# Käyttöönoton tutkimus

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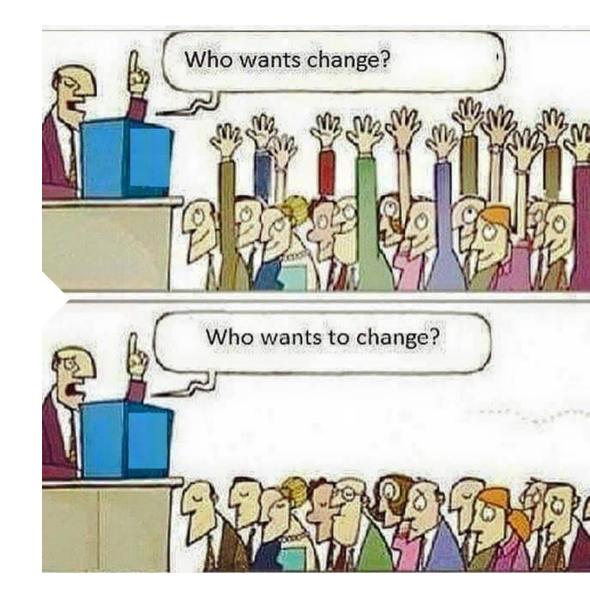
# Mitä on käyttöönoton tutkimus?



Parisod 2019

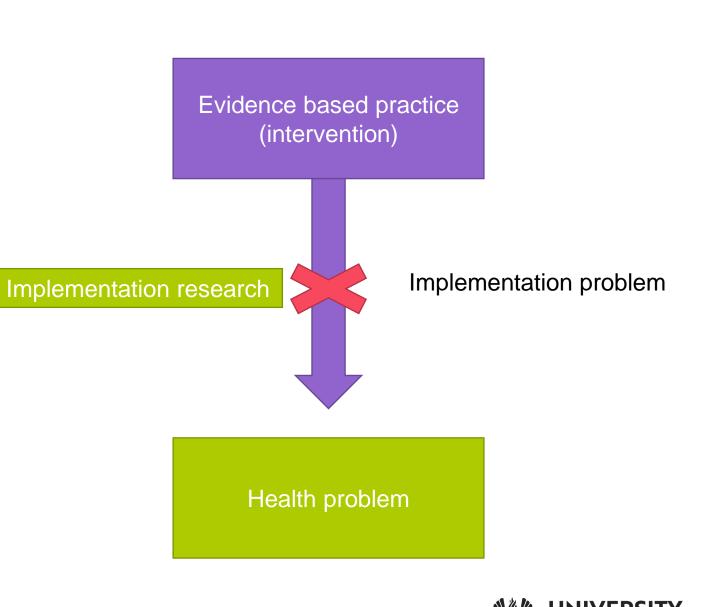
# Implementation science

• "the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services" (Eccles & Mittman, 2006).



# Implementation science

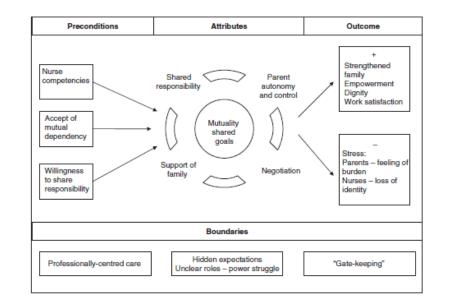
- Health problem e.g., overweight during pregnancy
- Evidence beased practice
- Promlems in the implementation of evidence
- Aims to find solution strategy – to implementation problem



# Why is implementation so difficult?

• We are only human, e.g. parallel with health behaviors *Change is difficult* 

• Many actors and stakeholders in healthcare add to complexity *Change is very difficult* 







# Mikä ero on käyttöönoton tutkimuksella ja kliinisen hoitotyön kehittämisprojektilla?



### Study designs



#### A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance

Kathryn Skivington, <sup>1</sup> Lynsay Matthews, <sup>1</sup> Sharon Anne Simpson, <sup>1</sup> Peter Craig, <sup>1</sup> Janis Baird, <sup>2</sup> Jane M Blazeby, <sup>3</sup> Kathleen Anne Boyd, <sup>4</sup> Neil Craig, <sup>5</sup> David P French, <sup>6</sup> Emma McIntosh, <sup>4</sup> Mark Petticrew, <sup>7</sup> Jo Rycroft-Malone, <sup>8</sup> Martin White, <sup>9</sup> Laurence Moore<sup>1</sup>

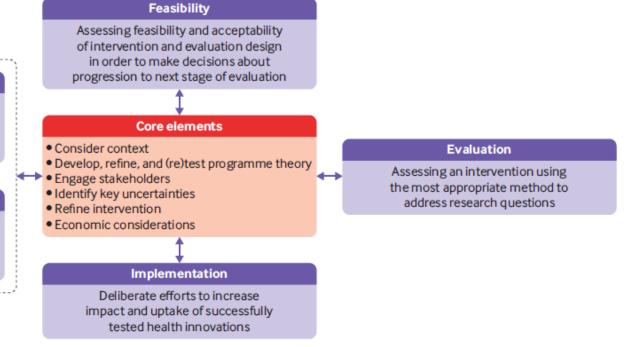
#### **Develop intervention**

Either developing a new intervention, or adapting an existing intervention for a new context, based on research evidence and theory of the problem

