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DECIPHer
Development and Evaluation of Complex Interventions for Public Health Improvement
A UKCRC Public Health Research Centre of Excellence

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Co-producing and prototyping interventions

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Overview

- Key features
- Co-production and prototyping preventative interventions
- Principles of user centred design and intervention development

- Case study one: adapting intervention content
- Case study two: developing new intervention content

- Critical reflections and conclusions

Co-production, key features

- "*the voluntary or involuntary involvement of public service users in any of the design, management, delivery and/or evaluation of public services*". (*Osborne et al., Public Management Review 2016;18:639–53*)

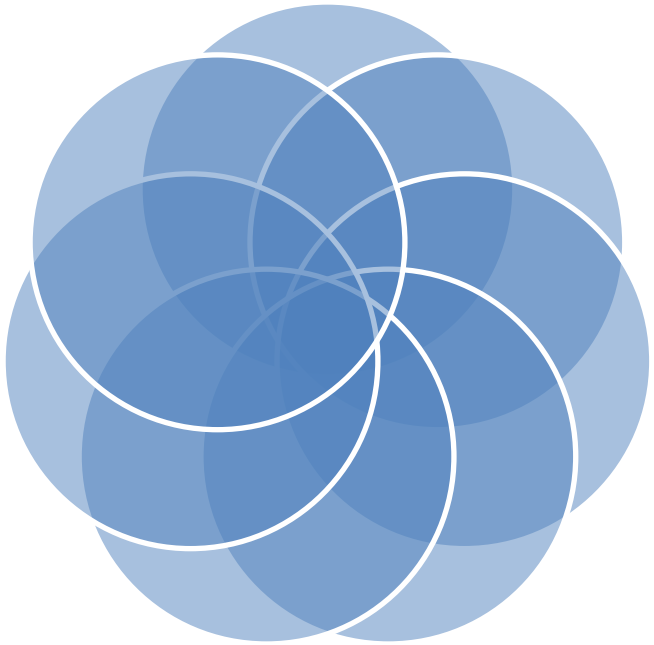
- "*…citizens can play an active role in producing public goods and services of consequence to them*" (*Ostrom, 1996; World development 1;24(6):1073-87*)

- "*[Co-production] … is about more than consultation and participation; it is about encouraging people to use their skills and experience so that public services are no longer solely in the domain of professionals, but are a shared responsibility."*(*Academy of Medical Sciences, 2016*.)"

