Making it real:
‘Best evidence’ meets a complex system

Experiences from evaluating the process of implementation of babyclear©
- a smoking cessation in pregnancy initiative –

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Elements of babyClear©

• Routine CO monitoring at booking by midwife
• Referral to stop smoking service (SSS)
• Structured schedule for follow up
• ‘Risk perception’ counselling by specialist midwife at dating scan
• Supported by training for all midwives, SSS advisors and admin staff, and those delivering SSS in the community
• Feedback loops
• Standardised **complex intervention** based on best evidence, but then...

• Implemented across **complex system** - multiple sites within 8 different NHS Trusts, each presenting different patterns of need, different existing service configurations and pathways, different staff profiles, different patterns of commissioned services, different budgets...
Overall aims of broader evaluation

**Outcome evaluation**
- To assess effect of intervention on referral rates, quit rates and pregnancy outcome (SGA and preterm delivery)
- To assess cost-effectiveness of the intervention (NHS costs per additional quit)

**Process evaluation**
- To assess acceptability and fidelity of intervention implementation, impact of intervention on midwifery and stop smoking services and extent to which changes are sustained
- To assess acceptability and perceptions of reconfigured service among pregnant women
“The ultimate goal of a process evaluation is to illuminate the pathways linking what starts as a hypothetical intervention, and its underlying causal assumptions, to the outcomes produced.”

(Moore et al 2014, p24)

RCTs oversimplify cause and effect, and ignore complexity of systems

However this complexity is the reason why many interventions are less successful than had been hoped
Key functions of a process evaluation

Context
- Contextual factors which shape theories of how the intervention works
- Contextual factors which affect (and may be affected by) implementation, intervention mechanisms and outcomes
- Causal mechanisms present within the context which act to sustain the status quo, or enhance effects

Implementation
- Description of intervention and its causal assumptions
  - How delivery is achieved (training, resources etc.)
  - What is delivered
    - Fidelity
    - Dose
    - Adaptations
    - Reach

Mechanisms of impact
- Participant responses to, and interactions with, the intervention
- Mediators
- Unanticipated pathways and consequences

Outcomes
Implementation

• How will delivery be achieved?

• What will be delivered?
  e.g. quantity and quality of implementation
Mechanisms

• How will change happen?

• Will it be ... feasible, acceptable and sustainable?
Some system mechanisms of change

• Change in professional discourse
  o Focused, motivational approach by all HCPs from initial contact
  o Motivational interviewing ‘plus’ – new language of concern

• Shift to universal system as the norm
  o Screening (everyone CO tested)
  o Opt out - assumption of SS take-up

• Fail-safe integrated systems
  o Surveillance (monitored)
  o Re-referral
  o High level of peer/professional follow up support
  o Closer integration of maternity and stop smoking services
  o Multiple options for follow up including home visits

• Reinforcement of value of intervention
  o Training
  o Feedback loops (between services, from services to pregnant women)
Context

• Context overarching in importance
• Recognised as shaping the theories of how intervention works
• Affects mechanisms of change and outcomes
• Contextual information proved to be extremely important in understanding how babyClear was delivered and what was actually delivered
What happened on the ground (1)

- Assumptions meet reality
  - Enormous variation
  - Service disruption
What happened on the ground (2)

- Mechanisms and context not well understood at the start
- Qualitative data helped to interpret quantitative data on outcomes
- Process evaluation able to improve reliability of outcomes data by establishing reasons for some of the ‘noise’ around findings
Conclusions

• Understanding system complexity is essential if a new intervention is to be successfully introduced and sustained

• Mechanisms of system change needs to be explicit from the start

• Local adaptations may need to be made in light of massive variation in contexts, so critical to understand what is ‘core’ and what other aspects - if altered or varied - will not undermine integrity of intervention

• “Will it work here?”
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