#### OR

#### Identify intervention

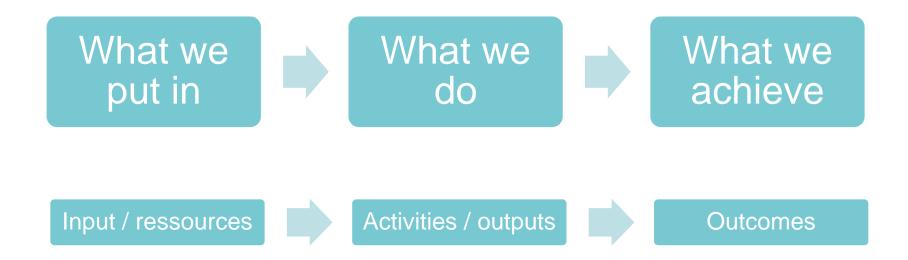
Choosing an intervention that already exists (or is planned), either via policy or practice, and exploring its options for evaluation (evaluability assessment)



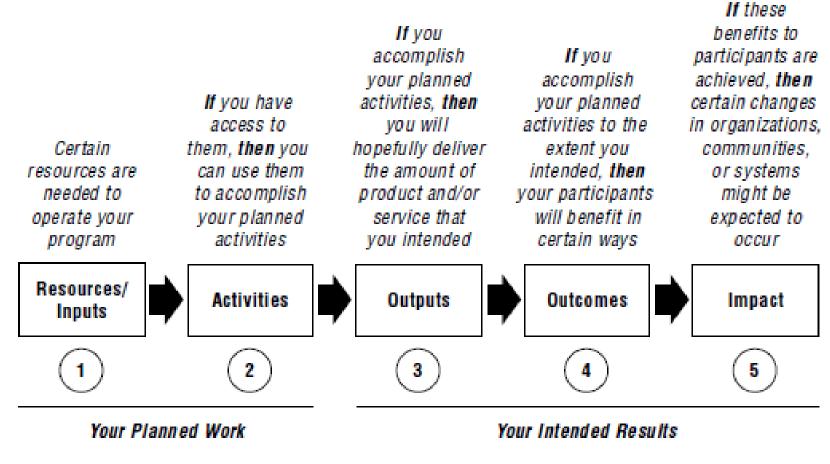


## What is a logic model?

• A chain of logical if-then relationships



### What is a logic model?





W. K. Kellogg Foundation. Logic Model Development Guide. 2004

### **Different approaches to intervention development** (O'Cathain et al. 2019)

- 1. Partnership Coproduction, cocreation, codesign, participatory research
- 2. Target population centered Person based; user centered
- 3. Theory and evidence based MRC Framework
- 4. Implementation based RE-AIM
- 5. Efficiency based Micro randomization trials
- 6. Stepped or phased Five actions model
- 7. Intervention specific Digital (e.g., Integrate, Design, Assess and Share)
- 8. Combination
- 9. Pragmatic

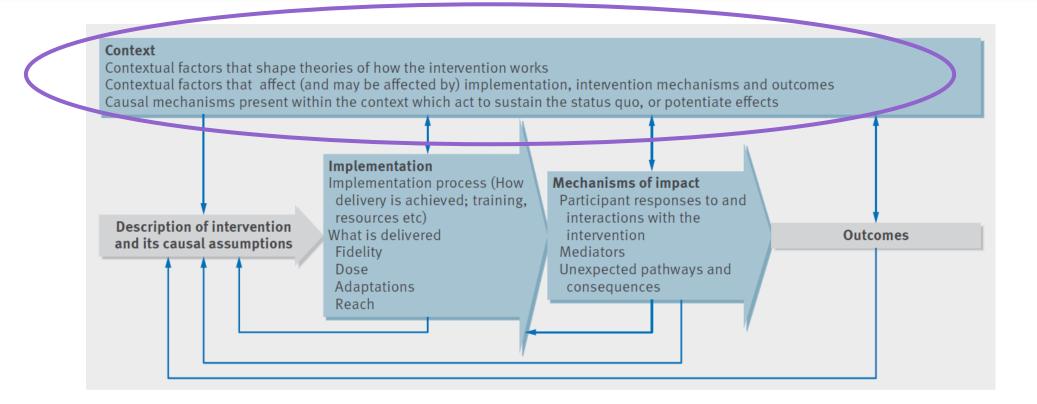


#### Process evaluation framework (Moore ym. 2014)

In addition to the effectiveness studies, it is recommended to evaluate and understand the implementation process of complex interventions. The findings will explain the results of the effectiveness studies and guide implementation processes.