Co-production

Patient engagement

Co-creation



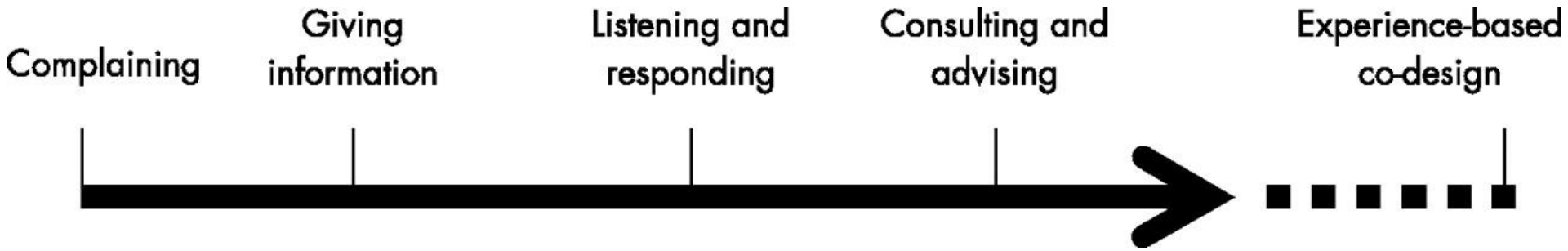
Patient involvement

Co-construction

Co-design

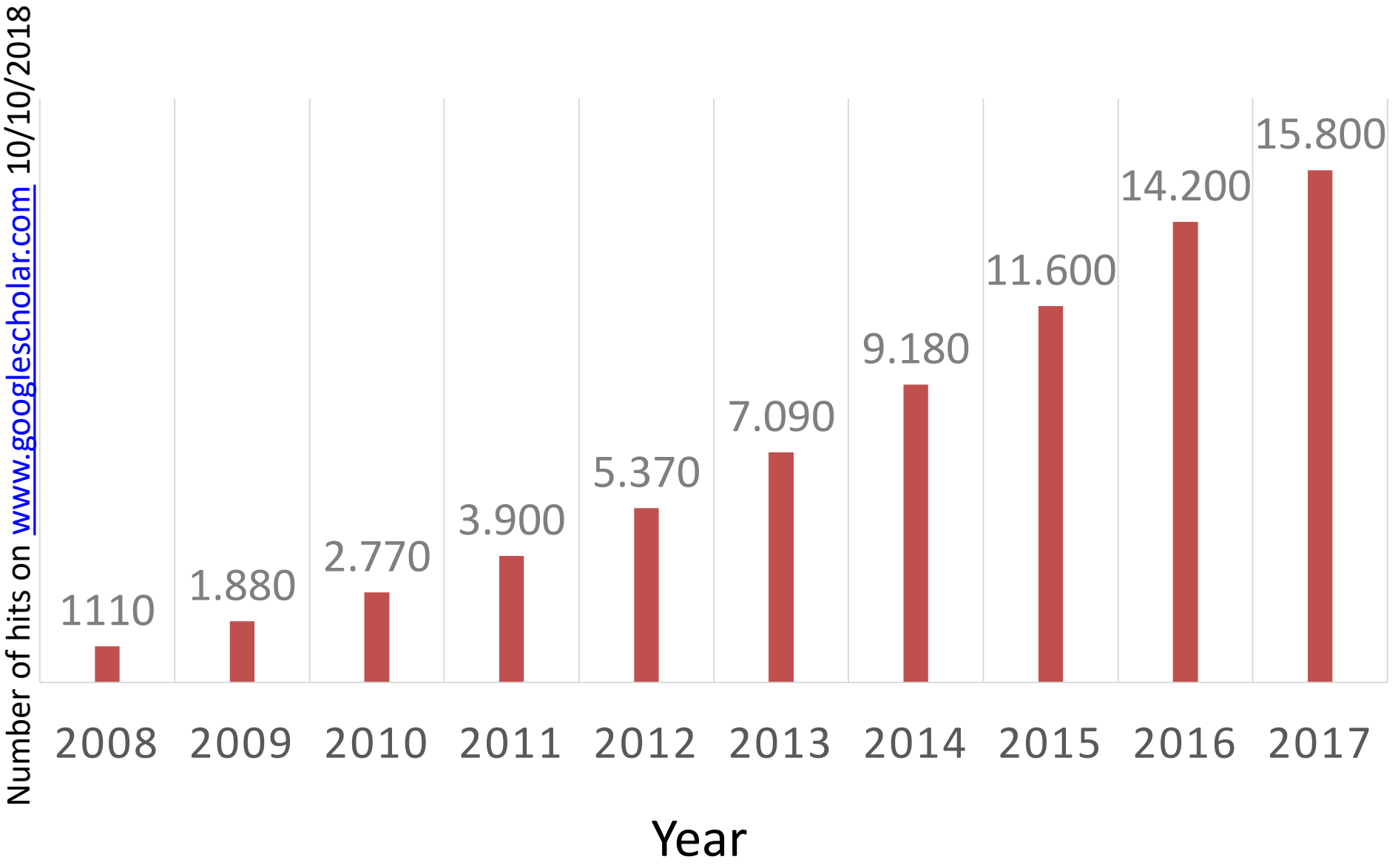
Co-innovation

Continuum of patient/ public involvement



Paul Bate, and Glenn Robert Qual Saf Health Care 2006;15:307-310

Number of hits for “co-production” AND “health”



Funders require public involvement

By 2025 we expect all people using health and social care, and increasing numbers of the public, to be aware of and choosing to contribute to research by:

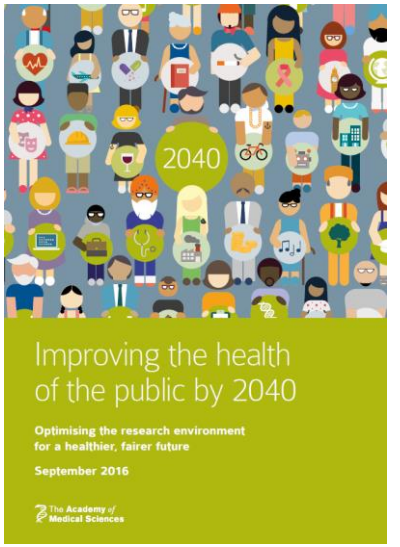
- Identifying future research priorities and research questions
- Informing the design and development of innovations
- Participating in research studies
- Advocating for the adoption and implementation of research in the NHS

Going the extra mile: improving the nation's health and wellbeing through public involvement in research, National Institute of Health Research, 2015

"The research should address the 'upstream' determinants of NCDs and be ***co-produced with users (e.g. policy makers, practitioners, health providers, the third sector, the public etc.)****."*

UKPRP
Prevention Research Partnership

*"**More needs to be done to ensure that meaningful and iterative public involvement takes place from early in the process of designing research** to produce the evidence base for influencing the health of the public. This is particularly the case when investigating potential interventions." (Academy of Medical Sciences.* Improving the health of the public by 2040*)*



Examples

- consultation with young people led to the addition of outcomes to a Cochrane review on preventing Multiple Risk Behaviours;
- effect of public involvement on meeting recruitment targets in a RCT; readability and length of information sheets;
- oncology service staff ideas led to a dictionary for new patients, new signage and maps; patients: choice on receiving treatment with another patient or alone;
- effect of collaborative group of users, carers and staff on perceived recovery in young people experiencing serious mental illness

- Development of interventions

Who to co-produce with and why?

Who	Why
Those who might buy/ commission the intervention	Policy fit/ priority; sustainability
Those who manage those who deliver	Identify structural barriers (existing commitments), free time for staff: reach, adoption, sustainability
Those who will deliver	Determine training needs; gain "buy-in"; exploit expertise with context and population: fidelity
Those who will receive	Determine level of knowledge, importance, acceptability of content: acceptability.
Other stakeholders (parents, carers, health professionals, policy makers)	Strategic fit, existing provision acceptability, adoption, sustainability

- **Aim: Harness latent expertise of those within the system to increase implementation**

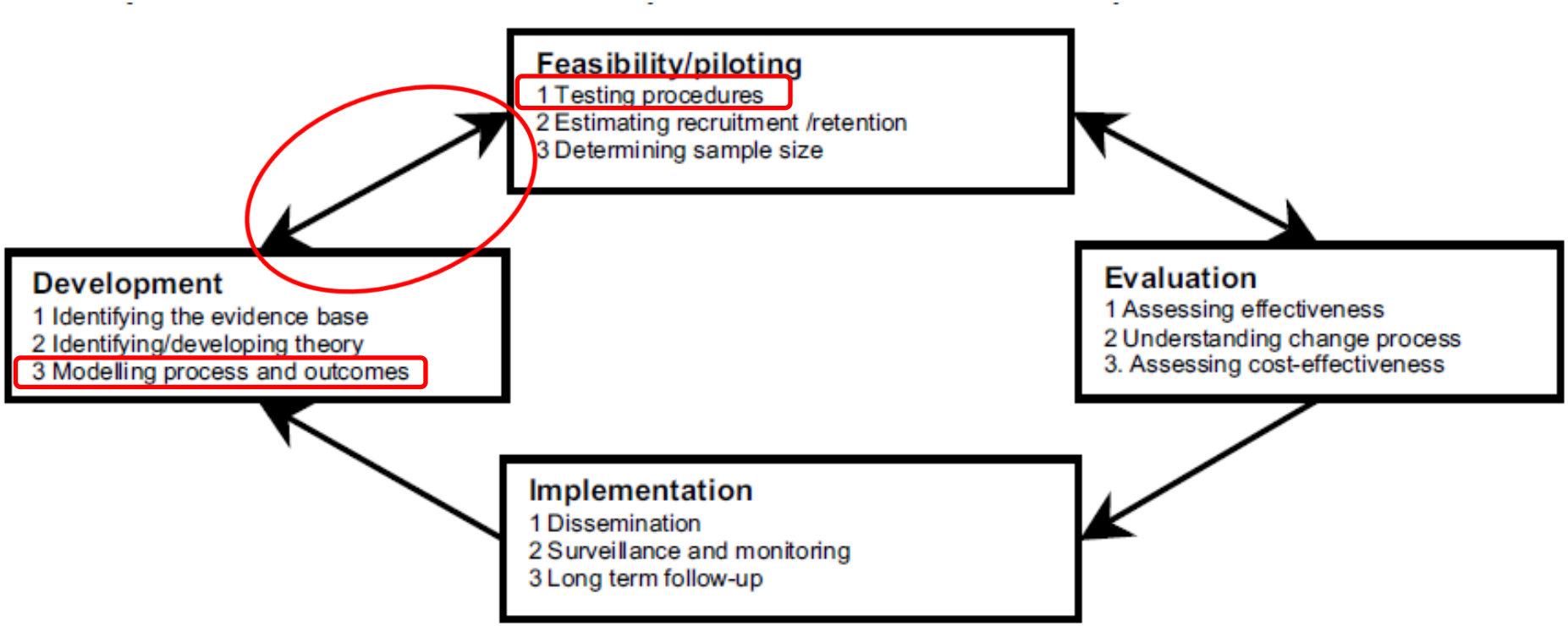
Co-production & prototyping = Usability engineering

- Principles
  - The more effort at the beginning, the less cost at the end;
  - Collect information about the individuals and settings where products will be used;
  - User participation in iterative-cyclic software development leads to optimal results;
  - Iterative-cyclic process model is a collection of meshed optimization cycles;
  - Design-time control vs. run-time control.

