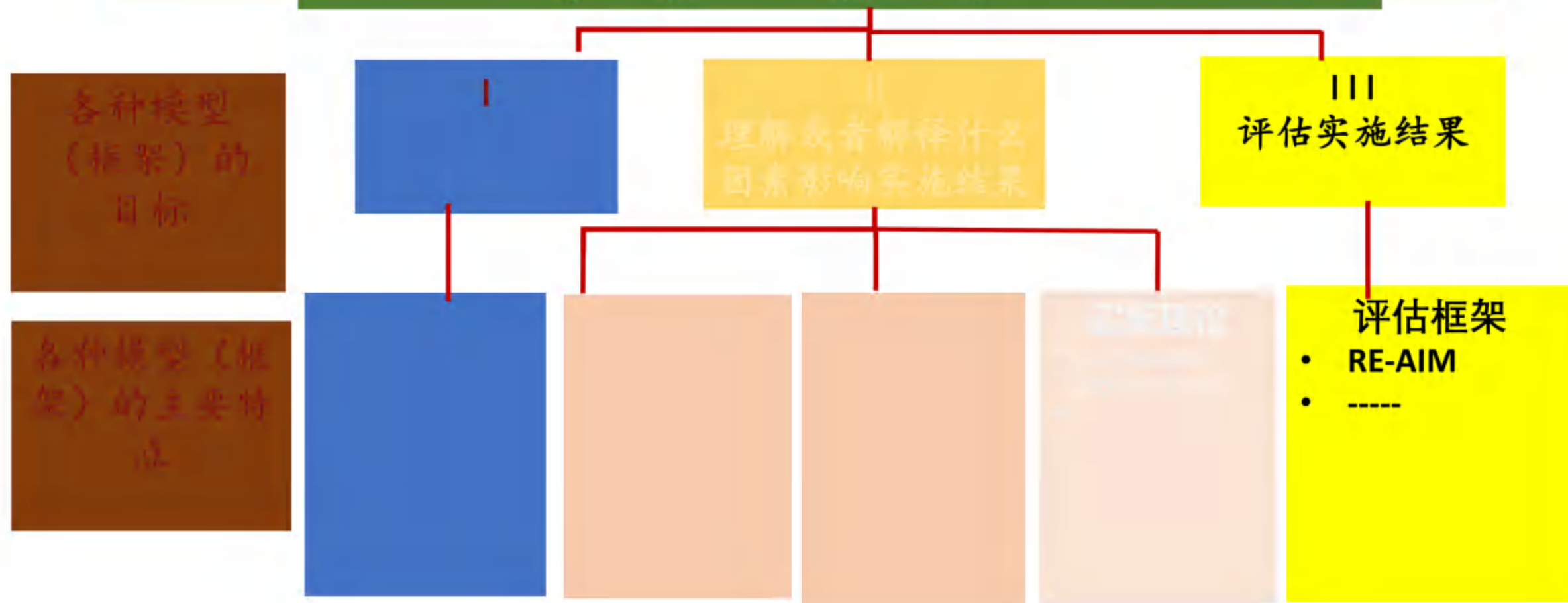
NPT强调，新技术的实施会冲击并改变原有工作模式和社会关系，而新技术能否最终得以常态化，又取决于其是否能适应更新后的工作模式和社会关系。

- <http://normalizationprocess.org/>



Murray, E., Treweek, S., Pope, C. *et al.* Normalisation process theory: a framework for developing, evaluating and implementing complex interventions. *BMC Med* 8, 63 (2010). <https://doi.org/10.1186/1741-7015-8-63>

实施科学中所使用的理论，模型和框架



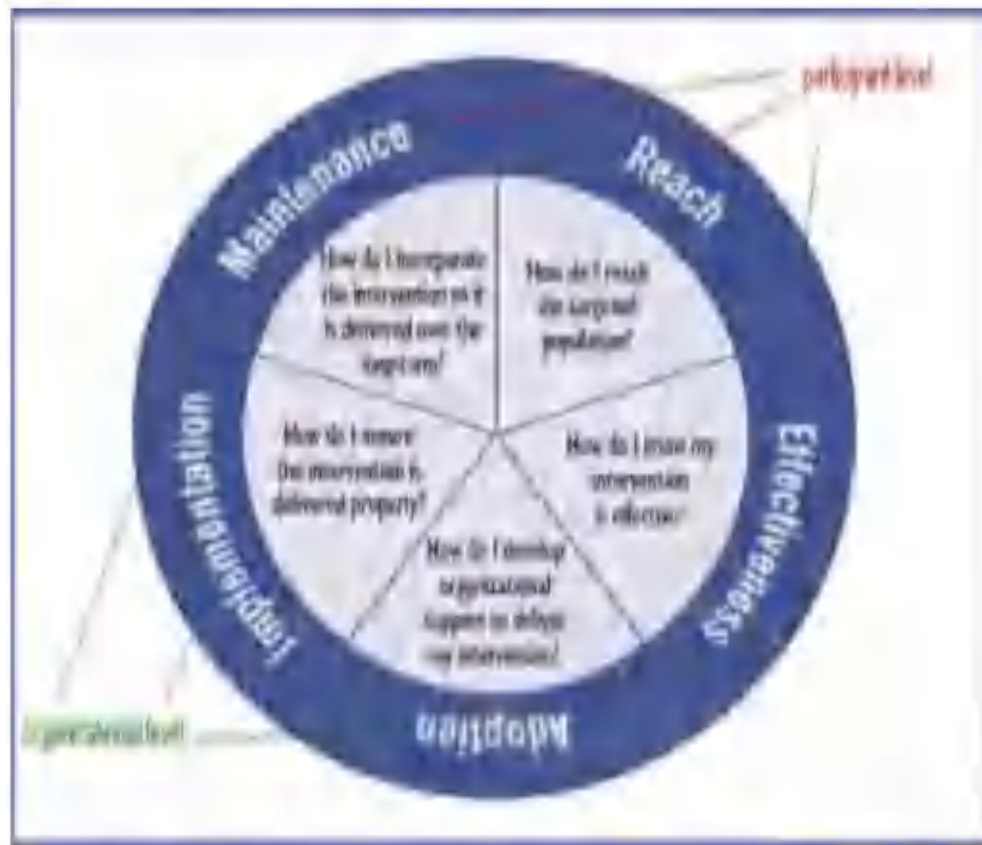
III 评估实施结果

案例：RE-AIM

RE-AIM

RE-AIM是由五个要素组成的首字母缩写

- **Reach**-如何选择干预人群
- **Efficacy or effectiveness**-如何检验干预措施的有效性
- **Adoption**-如何保证干预措施在目标场所或相关机构中被采纳和支持
- **Implementation**-如何保证干预措施被恰当地实施
- **Maintenance**-如何保证干预措施的可持续性



Glasgow RE, Harden SM, Gaglio B, Rabin BA, Smith YML, Porter GC, et al. RE-AIM planning and evaluation framework: adapting to new science and practice with a twenty-year review. *Front Public Health*. (2019)7:64.