#### Process evaluation aims to understand

- What is implemented and how?
- How does the delivered intervention produce change?
- How does context affect implementation and outcomes?



#### Hybrid effectiveness-implementation designs (Bauer et al. 2015)

- Hybrid Type I test the health impact of an EBP while explicitly collecting data on the implementation process to facilitate subsequent implementation efforts
- Hybrid Type II test both the EBP effects on health outcome and the implementation strategy effects on EBP use
- Hybrid Type III tests the ability of an implementation strategy to enhance use of an EBP while collecting data on health impact of the EBP during implementation
- Design is dependent on research question other designs apply accordingly





# Effective implementation strategy

- Method or technique which assists the sustainable implementation of evidence-based practice in health care
  - Elements: actor, action, object, and dose (who, what, why, how much)
  - Actors are at the different levels of organization
  - Separate or part of intervention
- Actives strategies more effective than passive
- Using several at the same time increases
   effectiveness
  - Simple reminder, teaching material
  - Complex targeted to different levels of organization e.g., SUSTAIN - project
- Expects common actions, process to achieve aim



### **Examples about the taxonomies**

#### Research Unit for Research Utilization taxonomy

- Knowledge provision
- Education
- Social influencing
- Collaboration between researchers and clinicians
- Incentives
- Reinforcement
- Facilitation

Expert Recommendations for Implementing Change

- External funding
- Audit and provide feedback
- Centralize technical assistance
- Change record systems or service cites
- Create new clinical teams
- Identify and prepare champions, early adapters
- Mandate change



### Teorioista ja viitekehyksistä



## Theory helps to understand the successful implementation (Nilsen 2015)



Process models = describe and/or guide the process of translating research into practice



Determinant frameworks = help to understand and explain what influences implementation outcomes

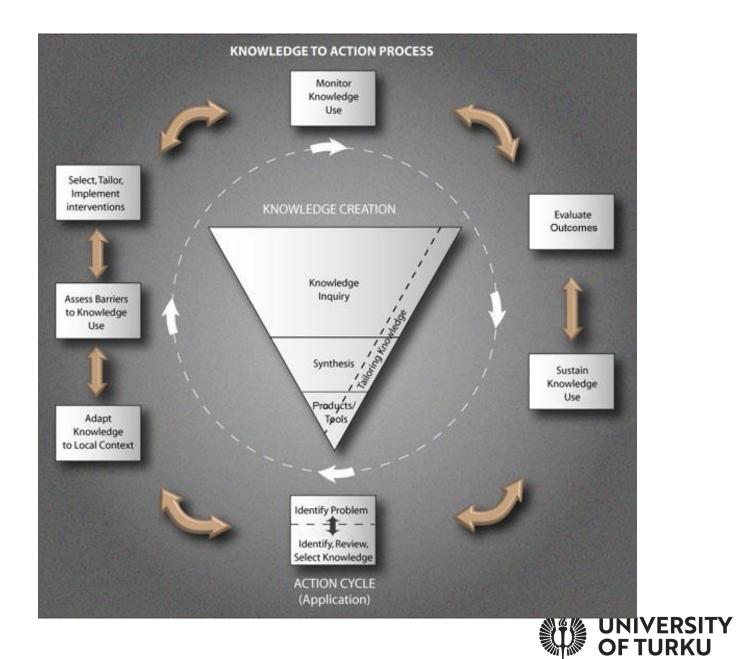


Evaluation frameworks = guide the evaluation of implementation



Theories can guide your process evaluation, research or quality improvement project

#### Process models



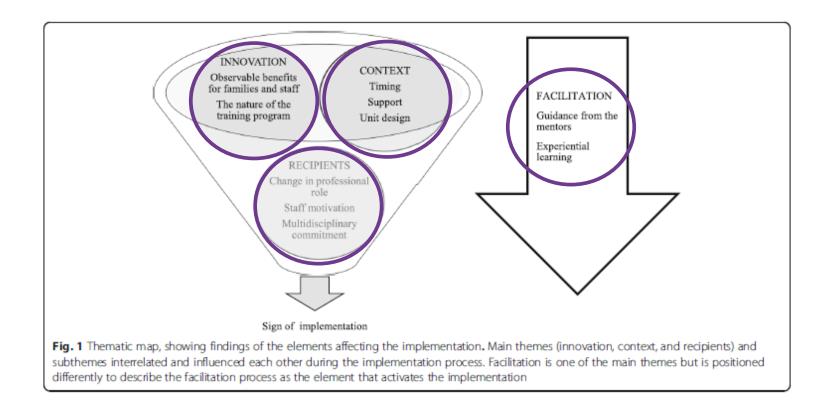
## **Determinant framework** What factors influence on implementation? The Promoting Action on Research Implementation in Health Services (PARiHS) framework (Kitson ym. 1998, 2008, Rycroft-Malone ym. 2013, Harvey G & Kitson A 2016)