- Continuous, nonlinear quality improvement process to quickly assess the viability of new concepts or variations.

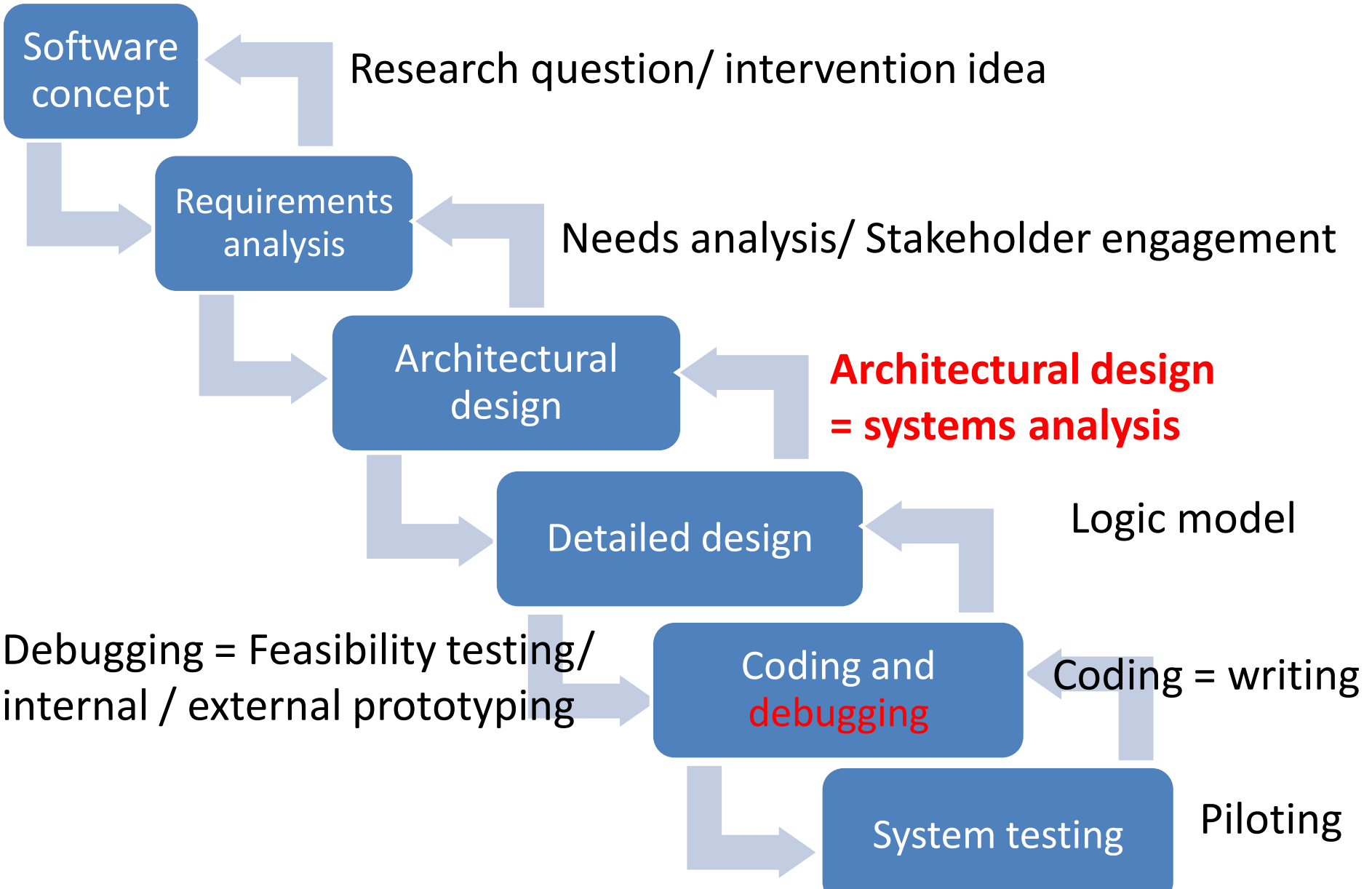
Rauterberg M. Usability engineering. Technischer Bericht, ETH Zürich, Zürich; 1996.

Co-production and prototyping in intervention design



Craig P, et al., Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ. 2008 Sep 29;337:a1655.