实施评估框架的应用：北京市学龄儿童校园流感疫苗接种项目质量改进实施评估

研究目的：

1. 基于情境开发的实施策略实施情况如何？
2. 实施的促进和阻碍因素有哪些？
3. 该实施策略能否提高学龄儿童流感疫苗接种率？

干预措施：校园流感疫苗接种

实施策略：多层次质量改进策略

- 体系层面：促进规划与协作
- 学校层面：培训主管校长和校医
- 受众层面：健康教育和提醒

实施评估框架：RE-AIM及常态化过程理论（NPT）



- 覆盖
- 效果
- 采纳
- 实施
- 维持



全面衡量实施^[1]



- 思想认同
- 认知参与
- 集体行动
- 反思性监测

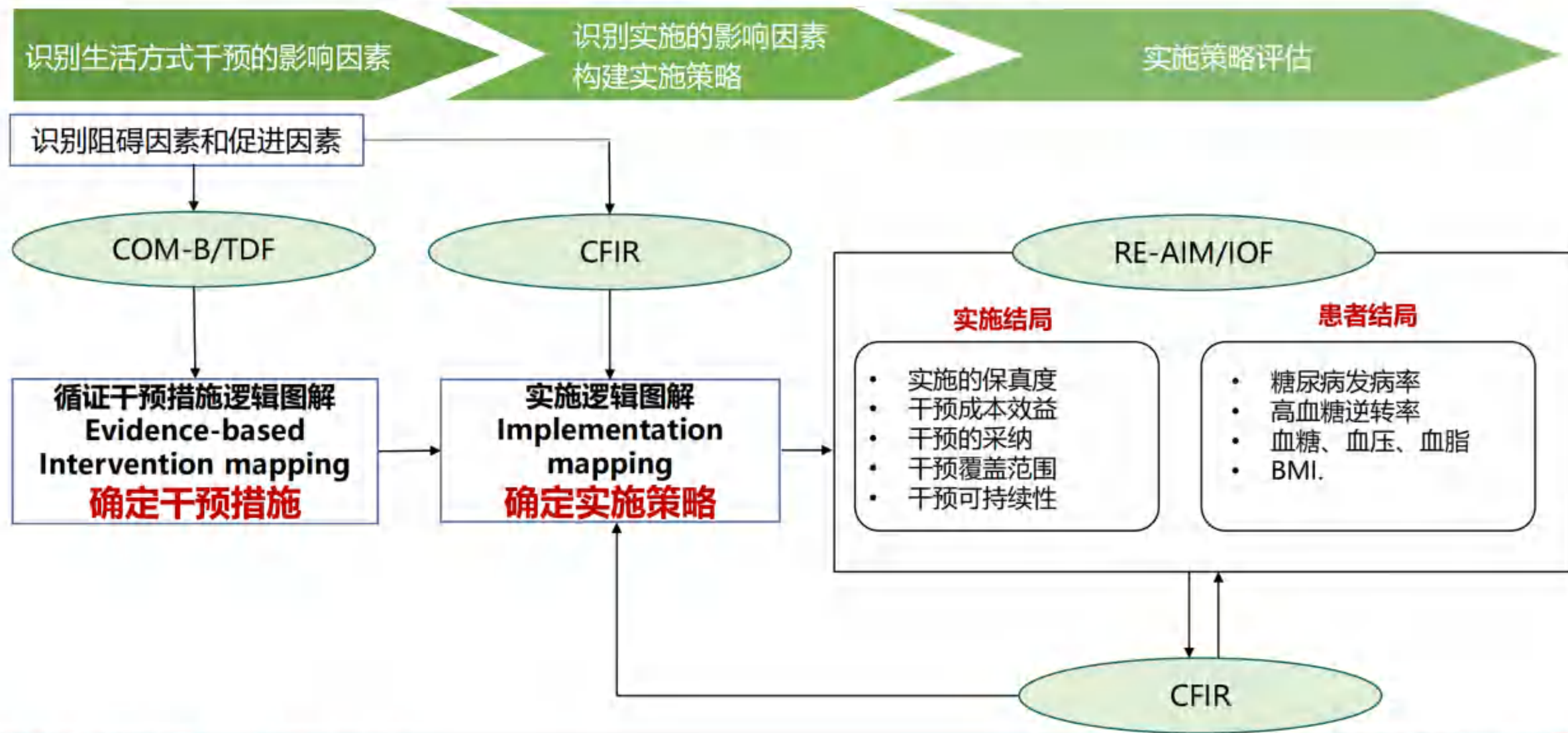


深入了解新实践
整合进常规工作
的动态过程^[2]

[1] <https://re-aim.org/>

[2] Murray E, et al. BMC Med. 2010;8:53.

大庆糖尿病预防研究II期项目



高血压、糖尿病级联效应项目研究 (CHICCs)

Unveiling pathways to enhance hypertension and diabetes care in rural China: a mixed methods study using the care cascade model

识别生活方式

CFIR fra

阻碍因素

CC

干预措施
Interventi

Xuejun Yin^{1,2*}, Zhengzhong Wang³, Jiao Li⁴, Jianxin Ke⁵, Bin Jing⁶, Wenhui Feng⁷, Dinglan Liu⁸, Jingsong Yang⁹, Alon Kessady¹⁰, Dnyk Benari¹¹, Kazuhiko Matsushita¹², Nihal Samraoudagan¹³, Yuxin Li¹⁴, Lijuan Feng^{15,16} and Rutai Shan^{17,18}

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¹⁴State Key Laboratory of Respiratory Health and Multimorbidity, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China

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选择实施研究需要的 理论，框架和模型

如何选择理论、模型、框架？

Sections of the D&I Models Webtool



View All D&I Models

The list of all D&I Models and their characteristics. You can compare up to five models by selecting the check box next to the model name. Additional information on each model can be found by clicking on the Description link under each Model name.

