Co-producing and prototyping interventions

Dr James White (whitej11@cf.ac.uk)
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

Co-creation

Co-construction

Co-innovation

Patient engagement

Patient involvement

Co-design
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.).”

“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?

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

> **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

Software lifecycle development (Royce, 1970)

- Software concept
- Research question/intervention idea
- Requirements analysis
- Needs analysis/Stakeholder engagement
- Architectural design
  - Architectural design = systems analysis
- Detailed design
- Logic model
- Coding and debugging
  - Debugging = Feasibility testing/internal/external prototyping
- Coding = writing
- System testing
- Piloting
A framework for co-producing & prototyping interventions

• Existing guidance focuses on developing evidence base and intervention theory
  – Evidence base for health problem already established
  – Intervention theory 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)
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

Hypothesised Mechanisms of Action

Core intervention activities

Network level
- Diffusion of non-smoking norms from peer supporters to peer group
- Smokers in peer network
- Frequency of communication on risks of smoking

Individual level
- Knowledge about smoking harms and norms
- Anti-smoking attitudes

School level
- Non-smoking norms diffused at a school level
- Perceived prevalence of smoking

Y8 survey to identify suitable pupils
- Top 18% invited to recruitment meeting

Deliver off-site training - Risks and harms of smoking - Skills (listening communication)

Follow-up school visits (x 4)

Informal conversations with peers

Commit to stop smoking

Certificate of contribution

Deliver off-site training - Risks and harms of drugs - TTF details - Refresh skills (listening communication)

Drug users in peer network
- Frequency of communication on risks of communication on risks of drugs

Re-engage pupils in Y9

Receive training

Commit to stop using drugs / reduce use

Informal conversations with peers

Certificate of contribution

Remote follow-up contact (x 2)

Reception training

Informal conversations with peers

Commit to stop using drugs / reduce use

Certificate of contribution

Reception training

Informal conversations with peers

Commit to stop using drugs / reduce use

Certificate of contribution

Talk to Frank (TTF) service

Follow-up school visits (x 2)

Mental health

Health Status

Anti Social behaviour

Methods of help seeking

Core intervention activities

School level
- Anti-drug norms diffused at a school level
- Perceived prevalence of drug use

Network level
- Diffusion of anti-drug norms in peer network
- Drug users in peer network
- Frequency of communication on risks of drugs

Individual level
- Knowledge about drug use harms and norms
- Anti-drug attitudes
- Normative levels of drug use
- Methods of help seeking

Desire to quit

School level
- Anti-drug norms diffused at a school level
- Perceived prevalence of drug use

Network level
- Diffusion of anti-drug norms in peer network
- Drug users in peer network
- Frequency of communication on risks of drugs

Individual level
- Knowledge about drug use harms and norms
- Anti-drug attitudes
- Normative levels of drug use
- Methods of help seeking

Desire to quit

Methods of help seeking
Focus groups (13-14 yrs)
Stakeholder consultation
Focus groups (ASSIST)
Observations of current practice

Consultation with ALPHA
Evidence review

DRAFT INTERVENTION MATERIALS PRODUCED
- Expert review of materials
- Minor refinements
- Test materials with ALPHA

PILOT INTERVENTION MATERIALS PRODUCED
- Researcher notes from training sessions
- Train delivery team
- Trainers’ evaluations of training sessions

1. Scoping & Engagement
2. Co-production
3. Prototyping

2013-2014
July 2014 – Nov 2014
Dec 2014 – Feb 2015

Intervention Development and Prototyping

Consultation with ALPHA
Evidence review
Focus groups (13-14 yrs)
Stakeholder consultation
Focus groups (ASSIST)
Observations of current practice

Consultation with ALPHA
Evidence review
Focus groups (13-14 yrs)
Stakeholder consultation
Focus groups (ASSIST)
Observations of current practice

Meetings with delivery team
Discuss content
Agree content
Refine
Feedback

Interviews with delivery team

Researcher notes from training sessions
Train delivery team
Trainers’ evaluations of training sessions
Recruit peer supporters

Train peer supporters

Deliver follow-ups

Post-intervention data collection

Deliver +FRANK 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

Deliver FRANK friends intervention in 1 school

Observations of delivery to assess fidelity

Peer supporters’ evaluations of intervention

Trainers’ self-assessments of delivery

Interviews with trainers about intervention

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

Refinements to intervention and materials

Focus group with trainers

Consultation with Trial Management Group
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

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

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.)