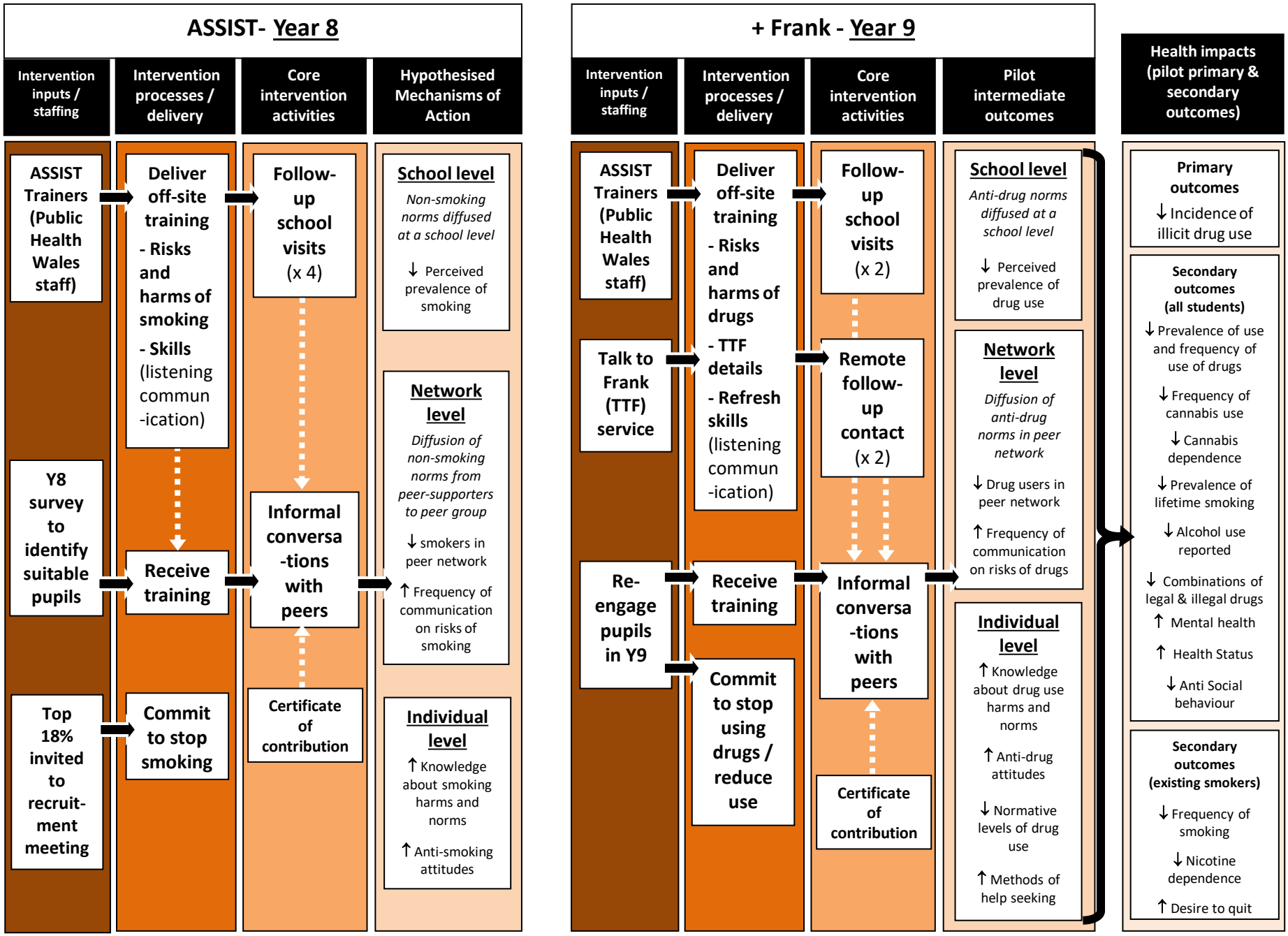
Software lifecycle development (Royce, 1970)



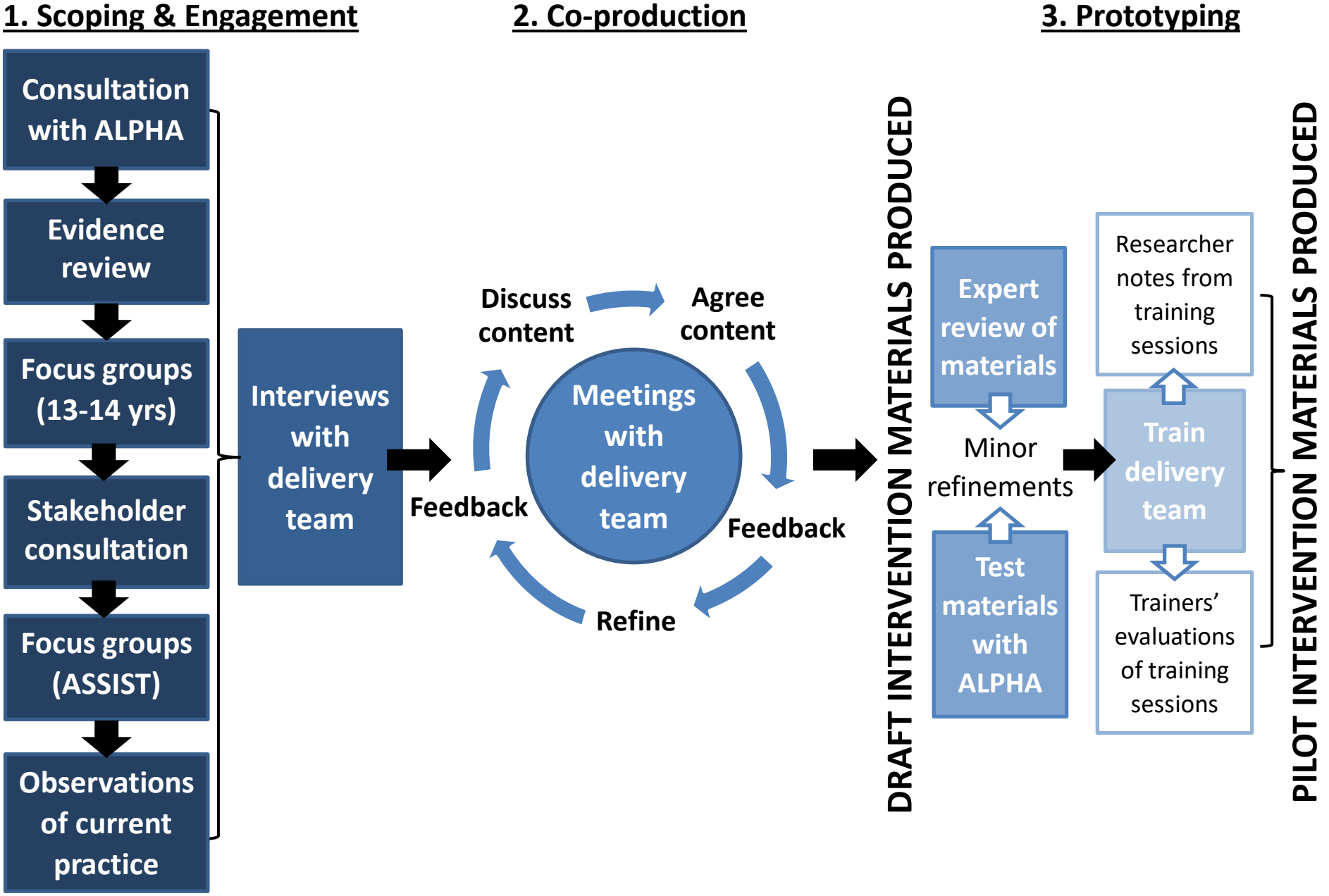
A framework for co-producing & prototyping interventions