Model	D&I Use	Contextual Prominence	System-Ecological Levels	Field of Impact	Rating
Consolidated Framework for Implementation Research	D=0	4	0-2	Health Services	91
Diffusion of Innovations	D=0	1	0-2	Agriculture	79, 94
Interactive Systems Framework	D=2	2	0-2-3	Veterinary Immunology	113
RE-AIM Framework	D=2	4	0-3	Public Health	728

“Experience without theory is blind, theory without experience is mere intellectual play.”

没有理论的经验是盲目的，没有经验的理论只是智力游戏。

——Immanuel Kant

www.dissemination-implementation.org

如何选择理论、模型、框架

View All D&I Models

The list of all D&I Models and their characteristics. You can compare up to five models by selecting the check box next to the model name. Additional information on each model can be found by clicking on the Description link under each Model name.

Compare Models

Model	D &/or I	Construct Flexibility	Socio-Ecological Levels	Field of Origin	Times Cited	Rating
☐ Consolidated Framework for Implementation Research Description	I-Only	4	Individual Organization Community System Policy	Health services	91	
☐ Diffusion of Innovation Description	D-Only	1	Individual Organization Community System Policy	Agriculture	39,364	
☐ Interactive Systems Framework Description	D=I	2	Individual Organization Community System Policy	Violence prevention	116	
☐ RE-AIM Framework Description	D=I	4	Individual Organization Community System Policy	Public Health	728	

Compare Models Keyboard Full List

Where to
find D&I
models

www.dissemination-implementation.org

五、实施研究逻辑框架

(Logic framework of ImpRes)

逻辑模型

逻辑模型（一般来讲）

Logic Models (in general)

- 展示项目或研究中各个元素之间共享关系的图形描述
A graphic depiction that presents the shared relationships among various elements of a program or study
- 在不同利益相关者之间就 “what” 和 “how” 达成一致
Develop agreement among diverse stakeholders of the "what" and the "how"
- 通过突出理论上的和实际上的差距来改进规划
Improve planning by highlighting theoretical and practical gaps
- 支持制定有意义的过程指标进行跟踪
Support the development of meaningful process indicators for tracking
- 重现成功的研究/识别不成功研究
Reproduce successful studies / identify failures of unsuccessful studies

Petersen, Taylor, & Peikes, 2013

实施科学逻辑框架全图

Implementation Science Logic Model (ISLM) Full Diagram

Completed Hypothetical IRLM

Obesity Management Intervention implemented in Community Health Centers (CHCs)



大庆糖尿病预防II期项目逻辑模型



图 2型糖尿病预防综合干预措施实施的逻辑模型

六、分析和匹配实施策略 (Matching ImpStrategies with ERIC)

选择实施策略

Mapping ImpRes strategy

什么是实施策略

What is implementation strategy?

实施策略是为加强循证干预措施的采用、实施和可持续性而采取的行动。

- 如何使正确的事情得以实施;
- 如何使容易的事情得以实施

Implementation strategies are the actions taken to enhance adoption, implementation, and sustainability of evidence-based interventions.

- How to make the “right thing to do”
- The “easy thing to do”

Address specific factors identified in implementation frameworks

Expert Recommendations for Implementing Change (ERIC)

1. **Lack of conceptual clarity** surrounding terms and definitions for implementation strategies
2. **Insufficient guidance** about how to select appropriate implementation strategies



73 Discrete Implementation Strategies

Definition: Collect and summarize clinical performance data over a specified time period and give it to clinicians and administrators to monitor, evaluate, and modify provider behaviour

[illegible]

CHICCs实施策略构建路径

第一步：基于级联照护模型，开展**定性访谈**，识别各地开展高血压和糖尿病管理的**障碍**

级联阶段	患者层面阻碍因素	卫生服务提供者层面阻碍因素	系统层面阻碍因素
意识	教育文化水平低	卫生服务提供者人力缺乏	健康教育考核缺乏量化细则
筛查	- 无症状，自觉健康 - 心理因素，害怕被诊断及污名化问题 - 社会负担重	- 卫生服务提供者人力缺乏 - 初筛精度较差	- 缺乏针对性适宜的干预措施 - 筛查耗材成本无专项资金支持
诊断	- 无症状，自觉健康 - 不信任基层医疗机构能力 - 认为诊断项目复杂产生的抗拒 - 就诊时患者健康问询等需求未被满足	诊断时间紧张所导致的诊断迅速但不全面	
治疗	- 无症状，自觉健康 - 不良地域饮食习惯与家庭生活方式 - 健康需求未满足 - 心理因素：服药顾虑与恐惧，效果缓慢焦虑等	- 治疗厨房机械重复 - 口头健康指导缺乏具体化与针对性	- 医保政策与医疗机构级别对药品可及性限制 - 分级诊疗缺乏有效衔接
长期管理与控制	- 无症状，自觉健康 - 教育文化水平低 - 电子工具使用障碍与利用率低 - 多病共存状态 - 不健康的生活方式 - 长期治疗的经济负担重 - 心理因素：服药顾虑与恐惧，效果缓慢焦虑等 - 药物使用技能不足与药物调整不及时 - 药物不良反应 - 缺乏有效的随访与提醒	- 疾病病因不明确 - 卫生服务提供者人力缺乏 - 基层医务人员水平较低 - 治疗处方机械重复 - 口头健康指导缺乏具体化与针对性	- 医保政策与医疗机构级别对药品可及性限制 - 分级诊疗缺乏有效衔接 - 人口流动 - 缺少专项资金支持 - 地区经济欠发达

The diagram illustrates the 'Ecosystem of Health Promotion' as a multi-layered system. At the center is 'Individuals Involved'. Surrounding this are four main components: 'Intervention' (top left), 'Outer Setting' (top right), 'Inner Setting' (bottom right), and 'Process' (bottom left). Each component has associated sub-elements:

- Intervention:** Audience, Addressors, Frequency, Intensity.
- Outer Setting:** External Goals & Resources, Time Resources, External Policy & Governance.
- Inner Setting:** Accessibility & Attractiveness, Time resources, Information.
- Process:** Planning, Implementing, Sustaining & Improving, Evaluating/Reflecting/Improving.