## **Factors influencing implementation**

- The successful implementation of Close **Collaboration with Parents Training Program** depends on four interconnected elements (Kitson ym. 1998, 2008, Rycroft-Malone 2013, Harvey & Kitson 2016)
  - Innovation (Training program)
  - Context (Your unit, hospital)
  - Facilitation (Mentor network)
  - Recipients (Staff and families)



#### Key factors supporting implementation of the Close Collaboration of Parents training program (Toivonen et al. 2019)





### **Aim and methods**

- To describe the staff's perceptions of the implementation of the Close Collaboration with Parents Training Program and to identify the barriers and facilitators of the implementation
- Setting: 8 NICUs in Finland
- Group interviews with 32 nurses and with the 19 unit managers (5 doctors, 14 head nurses) were conducted 6 months after the 18-month training

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• Data were analyzed using thematic content analysis

### Innovation

#### A Evidence

	Low	High
Research		
	Anecdotal evidence Descriptive information	Randomised controlled trials Systematic reviews Evidence-based guidelines
Clinical	Low	High
experience	Expert opinion divided Several "camps"	High levels of consensus Consistency of view
	Low	High
Patient		
preferences	Patients not involved	Partnerships



### Käyttöönottoon vaikuttaa innovaation

- Selkeys/ monimutkaisuus
- Relevanssi/ käyttökelpoisuus
- Yhteensopivuus/ muokkautuvuus kliiniseen työhön
- Testattavuus
- Käyttöönoton toteutettavuus esim. resurssit, vaadittavat taidot

#### (Roger's diffusion of innovation)



## Innovation

- The nature of the training program
  - Adaptability
  - Long enough duration, clear structure
  - Theory was applied to practice by bedside mentoring
- Observable benefits for families and staff
  - Staff perceived changes beneficial for infants, parents, and staff themselves  $\rightarrow$  motivated them to continue the implementation
  - Training program improved interactions among staff and helped them harmonize care practices



	B Context	Low		High Culture
Context	Culture	Task driven Low regard for individuals Low morale Little or no continuing education	Learning organisation Patient centred Valuing people Continuing education	accountability
	Leadership	Low Diffuse roles Lack of team roles Poor organisation or management of services Poor leadership	Clear roles Effective team work Effective organisational structure Clear leadership	High
	Measurement	Low Absence of: Audit and feedback Peer review External audit Performance review of junior staff	Internal measures used re Audit or feedback used re Peer review External measures	



### Context

#### Timing

- Need for a change
- Enough time to prepare for the training
- Not too many changes at the same time
- Support from leadership and multidisciplinary commitment
  - Enough resources allocated for mentoring
  - Prioritizing the training program



### Facilitation

C Facilitation

Characteristics	Low		High
Characteriotics	Respect Empathy Authenticity Credibility	Respect Empathy Authenticity Credibility	
<b>D</b> .1	Low		High
Role	Lack of clarity around: Access Authority Position in organisation Change agenda	Access Authority Change agenda successfully negotiated	
0.1	Low		High
Style	Inflexible Sporadic Infrequent Inappropriate	Range and flexibility of style Consistent and appropriate presence and support	



### **Mentor network**

#### Table 4 Novice, experienced and expert facilitators (adapted from [62])

Experience	Focus of facilitation
Novice facilitator	Working under the supervision of an experienced facilitator Focus on: What an innovation is; what evidence informs the innovation and how to assess and apply it Readiness to change at a local level What motivates individuals and teams and how teams work effectively What context is; what impact context has on implementation at a local and organisational level Identifying and engaging key stakeholders Planning, implementing, measuring and embedding change
Experienced facilitator	Working under the supervision of an expert facilitator Focus on: In depth understanding and knowledge of the organisation or organisations they are working with Awareness of competing tensions and how to manage these in relation to implementing innovation and change In depth understanding of individual and team motivation, team dynamics and productivity Experienced and knowledgeable in local context evaluation Able to assess system-wide activities and influence actions Aware of wider contextual issues and confident in terms of negotiating boundaries and political tensions
Expert facilitator	Expert facilitator operating as a guide and mentor to other facilitators Focus on: Coordinating and supporting networks of experienced and novice facilitators Working with health systems to improve implementation success Working across academic, service and other organisational boundaries to integrate facilitation and research activity Developing and testing theories of implementation, innovation and facilitation Evaluating implementation and facilitation interventions to generate newer knowledge Refining and improving learning materials and mentoring processes Running workshops and advanced master classes on facilitation approaches



## Facilitation

#### Mentoring

- The characteristics of good mentor
- Choosing mentors carefully and providing them education & support
- Experiental learning
  - Learning by doing



## **Recipients (staff / families)**

It is important to acknowledge the following factors which impact in implementation:

- Motivation
- Values, beliefs and goals
- Skills and knowledge
- Time, resources, support
- Local opinion leaders
- Collaboration and teamwork
- Existing networks
- Power and authority
- Presence of boundaries