• 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

Flowchart of MOST

- **Action**: square
- **Information Input/Output**: parallelogram
- **Decision**: diamond
- **Product**: oval

1. **Step 1**: Establishment of theoretical model
2. **Step 2**: Identification of set of intervention components to be examined
   - **Step 3A**: Experimentation to examine individual intervention components
   - **Step 3B**: Refinement via experimentations and other methods (optional)
3. **Step 4**: Assembly of beta intervention
4. **Step 5**: Confirmation of effectiveness of beta intervention via RCT
   - **Is beta intervention expected to be effective?**
     - **YES**
     - **Step 5**: Confirmation of effectiveness of beta intervention via RCT
     - **NO**
5. **Step 6**: Release of new intervention
   - **Is beta intervention effective?**
     - **YES**
     - **Step 6**: Release of new intervention
     - **NO**
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 Education (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.
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

<table>
<thead>
<tr>
<th>Component</th>
<th>Stage 1 Interviews/focus groups</th>
<th>Stage 2 Questionnaire</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Student-led sexual health action groups</td>
<td>❌</td>
<td></td>
</tr>
<tr>
<td>2. Sex and Relationship Education</td>
<td>✅</td>
<td>❌</td>
</tr>
<tr>
<td>3. On-site access to sexual health services</td>
<td>✅</td>
<td>✅</td>
</tr>
<tr>
<td>4. Staff training in safeguarding about sexual health and relationships</td>
<td>✅</td>
<td>✅</td>
</tr>
</tbody>
</table>

**Time**

**Intervention**
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

**Intervention resources: standard inputs at colleges**
- Publicity materials and staff to promote sexual health services on site (e.g. social media account to promote)
- Sexual health services staff (e.g. a trained sexual health worker) and resources (e.g. condoms)
- Sex Confident training resources for staff about (a) signposting sexual health services and (b) sexual harassment and safeguarding

**Core intervention activities implemented at each site**
- Publicity of on-site sexual health and relationship services
  - Via texts, emails, website, social media, posters, staff, etc.
- On-site sexual health services open for 2+ days per week
  - Free, confidential, access to non-judgemental professional advice, support & contraception
- Staff promotion of on-site sexual health services
- Sex Confident Staff training
  - Mandatory, regular, face-to-face training on signposting services, promoting a sex confident environment and safeguarding

**How will safe sex and healthy relationships be achieved?**
- **FE college (institutional) level**
  - ↑ Safe, respectful, “sex confident” college environment
  - ↑ Staff knowledge, skills and confidence in signposting services and relationship safeguarding
  - ↑ Access to condoms and other contraceptives
  - ↑ Access to sexual health advice
- **Individual level**
  - ↑ Knowledge about safe sex and relationships
  - ↑ Awareness of services / access
  - ↑ Self-efficacy, confidence and skills to negotiate and communicate about safe sex and relationships
  - ↑ Respectful attitudes
  - ↑ Empowerment

**Hypothesised health / wellbeing impacts**
- **Primary outcomes**
  - ↓ Unprotected sex
  - ↓ Dating and relationship violence
- **Secondary outcomes**
  - ↓ Incidence STIs
  - ↓ Incidence unplanned conceptions
  - ↓ Incidence sexual regret
  - ↓ Incidence harassment (girls)
  - ↓ Incidence non-volitional sex
  - ↑ Emotional wellbeing
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
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
Thank you

ASSIST+Frank team:
James White (Chief Investigator; Cardiff University)
Jemma Hawkins (Cardiff University)
Laurence Moore (Glasgow University)
Rona Campbell (Bristol University)
Adam Fletcher (Cardiff University)
Chris Bonell (London School of Hygiene and Tropic Medicine)
Simon Murphy (Cardiff University)
Matt Hickman (Bristol University)
Will Hollingsworth (Bristol University)
Aimee Grant (Cardiff University)
Vanessa Er (London School of Hygiene and Tropic Medicine)
Luke Midgely (Cardiff University)

SAFE team:
Honor Young (Chief Investigator; Cardiff University)
Chris Bonell (London School of Hygiene and Tropic Medicine)
Adam Fletcher (Cardiff University)
Catherine Turney (Cardiff University)
Ruth Lewis (Glasgow University)
Julia Townson (Cardiff University)

Public Health Wales ASSIST trainers:
Gemma Cox, Mathew Taylor, Shakira Leslie, Rebecca Williams, Elizabeth McIntosh, Eiddan Harries, Lynsey Northall, Alwen Jones, Buddug James, Rebecca Reed.

Brook sexual health team

Centre for Trials Research:
Kim Madden (Study Manager), Kerry Fuery, Katie Gillet, Julia Townson, Tim Pickles, Mark Kelson, Lianna Angel, Nigel Kirby.

We’d also like to thank the ALPHA young people’s involvement group, our participants, Zoe, and our colleagues at DECIPHer:IMPACT.

whitej11@cf.ac.uk
References


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


References


Acknowledgements

Funding Acknowledgement:
This project was funded by the National Institute for Health Research Public Health Research Programme (12/3060/03)

Department of Health Disclaimer:
The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Public Health Research Programme, NIHR, NHS or the Department of Health.

ISRCTN: 14415936