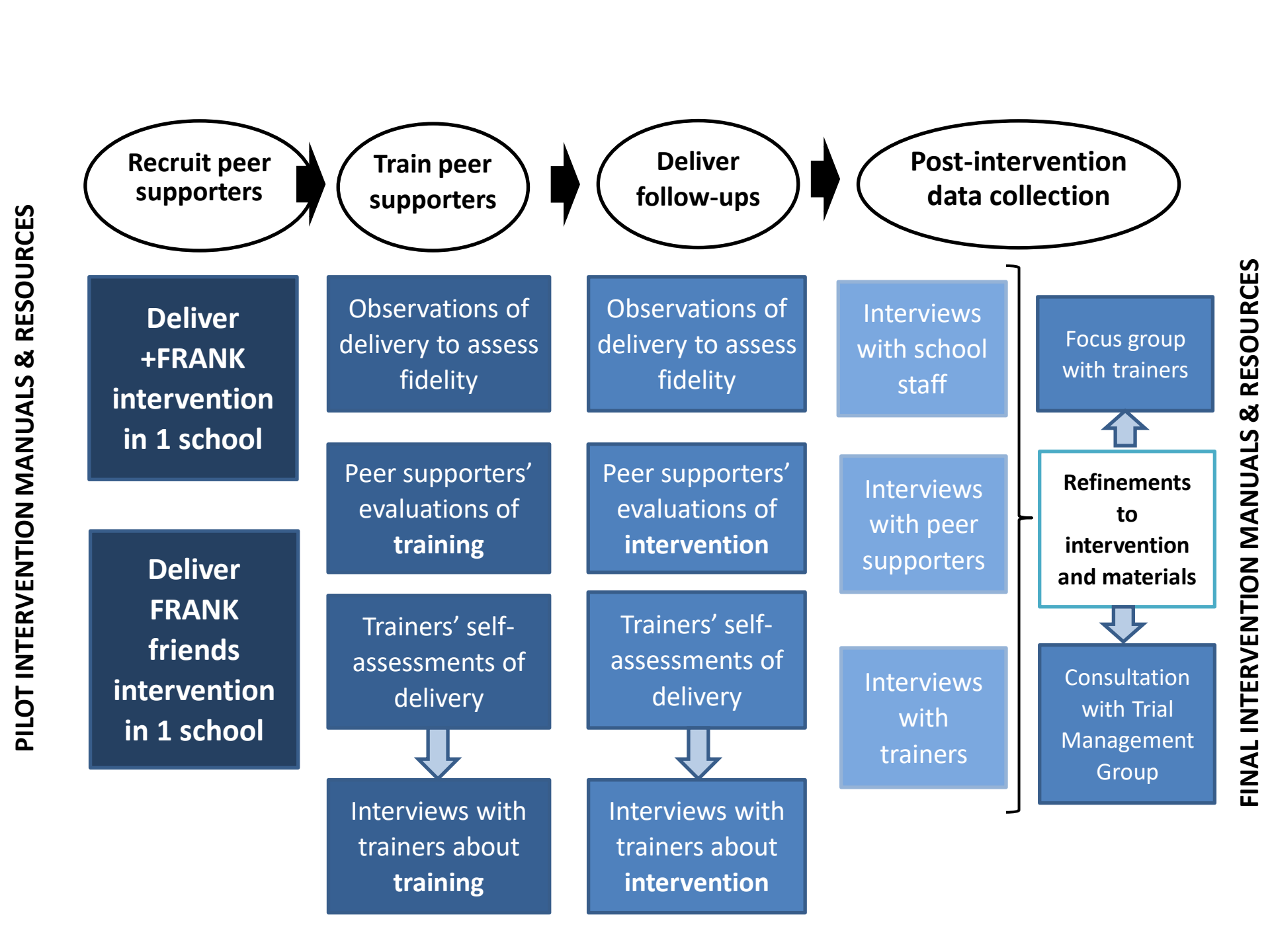
- **Existing guidance focuses on developing evidence base and intervention theory**
  - **<u>Evidence base</u> for health problem already established**
  - **<u>Intervention theory</u> already established**

- **Adaptation of an existing effective intervention for use with:**
  - A different health problem/health behaviour (tobacco → drugs)
  - A different target population (12-13 → 13-14 yrs)


ASSIST- Year 8
Intervention inputs / staffing
Intervention processes / delivery
Core intervention activities
Hypothesised Mechanisms of Action
ASSIST Trainers (Public Health Wales staff)
Deliver off-site training
- Risks and harms of smoking
- Skills (listening commun -ication)
Follow-up school visits (x 4)
School level
Non-smoking norms diffused at a school level
↓ Perceived prevalence of smoking
Y8 survey to identify suitable pupils
Receive training
Informal conversa -tions with peers
Network level
Diffusion of non-smoking norms from peer-supporters to peer group
↓ smokers in peer network
↑ Frequency of communication on risks of smoking
Certificate of contribution
Top 18% invited to recruit-ment meeting
Commit to stop smoking
Individual level
↑ Knowledge about smoking harms and norms
↑ Anti-smoking attitudes
+ Frank - Year 9
Intervention inputs / staffing
Intervention processes / delivery
Core intervention activities
Pilot intermediate outcomes
ASSIST Trainers (Public Health Wales staff)
Deliver off-site training
- Risks and harms of drugs
- TTF details
- Refresh skills (listening commun -ication)
Follow-up school visits (x 2)
School level
Anti-drug norms diffused at a school level
↓ Perceived prevalence of drug use
Talk to Frank (TTF) service
Remote follow-up contact (x 2)
Network level
Diffusion of anti-drug norms in peer network
↓ Drug users in peer network
↑ Frequency of communication on risks of drugs
Re-engage pupils in Y9
Receive training
Informal conversa -tions with peers
Commit to stop using drugs / reduce use
Certificate of contribution
Individual level
↑ Knowledge about drug use harms and norms
↑ Anti-drug attitudes
↓ Normative levels of drug use
↑ Methods of help seeking
Health impacts (pilot primary & secondary outcomes)
Primary outcomes
↓ Incidence of illicit drug use
Secondary outcomes (all students)
↓ Prevalence of use and frequency of use of drugs
↓ Frequency of cannabis use
↓ Cannabis dependence
↓ Prevalence of lifetime smoking
↓ Alcohol use reported
↓ Combinations of legal & illegal drugs
↑ Mental health
↑ Health Status
↓ Anti Social behaviour
Secondary outcomes (existing smokers)
↓ Frequency of smoking
↓ Nicotine dependence
↑ Desire to quit

Intervention Development and Prototyping




PILOT INTERVENTION MANUALS & RESOURCES
Recruit peer supporters
Train peer supporters
Deliver follow-ups
Post-intervention data collection
Deliver +FRANK intervention in 1 school
Deliver FRANK friends intervention in 1 school
Observations of delivery to assess fidelity
Peer supporters' evaluations of training
Trainers' self-assessments of delivery
Interviews with trainers about training
Observations of delivery to assess fidelity
Peer supporters' evaluations of intervention
Trainers' self-assessments of delivery
Interviews with trainers about intervention
Interviews with school staff
Interviews with peer supporters
Interviews with trainers
Focus group with trainers
Refinements to intervention and materials
Consultation with Trial Management Group
FINAL INTERVENTION MANUALS & RESOURCES