## **Recipients (staff / families)**

- Change in professional role
  - Participation of doctors multidisciplinary approach is important
  - Differences in adopting the new practice among the nurses
    - Newly graduated nurses had fewer difficulties in adopting the new care practice
    - Nurses who had more work experience occasionally missed the old care practice
  - Some parents signaled insecurity about their role and how much time they should spend in the unit
- Staff motivation
  - Nurses' attitudes toward parents became more positive



## Conclusions

- This study showed that a unit-wide, systematic and structured training program (the Close Collaboration with Parents<sup>™</sup>) facilitated significant improvements in FCC in eight neonatal intensive care units
- Critical elements in implementation were support from the leadership, right timing, unit-wide commitment, feedback from families, and the use of mentoring in learning

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To determine implementation success (Process evaluation)
EVALUATION FRAMEWORKS

#### RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) http://www.re-aim.org/about/

Evaluation framework to expand assessment of interventions beyond efficacy to multiple criteria that may better identify the translatability and public health impact of health promotion interventions

- Reach into the target population
- Effectiveness or efficacy
- Adoption by target settings, institutions and staff
- Implementation consistency and cost of delivery of intervention
- Maintenance of intervention effects in individuals and settings over time



#### <sup>©</sup>Anna Bergström, Uppsala University, Sweden

UPPSALA UNIVERSITET RE-AIM (re-aim.org) cont				
Example of translation of interventions into practice				
Steps	<b>RE-AIM</b> Concept	% Impact		
50% of settings use intervention	Adoption	50.0%		
50% of staff take part	Adoption	25.0%		
50% of patients identified, accept	Reach	12.5%		
50% follow regimen correctly	Implementation	6.2%		
50% benefit from the intervention	Effectiveness	3.2%		
50% continue to benefit after six months	Maintenance	1.6%		



## Implementation outcomes (Peters et al. 2013)

#### Table 1 Implementation outcome variables

Implementation outcome	Working definition*	Related terms†						
Acceptability	The perception among stakeholders (for example, consumers, providers, managers, policy makers) that an intervention is agreeable	Factors related to acceptability (for example, comfort, relative advantage, credibility)						
Adoption	The intention, initial decision, or action to try to employ a new intervention	Uptake, utilisation, intention to try						
Appropriateness	The perceived fit or relevance of the intervention in a particular setting or for a particular target audience (for example, provider or consumer) or problem	Relevance, perceived fit, compatibility, perceived usefulness or suitability						
Feasibility	The extent to which an intervention can be carried out in a particular setting or organisation	Practicality, actual fit, utility, trialability						
Fidelity	The degree to which an intervention was implemented as it was designed in an original protocol, plan, or policy	Adherence, delivery as intended, integrity, quality of programme delivery, intensity or dosage of delivery						
Implementation cost	The incremental cost of the implementation strategy (for example, how the services are delivered in a particular setting). The total cost of implementation would also include the cost of the intervention itself	Marginal cost, total cost‡						
Coverage	The degree to which the population that is eligible to benefit from an intervention actually receives it.	Reach, access, service spread or effective coverage (focusing on those who need an intervention and its delivery at sufficient quality, thus combining coverage and fidelity), penetration (focusing on the degree to which an intervention is integrated in a service setting)						
Sustainability	The extent to which an intervention is maintained or institutionalised in a given setting	Maintenance, continuation, durability, institutionalisation, routinisation, integration, incorporation						

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Implementation outcome	Level of analysis	Theoretical basis	Other terms in literature	Salience by implementation stage	Available measurement		
		Rogers: "complexity" and to a certain extent "relative advantage"	Satisfaction with various aspects of the innovation (e.g. content, complexity, comfort, delivery, and credibility)	Early for adoption Ongoing for penetration Late for sustainability	Survey Qualitative or semi-structured interviews Administrative data		
Adoption	Individual provider Organization or setting	RE-AIM: "adoption" Rogers: "trialability" (particularly for early adopters)	Uptake; utilization; initial implementation; intention to try	Early to mid	Refused/blank Administrative data Observation Qualitative or semi-structured interviews		
Appropriateness	Individual provider Individual consumer Organization or setting	Rogers: "compatibility"	Perceived fit; relevance; compatibility; suitability; usefulness; practicability	Early (prior to adoption)	Survey Survey Qualitative or semi-structured interviews		
Feasibility	Individual providers Organization or setting	Rogers: "compatibility" and "trialability"	Actual fit or utility; suitability for everyday use; practicability	Early (during adoption)	Focus groups Survey Administrative data		
Fidelity	Individual provider	RE-AIM: part of "implementation"	Delivered as intended; adherence; integrity; quality of program delivery	Early to mid	Observation Checklists Self-report		
Implementation Cost	institution "costs" and "resources" cost-benefit feasibilit Mid for pe		Early for adoption and feasibility Mid for penetration Late for sustainability	Administrative data			
Penetration	Organization or setting	RE-AIM: necessary for "reach"	Level of institutionalization? Spread? Service access?	Mid to late	Case audit Checklists		
ustainability Administrators RE-AIM: "maintenance" Organization or setting Rogers: "confirmation"			Maintenance; continuation; durability; incorporation; integration; institutionalization; sustained use; routinization;	Late	Case audit Semi-structured interviews Questionnaires Checklists		

#### Table 1 Taxonomy of implementation outcomes

# The challenge of sustainability

- Clinical context is complex, unpredictable, often characterized by unstable resources, high workloads, competing demands, and lack of dedicated funding for implementation of practice change
- At least 33% of costly healthcare practice improvement projects return to previous ways of working within one year
- How to make and support sustainable change?