Vertical bars on the left and right sides represent 'Audience Engagement' and 'Audience Participation' respectively. The entire system is supported by a base of red circles, with a small group of people icons at the top center.

工作模块	主要任务	技能要求	所需资源	个人素质	过程
项目启动			Assess project feasibility & resources		Project Charter & Business Case
项目规划	Customer Goal		Define Project Activities & Milestones		Project Plan & Schedule
项目执行	Customer Requirements	Project Plan & Schedule	Allocate Resources		Project Plan & Schedule
项目监控	Customer Requirements & Quality	Project Plan & Schedule	Monitor Progress		Project Plan & Schedule
项目收尾	Customer Requirements & Quality	Project Plan & Schedule	Final Review & Closeout		Project Plan & Schedule
项目总结	Customer Requirements & Quality	Project Plan & Schedule	Final Review & Closeout		Project Plan & Schedule
项目评估	Customer Requirements & Quality	Project Plan & Schedule	Final Review & Closeout		Project Plan & Schedule
项目改进	Customer Requirements & Quality	Project Plan & Schedule	Final Review & Closeout		Project Plan & Schedule
项目交付	Customer Requirements & Quality	Project Plan & Schedule	Final Review & Closeout		Project Plan & Schedule
项目维护	Customer Requirements & Quality	Project Plan & Schedule	Final Review & Closeout		Project Plan & Schedule
项目支持	Customer Requirements & Quality	Project Plan & Schedule	Final Review & Closeout		Project Plan & Schedule
项目培训	Customer Requirements & Quality	Project Plan & Schedule	Final Review & Closeout		Project Plan & Schedule
项目推广	Customer Requirements & Quality	Project Plan & Schedule	Final Review & Closeout		Project Plan & Schedule
项目合作	Customer Requirements & Quality	Project Plan & Schedule	Final Review & Closeout		Project Plan & Schedule
项目竞争	Customer Requirements & Quality	Project Plan & Schedule	Final Review & Closeout		Project Plan & Schedule
项目创新	Customer Requirements & Quality	Project Plan & Schedule	Final Review & Closeout		Project Plan & Schedule
项目变革	Customer Requirements & Quality	Project Plan & Schedule	Final Review & Closeout		Project Plan & Schedule
项目重组	Customer Requirements & Quality	Project Plan & Schedule	Final Review & Closeout		Project Plan & Schedule
项目解散	Customer Requirements & Quality	Project Plan & Schedule	Final Review & Closeout		Project Plan & Schedule



- CFIR: 综合性框架, 用于系统性地分析实施的影响因素, 涵盖外部环境、内部环境、干预特征、个体特性和实施过程五个维度

Consolidated Framework of Implementation Research (CFIR)				
外部环境	内部环境	干预对象	干预特点	实施过程
诊断: 诊断: 治疗: 控制: 外部政策因素是否可行	诊断: 缺乏人力和资金支持 诊断: 启动时间有限 治疗: 控制: 缺乏人力和资金支持	诊断: 诊断: 治疗: 控制: 基层医务人员水平有限	诊断: 干预手段难度较高 诊断: 检测项目繁多 治疗: 口头健康指导 控制: 循证不明确	诊断: 缺乏效果考核机制 诊断: 治疗: 分设诊疗缺乏有效衔接 控制:

[illegible]

七、实施研究设计和方法

(Study design and method in ImpRes)

效力 vs. 效果

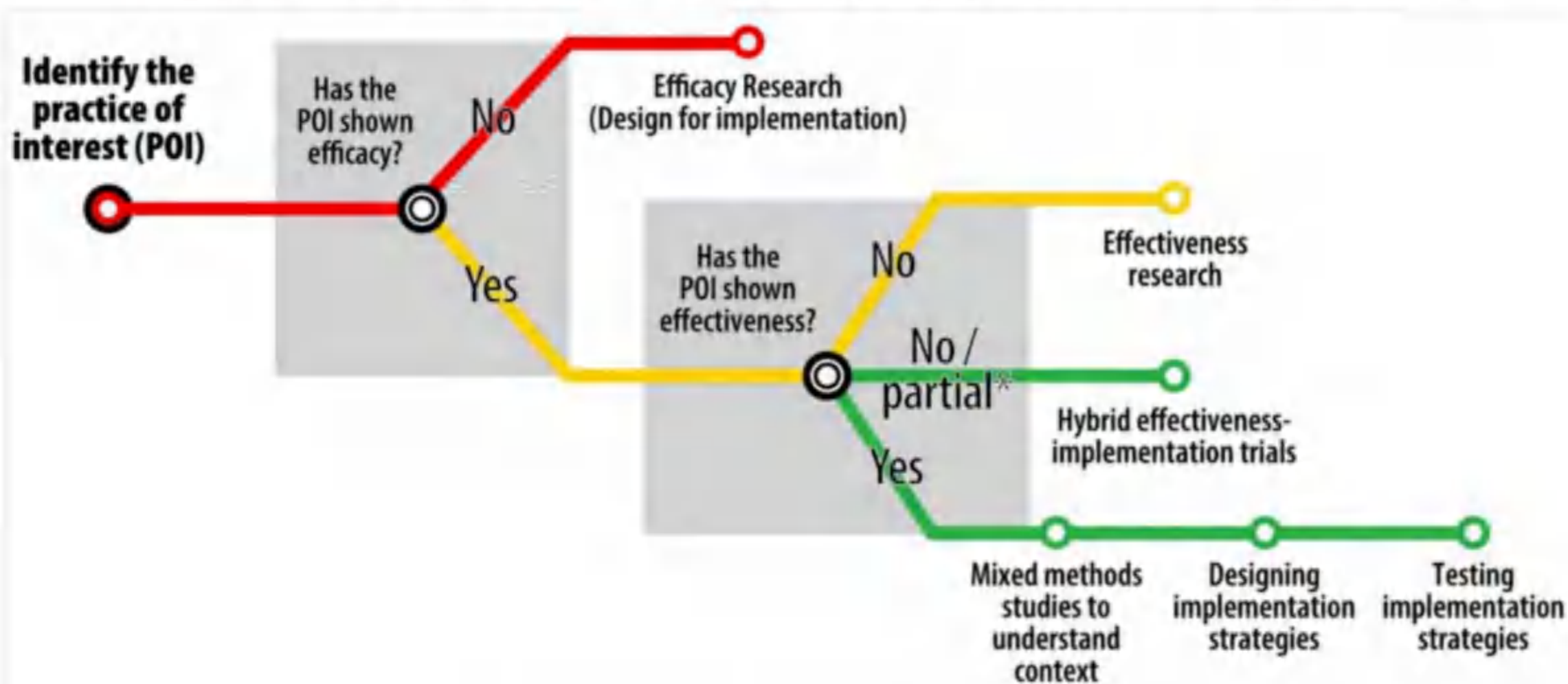
Efficacy study Vs effectiveness study:

Differences between efficacy and effectiveness studies

	Efficacy study	Effectiveness study
Question	Does the intervention work under ideal circumstance?	Does the intervention work in real-world practice?
Setting	Resource-intensive 'ideal setting'	Real-world everyday clinical setting
Study population	Highly selected, homogenous population Several exclusion criteria	Heterogeneous population Few to no exclusion criteria
Providers	Highly experienced and trained	Representative usual providers
Intervention	Strictly enforced and standardized No concurrent interventions	Applied with flexibility Concurrent interventions and cross-over permitted

指导研究人员开展基于证据的干预措施的实施研究示意图

“Subway” schematic to guide researchers contemplating implementation studies of evidence-based interventions



Lane-Fall et al. BMC Medical Research Methodology (2019) 19:133 <https://doi.org/10.1186/s12874-019-0783-z>

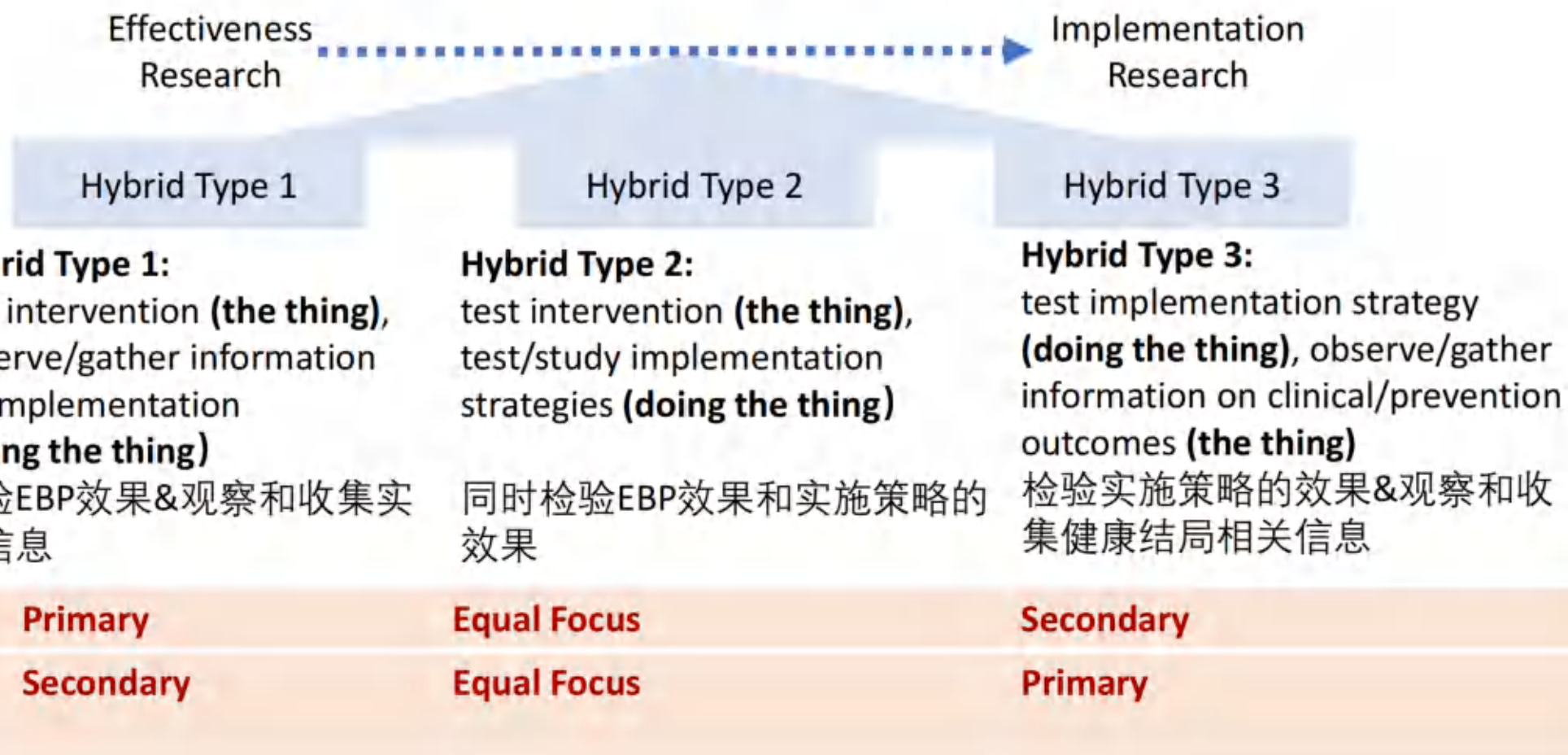
实验、准实验和观察研究设计

研究设计类型	定义	应用	实施科学的例子
实验设计			
Between-site design/ 跨中心间设计	此类设计比较了具有不同暴露情况的中心之间的卫生保健过程和产出。	允许研究者比较具有不同暴露情况的中心之间的卫生保健过程和产出。	Ayieko et al. [13], Finch et al. [14], Kilbourne et al. [15]
Within- and between-site design 中心内和不同中心间的比较设计	此类设计的比较可以通过交叉设计进行, 即研究中心从一个实施条件开始, 然后切换到另一个条件。	接受新的实施策略, 或者在整个研究期间拒绝采用新的实施策略是不符合伦理的。	Smith and Hasan [16] Fuller et al. [17]
准实验设计	Quasi-experimental design		
Within-site design/ 单中心内设计	此类设计研究了暴露于相同传播或实施策略的一个或多个中心随时间变化的情况。	这类单一中心或单一单位(从业人员、临床团队、医疗系统和社区)的研究设计通常与它们自身以往的情况作比较。	Smith et al. [18] Smith et al. [19] Taljaard et al. [20] Yelland et al. [21]
观察性研究	Observational design		
观察性研究(描述性研究)	描述感兴趣的结果及其在自然环境中的前因后果。	用于评估证据在现实世界中的适用性	Harrison et al. [22] Salanitro et al. [23]