Results: adapting content

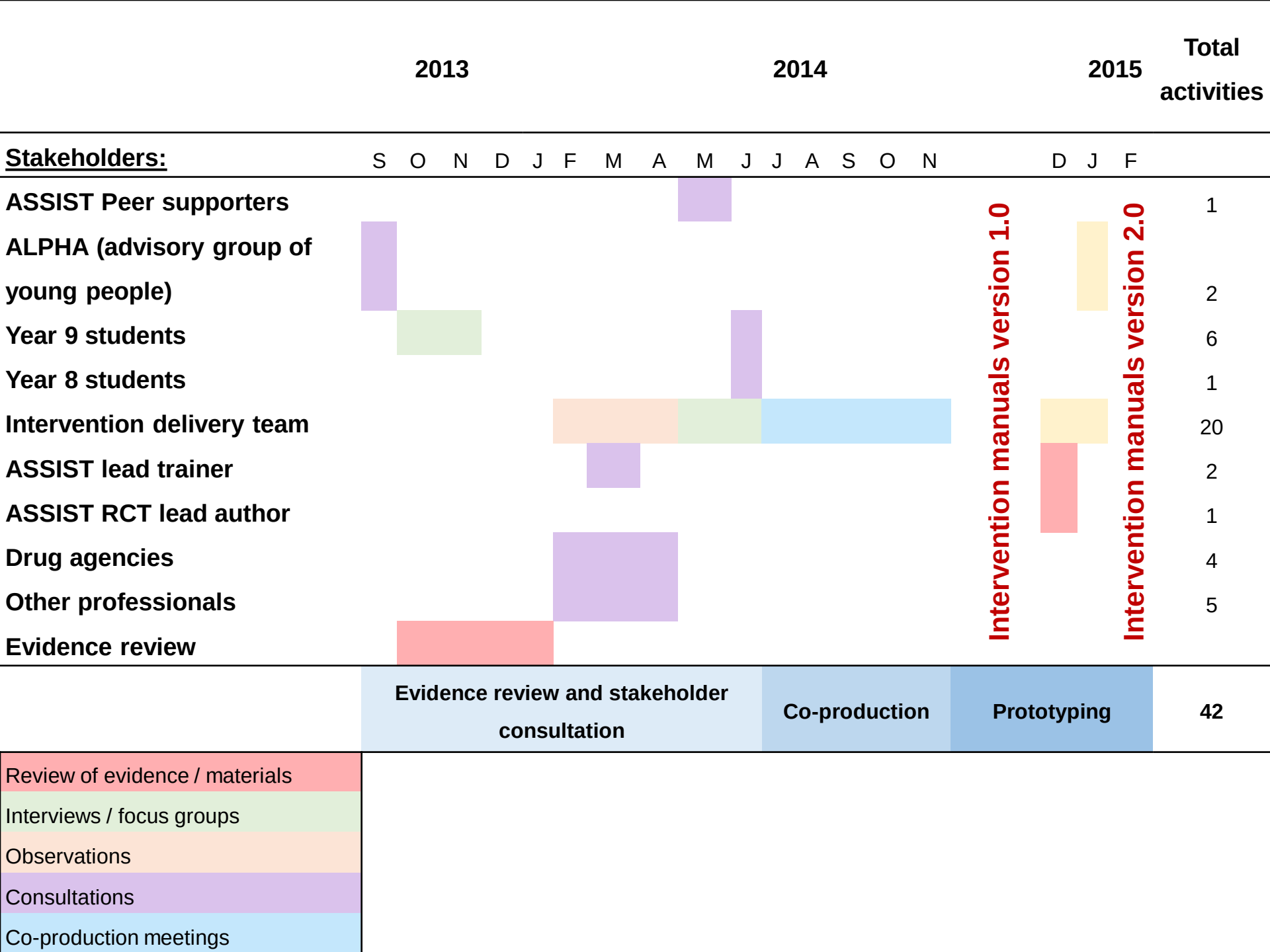
- **Consultation with delivery staff**
  - Tobacco vs. multiple drugs; legal sensitivity; training need;
  - Activities may be to immature for older year group
- **Consultation with young people (ALPHA)**
  - Highlight key features of the talk to FRANK website
- **Consultation with ASSIST lead trainer**
  - Ensure activities are linked to role of peer supporter
  - Ensure plenty of time for discussion in activities

White, J. et al., Public Health Research. 2017;5(7).
Hawkins, J., et a., BMC Public Health. 2017 Dec;17(1):689.

Results: co-producing content

- **Consultations and focus groups with young people**
  - Health consequences vs other (legal consequences, school sanctions, shame and problems for parents/family, impact on education and employment)
- **Acceptability of TTF content**
  - Novel psychoactive substances
  - Impact of drugs being unregulated – variable purity, unknown compound and dose
- **Observing ASSIST delivery and training**
  - Use of own energisers, provision of prizes for games
  - Frequent reiteration of facts, how to use in conversations

White, J. et al., Public Health Research. 2017;5(7).
Hawkins, J., et a., BMC Public Health. 2017 Dec;17(1):689.


2013
2014
2015
Total activities
Stakeholders:
S O N D J F M A M J J A S O N D J F
ASSIST Peer supporters 1
ALPHA (advisory group of young people) 2
Year 9 students 6
Year 8 students 1
Intervention delivery team 20
ASSIST lead trainer 2
ASSIST RCT lead author 1
Drug agencies 4
Other professionals 5
Evidence review
Intervention manuals version 1.0
Intervention manuals version 2.0
Evidence review and stakeholder consultation
Co-production
Prototyping
42
Review of evidence / materials
Interviews / focus groups
Observations
Consultations
Co-production meetings

An illustrative example of prototyping content

An introductory activity to cover existing drugs knowledge and to learn about drug categories and their effects

First iteration of activity involved peer supporters producing lists of drugs they have heard of, and grouping them by their effects.

- Feedback from trainers during co-production of content:
  - Perceived need to have an encyclopaedic knowledge about drugs was creating anxiety about delivering this activity

Refinement: Provided drug education session and resources; included a flipchart in the activity for drugs 'new to trainers'; reduced focus to 10 most prevalent drugs; encouraged emphasis on asking FRANK when unsure.

- Feedback from trainers following training sessions:
  - Drugs with dual classification of effects are confusing, timing issues

Refinement: Focus on main effect of drug; remove opiates classification as use in 13-14 year olds is rare (Natcen any opiates = 0.1 @13; 0.2@14 years).