# How to maintain the change?

- Aim intervention to become routine care
- Relevant and well-developed intervention
- Organizational/Unit/Individual level plan on how to secure sustainable change
- Permanent resources for the training/implementation
  - Orientation for new staff members
- Regular audits
- Continuous sensitivity towards patient needs – readiness for new EBP



## **De-implementation**



# **De-implementation**

- Professionals secure quality care by creating routines
- Evidence-based practice is not only about implementing new evidence-based interventions
- Requires de-implementation of ineffective, unnecessary or even harmful practices
  - e.g., Any limitations for parents' presence in NICU
- Final decision often made by each health care professional
  - e.g., Do you invite parent to stay overnight in the NICU?





# Influencing factors

- Health care professionals' values, professional role, status, fear of malpractice
  - e.g., we do not want to burden parents
- Patient preferences can  $\downarrow\uparrow$  de-implementation
  - e.g., beliefs about parents' role in hospital
- Outer context social, political, geographical factors
  - e.g., government resource allocation for rebuilding of hospitals single family rooms

Photo credit: Department of Paediatrics, Drammen hospital, Vestre Viken Hospital Trust

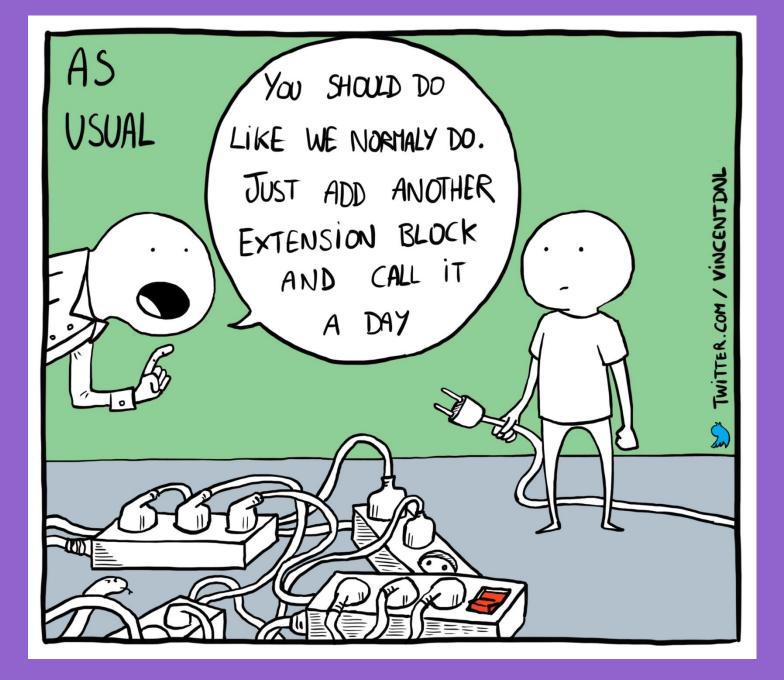


- Inner context social and physical environment of care context
  - e.g., transportations from Level 3 NICU to Level 2 NICU
- Process routine for managing changes
  - e.g., leadership's, staff's experience of change processes
- Level of evidence is alternative practice available if needed?
  - e.g., Zero separation vs. is immediate skin-to-skin contact for very preterm infants safe?





## Why Does De-implementation Matter?



- We will consistently expend energy solving the problems that temporary workarounds produce
- We will not get to the heart of ineffective, unnecessary practice
- We will struggle to see quality improvement if essential problems are not identified





Before adding anything to your practice, think if you can remove something.