实验、准实验和观察研究设计

研究设计类型	定义	应用	实施科学的例子
Configurational comparative methods/ 配置比较方法	将内部案例分析与基于逻辑的跨案例分析相结合，以确定实施等结果的决定因素。	有助于识别多种可能的干预组成部分、实施方式和环境特征的组合，这些组合相互作用而产生效果。	Kahwati et al. [24] Breuer et al. [25]
Simulation studies/ 模拟研究	一种通过描述系统实体及其相互作用的行为规则来模拟复杂系统行为的方法。	提供一种解决方案，用于理解实施的驱动因素以及实施策略可能的影响。	Zimmerman et al. [26] Jenness et al. [27]
Hybrid Type 1/混合 I 型研究	在测试临床干预措施的同时，收集有关其实施情况和/或在实际情境中实施的潜力的信息，重点是评估干预措施的有效性。	提供了探索实施计划未来实施的理想机会。	Lane-Fall et al. [28] Ma et al. [29]
Hybrid Type 2/混合 II 型研究	同时测试临床干预和实施干预/策略。	能够同等强调评估干预措施的有效性、可行性以及/或者实施策略的潜在影响。	Garner et al. [30] Smith et al. [31]
Hybrid Type 3/混合 III 型研究	主要测试实施策略，其次是收集临床干预和相关结局的数据。	当研究人员打算在没有完成完整的有效性研究，甚至有时没有进行适度的有效性研究的情况下进行实施研究时。	Bauer et al. [32] Kilbourne et al. [33]

为什么需要混合设计？



大庆糖尿病预防II期项目：一项复合研究设计

研究步骤

研究问题分解

干预

实施

需求评估

循证生活方式干预措施与现实世界实施糖尿病预防之间存在鸿沟，其关键影响因素是什么？

识别现有循证干预措施在现实世界实施的促进因素与阻碍因素

确定干预措施及实施策略

如何调整让现有的循证干预措施适用于现实世界，什么实施策略可以促进其实施？

筛选出现实世界可行的循证干预措施

促进干预实施

构建多层次实施策略

实施干预措施并开展效果评估与实施评估

综合干预措施的减重效果如何？
不同干预组分的减重效果如何？
开发的实施策略实施效果如何？

开展混合2型研究（Hybrid Type 2 Design）
同时探究综合干预措施和多层次实施策略的效果

评价综合干预措施中不同干预组分的效果

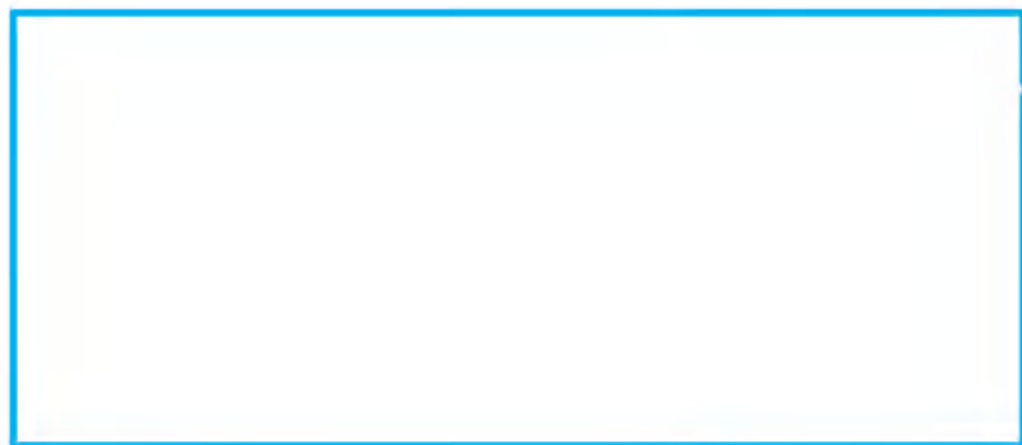
评价多层次实施策略中不同实施策略的效果

确定现实世界实施的有效干预措施及实施策略，弥合证据-实践的差距

八、干预结果与实施效应评估

(Evaluation of the intervention and IR)