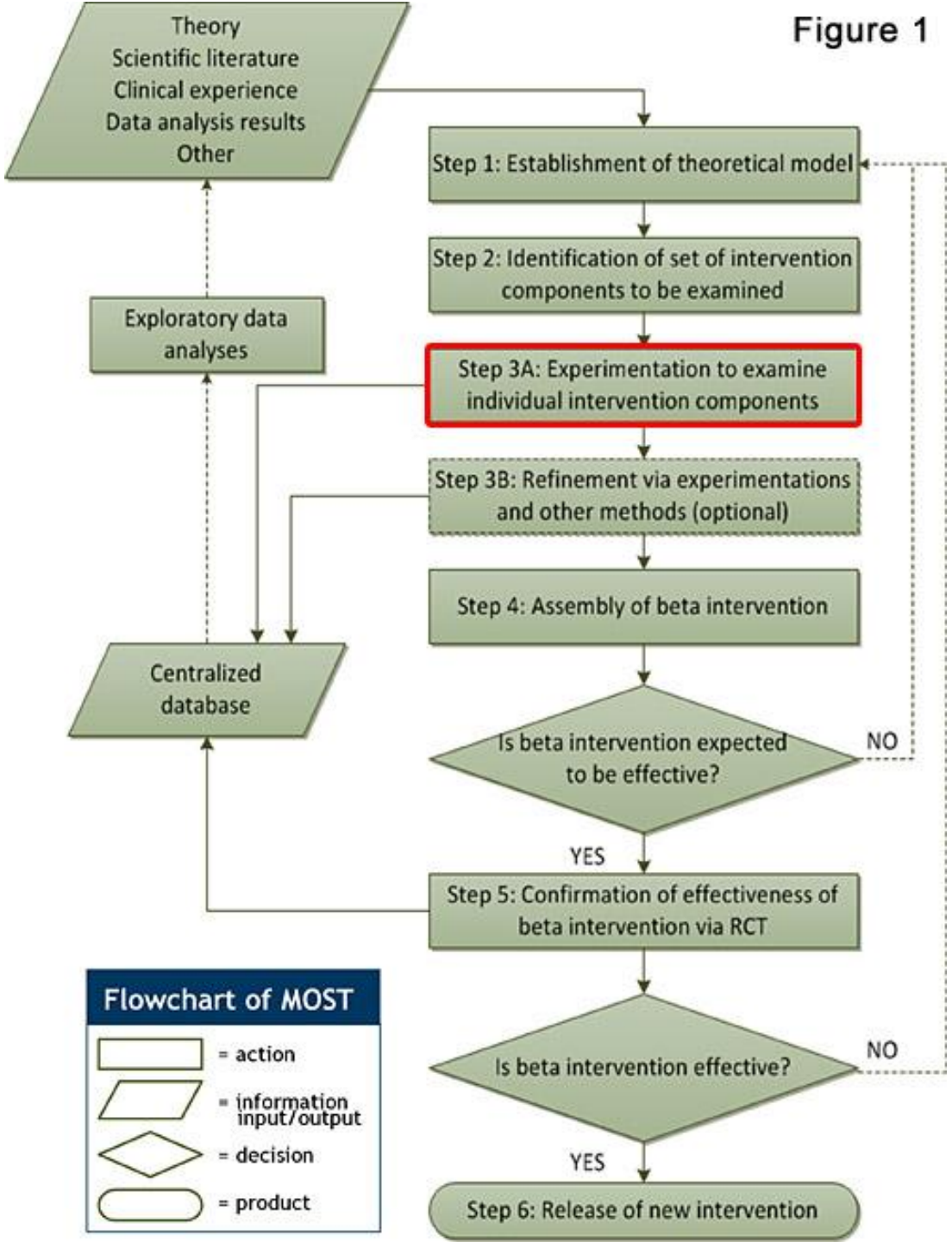
Prototyping intervention components

- Multiphase optimization strategy (MOST): pre-specified components are randomised and only carried forward if show evidence of effect OR all components are tested in a factorial design (*Murphy, Statistics in medicine. 2005 May 30;24(10):1455-81.)*
- Clinical trials – pick a winner, treatment switching, biomarker sensitive (*Chow & Chang. Orphanet journal of rare diseases. 2008 Dec;3(1):11.*)

- Components are pre-specified by a research team;
- Feedback is on outcome response not on implementation;

- Ineffectiveness may result from implementation not intervention failure.

Figure 1



Ann Behav Med. 2010;41(2):208-226.
doi:10.1007/s12160-010-9253-x

Case study two: triaging candidate components

- The SaFE Project
- Funded by the Medical Research Council Public Health Intervention Development Scheme
- Collaboration between the sexual health charity Brook, DECIPHer (Cardiff University), The Institute of Eductaion (UCL) and London School Hygiene Tropical Medicine

- Develop the first comprehensive sexual health and relationship intervention for Further Education (FE) settings to promote safe sex and relationships among 16-19 year-olds
- Candidate components triaged on the basis of need and acceptability by stakeholders

Young et al., (under review). Formative mixed method multi-case study research to inform development of an intervention to promote safe sex and healthy relationships in Further Education (FE) settings: The SaFE Project

The candidate intervention components

1. Student-led sexual health action groups
2. Sex and Relationship Education
3. On-site access to sexual health and relationship services
4. Staff training in safeguarding about sexual health and relationships

Identified from reviews, consultation with young people, sexual health charity staff, NUS, NSPCC

Harden, A., BMJ. 2009 Nov 13;339:b4254.
Oringanje, C., Cochrane Database Syst Rev. 2009 Jan 1;4(4).
Goesling, B., Journal of Adolescent Health. 2014 May 1;54(5):499-507.
De La Rue, L., Campbell Systematic Reviews 2014: 7. 2014 Jul 17.

Method

Design: Mixed method, multicase study design to develop an in-depth understanding on each component across a range of FE settings.

Sample: Six FE settings across England and Wales

Methods

1. Focus groups with FE students (n=4 per college), staff (n=1-2 per college), interviews with managers (n=1-2 per college) and Brook staff (n=10)
2. Survey with all students (n=2105) and staff (n=163) to examine how the components may have differential uptake and acceptability;
3. Key findings and recommendations reported at consultation event with key stakeholders to finalise intervention design

Process of development

Component	Stage 1 Interviews/focus groups	Stage 2 Questionnaire
1. Student-led sexual health action groups	✗	
2. Sex and Relationship Education	✓	✗
3. On-site access to sexual health services	✓	✓
4. Staff training in safeguarding about sexual health and relationships	✓	✓

Intervention

Time

Student-led sexual health action groups

- Students lacked motivation to engage in groups;
- The topic of the group also put students off;
- Sexual health and relationships needs to be incorporated as part of wider student action;
- More suitable for school settings where students have more impetus to change (investment/longevity)

"I think the problem with students of that age as well is that there's that element of, of embarrassment of kind of, do I really want to be part of this 'cause it's all to do with sex, are people going to think that I'm having sex all the time?" FE College 1 (Wales) Staff Focus Group 1

Not taken forward as a potential component after Stage 1

Results: Sex and relationship education

- Varied level of FE student knowledge and skills relating to sexual health and relationships
- FE setting considered “too late” for SRE
- Diverse FE settings introduce challenges for delivering SRE
- Needs to be introduced from a younger age and delivered by specialist staff/external organisations

- Not taken forward as a potential component after Stage 2

On-site sexual health and relationship services in FE setting

- All colleges had some sexual health and relationship service;
- Almost a half (46%) to two thirds (68%) of students do not know what services their FE setting provided;
- 35% of staff do not know what services their FE setting provides;
- 88% of sexually active students have never attended an on-site service;
- 44% said they would attend.