# 2. tutkimusesimerkki Scaling Up Safer Birth Bundle Through Quality Improvement in Nepal (SUSTAIN)

Ashish Kc Anna Axelin





UPPSALA UNIVERSITET

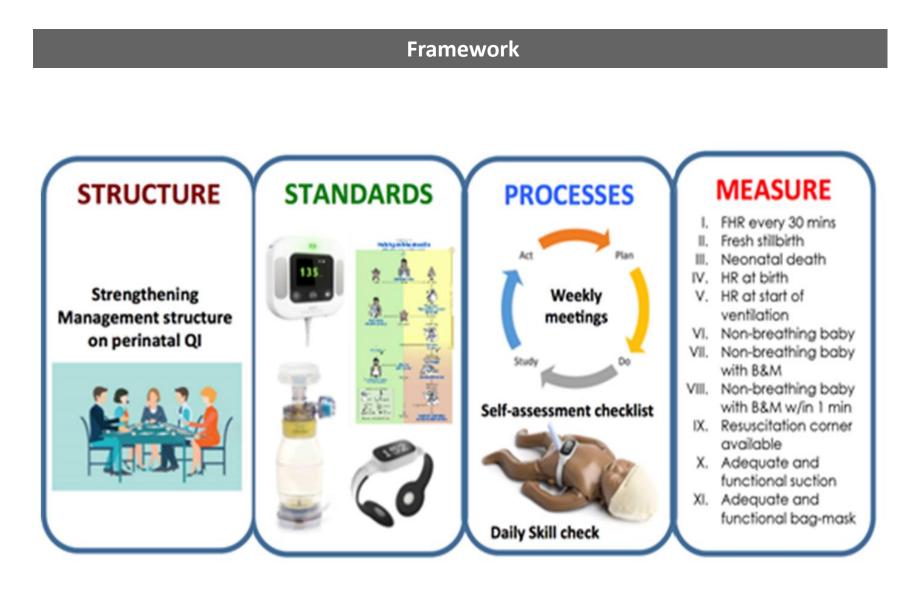


## Taustaa

- Kehittyvissä maissa hoito on harvoin näyttöön perustuvaa
  - Näytön käyttöönottolla voi saada aikaan suuria terveysvaikutuksia
- Vuosittain maailmassa kuolee synnytyksen yhteydessä 2,2 miljoonaan vastasyntynyttä (99% kehittyvissä maissa)
  - Sairaalan ulkopuolella tapahtuvat synnytykset
  - Hoidon heikko laatu
- Tutkimuksen tarkoitus: We aim to evaluate the quality improvement package (SUSTAIN) and its impact on intrapartum care related mortality in Nepal



The SUSTAIN project aims to improve intrapartum care through a set of quality improvement interventions

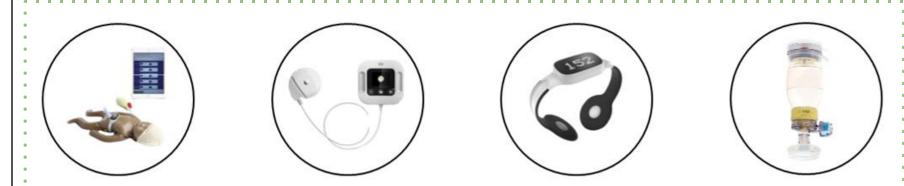


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## Brief introduction on SUSTAIN

### Scaling up

• Safer Birth Bundle



• Quality improvement interventions



### **MOYO** and NeoBeat





## **Daily Skill Drill**

### Skill Drill Registration

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## **Tutkimusasetelma**



# Study design - a stepped wedge cluster randomized controlled trial

Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Cluster hospital 1																			
Cluster hospital 2																			
Cluster hospital 3																			
Cluster hospital 4																			
Cluster hospital 5																			
Cluster hospital 6																			
Cluster hospital 7																			
Cluster hospital 8																			

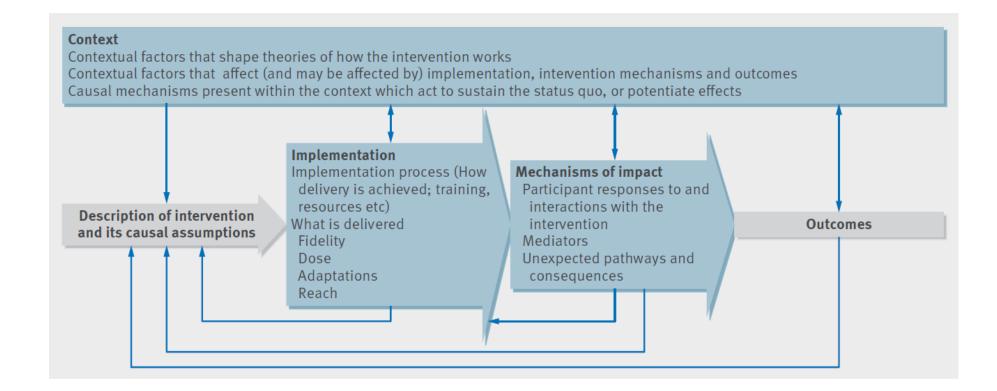
Note: Grey shading is the control period, white is the implementation transition period and dark blue is the intervention period.

### Process evaluation framework (Moore ym. 2014)

In addition to the effectiveness studies, it is recommended to evaluate and understand the implementation process of complex interventions. The findings will explain the results of the effectiveness studies and guide implementation processes.

#### Process evaluation aims to understand

- What is implemented and how?
- How does the delivered intervention produce change?
- How does context affect implementation and outcomes?