实施科学研究的阶段

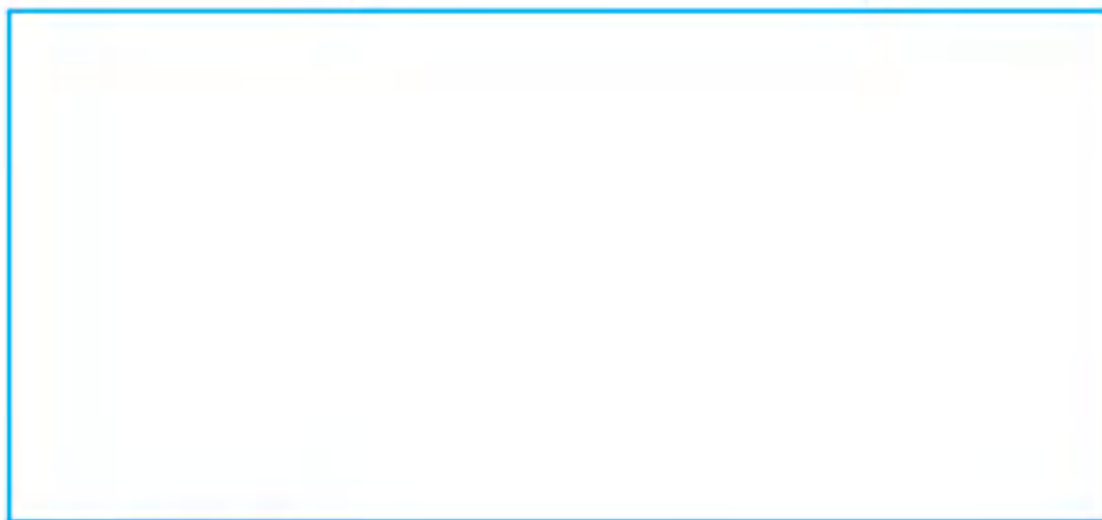


第四阶段

Phase four

过程评估与结果评估：理解变化的原因和健康结局

1. 过程评估：定期收集收集进度数据并反馈
2. 健康结果评估
3. 分析资料
4. 报告过程评估与结果评估结果



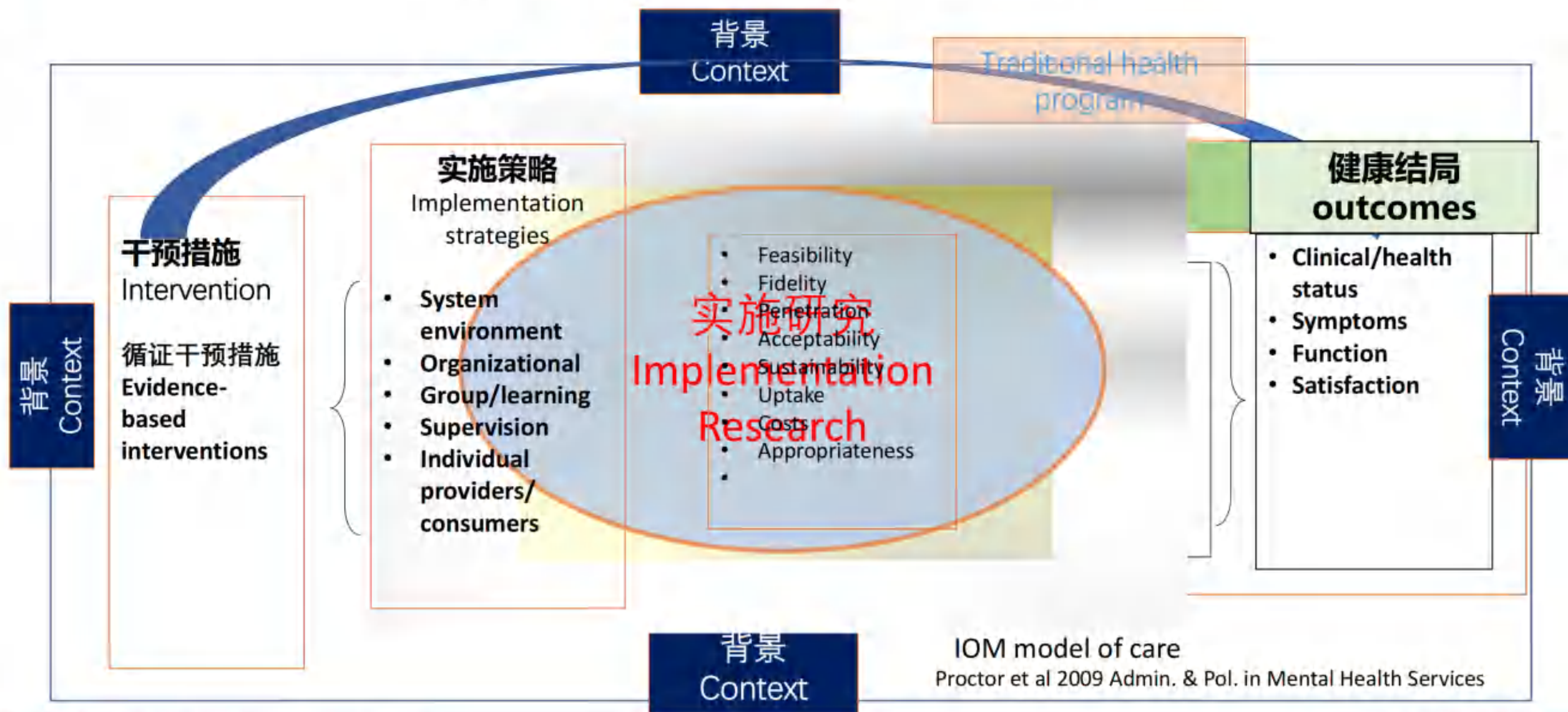
逻辑模型用于评估

A logic model for evaluation



INPUTS	ACTIVITIES	OUTPUTS	Outcomes		
			Short-Term	Medium-Term	Long-Term
What we invest	What we do	Direct products from program activities	Changes in knowledge, skills, attitudes, opinions	Changes in behavior or action that result from participants' new knowledge	Meaningful changes, often in their condition or status in life

干预与实施研究评估概念框架



实施结局

Implementation Outcomes

“We define implementation outcomes as the effects of deliberate and purposive actions to implement new treatments, practices and services.”

- ✓ Indicators of implementation success
- ✓ Proximal indicator of implementation process
- ✓ Intermediate outcomes in relation to service system or clinical outcomes in treatment effectiveness and quality of care research

Implementation outcomes

- Acceptability
- Appropriateness
- Feasibility
- Adoption/Uptake
- Fidelity
- Penetration
- Sustainability
- Costs
- ...