Important component to be taken forward for intervention development

Staff training in safeguarding about sexual health and relationships

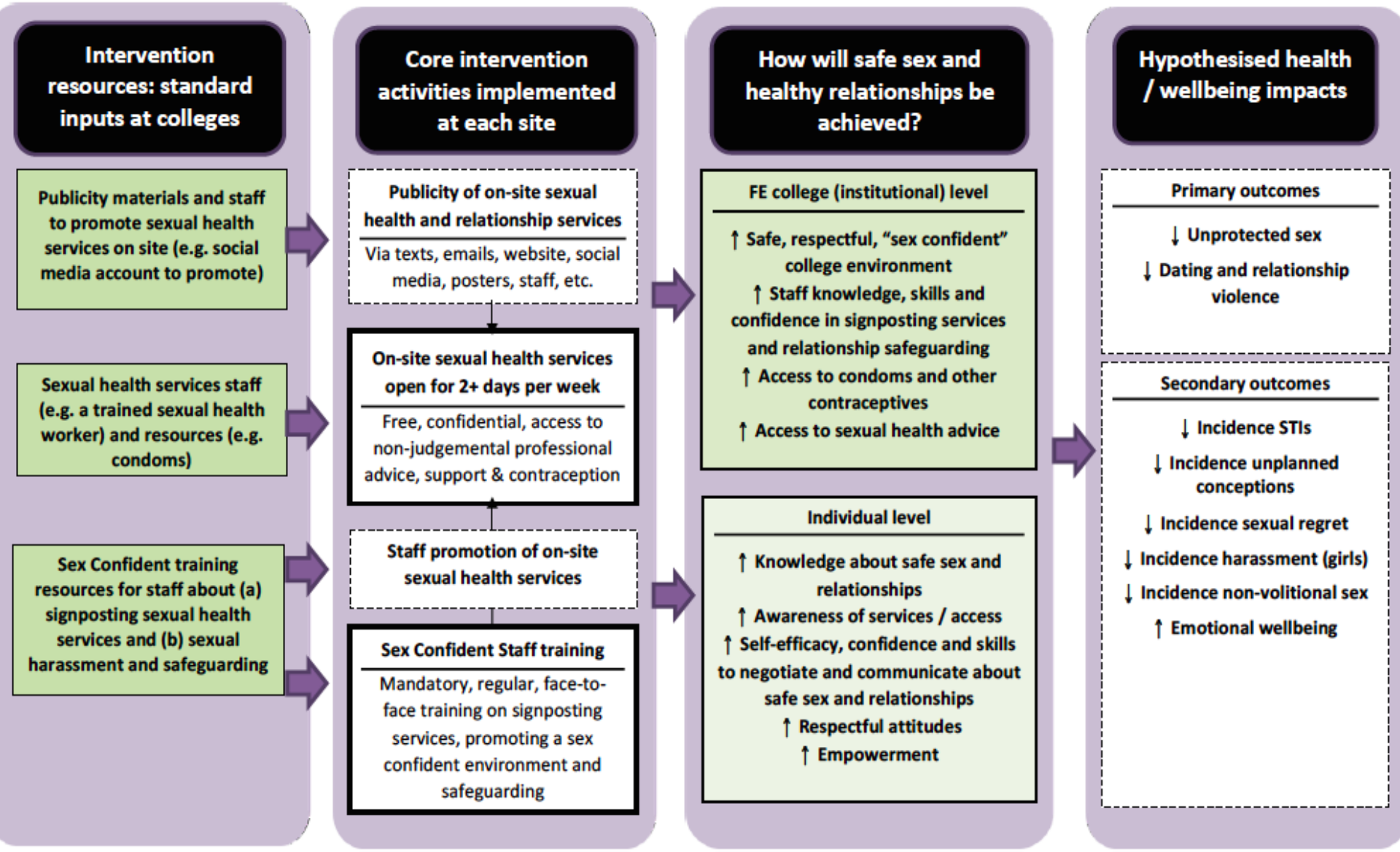
- 80-90% staff felt confident intervening with safeguarding issues, but only around 40% of students reported that staff took appropriate action;

- Over 50% of staff did not receive, or did not *know* if they received training about safeguarding in sexual health and relationships;

- Three quarters of staff wanted compulsory training and two thirds wanted *all* staff to be trained

Important component to be taken forward for intervention development

Results: SAFE intervention logic model



Critical reflections on co-production

- 'dark side' potential to reproduce inequalities if only those who are most able are involved
- participants are compelled to solve problems as a substitute for labour
  - adding co-production to workload = tension with researchers;
- tokenistic cover for already made political decisions
- threat to fidelity if co-production continues into piloting

Clarke, D, et al. BMJ open. 2017 Jul 1;7(7):e014650
Bombard, Y, et al. Implementation Science. 2018 Dec;13(1):98.

Need for outcome evaluations

- Few evaluations on impact of co-production on health

- "…whether these outcomes translate into improved quality of care" (*Bombard, Y, et al. Implementation Science. 2018 Dec;13(1):98*.)
- "…evaluate clinical and service outcomes as well as the cost-effectiveness of co-production relative to other forms of quality improvement." *(Clarke, D, et al. BMJ open. 2017 Jul 1;7(7):e014650)*
- *"impact is by no means guaranteed". (Greenhalgh et al., Milbank Q 2016;94:392–429.)*

- 712 papers acute care: 11 included, one health outcome (Clarke et al., 2017)
- Voorberg, Bekkers & Tummers (2015): 4,716 papers (122 included), 18 outcomes, none health

Conclusions

- Acceptability – implementation – effectiveness
  - Advancing prevention science is dependent on knowing if an intervention is effective or not;
  - Reducing implementation failure as an explanation means you get a better test of an intervention;
- Need for evaluations on effect of co-production on health outcomes
- Principles of user centred design – systems analysis within context and phased cyclical prototyping may be useful augmentations of existing frameworks for intervention development
- More funding is needed to widen pipeline from intervention development to piloting

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Thank you

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ASSIST+Frank team:

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Athena SWAN Bronze Award

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Funded by Welsh Government

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

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