# Health outcomes

 Intrapartum-related mortality - defined as intrapartum stillbirth (no breathing 10 min after delivery) and neonatal death within the first 24 h of life

## • Proportion of

- deliveries with fetal heart rate monitoring as per standard protocol
- deliveries in which abnormal fetal heart rate during labor is followed by neonatal resuscitation
- deliveries resulting in emergency cesarean sections and instrumental deliveries due to fetal distress
- non-breathing babies who receive a bag and mask ventilation within 1 min of birth
- The perception of women for intrapartum care



# Process evaluation questions

- The impact of the package on health workers' performance on monitoring fetal heart rate, essential newborn care, and neonatal resuscitation
- The appropriateness of implementation
- The acceptability of the SUSTAIN package in the hospitals



# Mikä on efficacy trial ja effectiveness trial tutkimusten ero?

Table 1         Characteristics of Efficacy vs. Effectiveness Trial Designs (after [8])								
	Efficacy Trial	Effectiveness Trial						
Validity Priority	Internal > External	External ≥ Internal						
Population and Sample	Highly selected for condition of interest, narrowly defined	<ul> <li>Selected for condition of interest, reflecting presentation in source population</li> </ul>						
	Few comorbidities	<ul> <li>Comorbidities resemble those in population to which results will be applied; only those who cannot practically or ethically participate are excluded</li> </ul>						
	Willing and motivated participants							
Intervention	<ul> <li>Intervention staff are highly qualified</li> </ul>	Staff selection, training, and fidelity monitoring resemble those						
	Training may be intensive	likely to be feasible in target sites outside of the protocol proper						
	<ul> <li>Fidelity monitoring may be similarly intensive</li> </ul>							
Outcome Measures and Data Collection	<ul> <li>Outcome measurements can be extensive, casting a wide net for potential secondary effects, moderators and mediators, or adverse effects</li> </ul>	<ul> <li>Outcome batteries minimize respondent burden (in terms of both frequency and length of assessments) since subjects are heterogeneous in their willingness and capability to participate</li> </ul>						
	<ul> <li>Since subjects are motivated, respondent burden less of a concern</li> </ul>	<ul> <li>Accordingly, outcome measures chosen carefully to target fewer outcomes, and must be simple to complete</li> </ul>						
Data Analysis	Standard statistical approaches suffice, and data-intensive	Analyses to account for greater sample heterogeneity						
	analyses may be feasible	<ul> <li>Analyses account for more missing data and data not missing a random</li> </ul>						

## Data for process evaluation





## Orientation





## **Bottleneck Analysis**





## **Orientation and Bottleneck analysis**

- Orientation of SUSTAIN were done to all the nursing in-charge, medical doctors, pediatricians
- Leadership participated in the bottleneck analysis
- Data: Records on problems discussed around service availability of the hospital, health information system; human resource; infrastructure, equipment and supply; governance and financing.

## HBS - Hospital level training









# Helping Babies Survive (HBS) training

- Four-day training
- Participants were nurses from intrapartum area including NICU and OT and some of them were medical doctors.
- Teaching materials: PPT, HBB flipcharts, Videos, Posters of AAP action plan, Neonatalie manikins, Mama Breast, NG tube feeding Manikin, Kangaroo Mother care wrapper, Delivery set, Training Manuals: Participant Handbook, Chartpaper, White board.
- **Teaching methods:** Lecture, Group work, OSCE, Demonstration, Role play, Discussion
- Number of participants: Maximum 20 in each batch.
- Data: the background information of the training participants, evaluation at the end of 4-day training.



# Plan – Do – Study – Act (PDSA) meetings

- PDSA harnesses the local ownership of challenges and provides an actionable framework to monitor and evaluate progress to improve and sustain QI changes.
- PDSA meetings were facilitated and led by the nursing incharge/matron. PDSA is only conducted in maternity ward biweekly.
- Data: Records of the problems identified in each meeting, goal set and plan executed. The record of PDSA participants and changes made through PDSA meeting.
- Data: Liveborn Observation (collect data on cord clamping, skin to skin contact and time of ventilation; its time stamped) and data from dashboard of NeoBeat, Advanced Neonatalie and Moyo.



## **Track Record**

PDSA meeting	4
Daily Skill Drill	690 (17 staffs)
Frequency of Moyo placed on mothers	318
Number of non-crying babies on whom NeoBeat was used	54

Significant Outcomes

- Request for additional upright bag and mask and penguin suction to improve quality of care during resuscitation.
- Penguin suction was used instead of electric suction to reduce duration of suctioning.
- Rearrangement of Labor bed and newborn corner.

# Interviews with the key informants

- We will develop an interview guide for people who 1) participated in the training and who 2) carried out the training
- Aim to understand
  - Facilitators and barriers of the implementation of the SUSTAIN
  - What can we learn from the process and do better the next time?
- Data collection
  - Individual or focus group interviews



**Findings -** Facilitators and barriers for implementation of a novel resuscitation package in public referral hospitals of Nepal

- Practice Change Move to a more systematic resuscitation
- Innovation Neonatal heart rate monitoring driving the change
- Recipients Feedback supporting the change
- Facilitation An enabler for change and a barrier for sustainable change
- Context The unclear role of leadership and medical doctors



## Miten käyttöönoton tutkimuksen luotettavuutta ja eettisyyttä arvioidaan?







## References

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Implementation Science

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