实施结局的选择

Selection of implementation outcomes

Implementation outcome	Unit of analysis	Salience by phase	Data collection approach
可接受性 Acceptability	Individual provider Individual health users (patients)	Early, ongoing	Survey, qualitative or semi-structure interview, administrative data
采纳 Adoption	Individual provider Organization or health setting	Early to mid	Administrative data, observation, qualitative or semi-structured interviews
适当 Appropriateness	Individual provider Individual health user Organization or setting	Early (prior to adoption)	Survey, qualitative or semi-structure interview, focus group
可行 Feasibility	Individual providers Organization or setting	Early (during adoption)	Survey, Administrative data
保真 Fidelity	Individual provider Provider teams (aggregated)	Early, mid, overtime (drift)	Observation, Checklist, self-report
实施成本 Implementation cost	Provider Organization or health setting	Early, mid, late	Administrative data
整合 Penetration	Organization or setting	Mid to Late	Case audit, checklists
可持续 Sustainability	Administrators Organization or setting	Late	Case audit, checklist, questionnaire, semi-structured interviews

实施结局数据收集：混合方法研究

RE-AIM 维度	指标	数据来源	数据类型	数据收集 阶段
覆盖	参与本研究的学龄儿童/家长比例和代表性	招募数据和家长基线调查	定量	实施前
	拒绝参与本研究的原因	利益相关者个人深度访谈	定性	实施后
采纳	采纳多层次质量改进策略的学校数量和比例	工作清单共享文档	定量	实施中
	NPT思想认同：对多层次质量改进策略的理解	校医和班主任随访调查NoMAD工具	定量	实施后
		利益相关者个人深度访谈	定性	实施后
	NPT认知参与：对多层次质量改进策略融入常规的理解	校医和班主任随访调查NoMAD工具	定量	实施后
		利益相关者个人深度访谈	定性	实施后
	依照方案实施多层次质量改进策略的学校数量和比例	工作清单共享文档	定量	实施中
实施	NPT集体行动：实施过程中的工作分配、资源和困难	校医和班主任随访调查NoMAD工具	定量	实施后
		利益相关者个人深度访谈	定性	实施后
	NPT反思性监测：对多层次质量改进策略的调整、评价和反馈	校医和班主任随访调查NoMAD工具	定量	实施后
		利益相关者个人深度访谈	定性	实施后
维持	维持多层次质量改进策略的意愿	校医、班主任和家长随访调查	定量	实施后
	愿意或不愿意维持多层次质量改进策略的原因和改进期望	利益相关者个人深度访谈	定性	实施后
效果	家长报告的2022—2023年流感季学龄儿童是否接种流感疫苗	家长随访调查	定量	实施后

实施结局数据收集方式

SLIV工作清单 共享文档

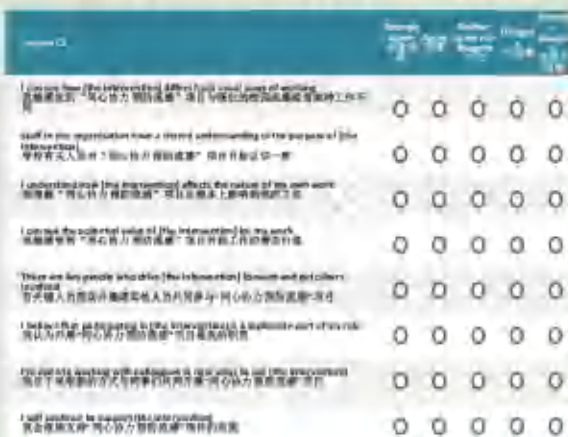
干预过程中 干预组校医填写

- 是否开展相关活动
- 开展相关活动时间
- 开展相关活动照片或截图

学校实施人员 随访调查

干预后 干预组校医、班主任填写

- NoMAD工具（基于NPT开发的定量结构化工具）



The screenshot shows the NoMAD tool interface. It contains a list of statements in English and Chinese, each followed by a Likert scale response option (0 to 4). The statements are:

- I know how (the intervention) differs from usual ways of working.
- I understand how (the intervention) affects the nature of my own work.
- I cannot see the potential value of (the intervention) to my work.
- There are key people who drive (the intervention) forward in my school.
- I believe that (the intervention) is (a) necessary (a) and (b) a good use of my time.
- I am not sure whether my participation is really useful to my school.
- I will continue to support (the intervention).

学龄儿童家长 随访调查

干预后 干预组家长填写

- 对健康教育和提醒活动的评价，包括是否希望以后继续参与活动等

利益相关者个人深度访谈

干预后，区教委相关工作人员，常规组校医 干预组校医、班主任和家长

RE-AIM 维度	NPT 维度	核心问题
范围	-	• 他认为多层次质量改进策略在多大程度上覆盖了目标人群？ • 有部分家长拒绝参与研究，他认为是什么原因？
采纳	思想 认同	• 您如何理解多层次质量改进策略？ • 多层次质量改进策略有哪些主要内容或活动？ • 今年开展的这些活动与往年的常规工作有什么不同？
认知	参与	• 多层次质量改进策略和您本职工作的关系是什么？工作量如何？ • 对推动多层次质量改进策略的实施而言，有哪些关键人物？
实施	集体 行动	• 您和其他人员是如何合作来开展多层次质量改进策略的？ • 您参加了哪些培训，帮助您实施多层次质量改进策略？您觉得自己具备了实施多层次质量改进策略所需的相关能力吗？ • 多层次质量改进策略和您日常工作融合得怎么样？与您自身或现有工作方式哪些方面不契合？ • 实施多层次质量改进策略的过程遇到了哪些困难？如何解决的？
反思	反思	• 多层次质量改进策略的灵活性和可调整性如何？您根据实际情况对哪些活动进行了一些调整？进行了哪些调整？
维持	维持	

基于RE-AIM和NPT构建的访谈提纲

实施科学研究的阶段

1. 确定实施什么以及来源（如指南）
2. 干预措施实施差距或存在问题是什么？科学问题？
3. 评估场境及资料收集方法和工具，评估造成差距的原因（有利因素和不利因素）
4. 选择实施科学的理论或者模型指导实践

现状评估;明确问题以及原因

Phase one

1. 提高项目执行能力(如培训)、调整机构配置与功能
2. 提供必要的基本仪器、工具、指南和其他材料
3. 规律地监督执行和反馈结果。
4. 根据反馈结果调整执行方案

按照研究方案实施干预措施和策略

Phase three

第一阶段

第二阶段

第三阶段

第四阶段

Phase two

实施实施研究方案：筛选干预措施、实施策略以及研究设计

1. 制定实施研究方案
 - ✓ 确定项目目标、确定干预措施、确定实施策略
 - ✓ 确定逻辑框架与路线图
 - ✓ 设计评估方案与资料收集方法：实施研究还是干预结合实施研究？
2. 确定研究项目执行质控方案

Phase four

过程评估与结果评估：理解变化的原因和健康结局

1. 过程评估：定期收集收集进度数据并反馈
2. 健康结果评估
3. 分析资料
4. 报告过程评估与结果评估结果

请批评指正！