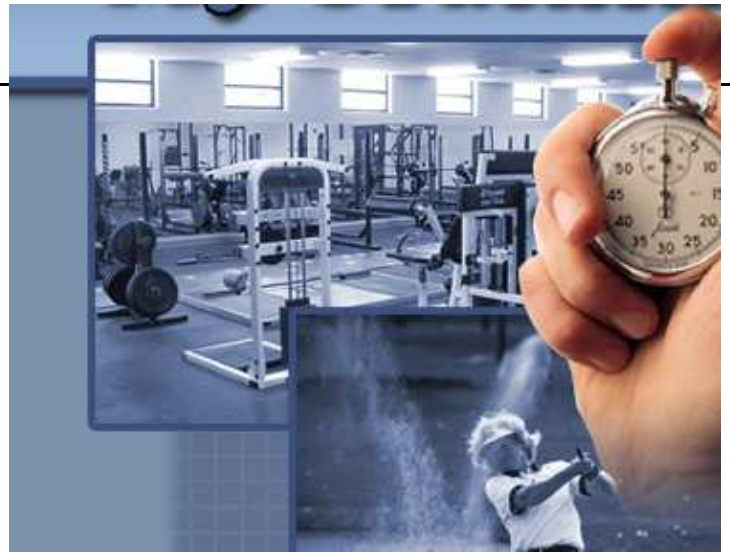
Facilitating and implementing policy trials of complex interventions : the evaluation of the National Exercise Referral Scheme in Wales



Aims

- To understand barriers and facilitators to policy trials
- To identify strategies to facilitate and implement policy trials
- To identify panel discussion questions

Barriers to policy trials – government perspective

Key themes:

Public health policies clearly work and do no harm – why evaluate?

- Policy makers and researchers – two communities?
- Incompatibility of political processes and policy trials.
- Limited knowledge and expertise within government.
- Ethical concerns.
- Prohibitive costs.
- Lack of incentives to champion policy trials.
- Policy maker churn.
- Pejorative use of term experimentation.

(See for example Macintyre, 2011; Roberts *et al*., 2008; Creegan and Hedges, 2007; Jowell, 2003)

Barriers – political processes

- Rigorous evaluation can be challenging i.e. policy-based evidence versus evidence-based policy – importance of incentives.
- Reluctance to pilot, as ‘big bang’ often preferred.
- Political timetables
  - Short Ministerial tenure – desire for rapid and comprehensive roll-out
  - Sufficiently well developed interventions
  - Adequate time for follow-up
- Language e.g. when policies communicated as being successful prior to evaluation can have ethical implications.
- Technocratic arguments – can ignore evidence but shouldn’t be ignorant of it.
- Arguments generic to an extent but policy trials seen to provide definitive evidence that is harder to ignore.

Barriers – policy/research relationship

Policy trials associated with discredited linear-rational model of policy process and instrumental impact?

- Realism versus over-enthusiasm
- Some instrumental impact can be found

- Two Communities?
  - Limited policy maker understanding of role of policy trials?
  - Limited researcher understanding of political constraints of policy trials?
  - Suggest that this model is exaggerated.

- PHIRN illustrates the potential of interactive model to developing and implementing policy trials.

Barriers – ethical concerns

- Withholding a service frequently raised as an issue – part of ‘stylised critique’ of policy trials (Oakley, 2006).
- Suspicion – UK respondents (Jowell, 2003) not convinced by:
  - Universal use in medicine; or
  - Benthamite argument on individual inequity for societal benefit.
- Exacerbated when:
  - Policies prematurely described as being effective;
  - Decision makers (and stakeholders) convinced of effectiveness;
  - Existing, rather than new service, being trialled.
- Can be politically challenging e.g. use of financial incentives in welfare to work policy.
- ‘*It seems perverse to see it as ethical to give or withhold programmes of unknown benefit to 100% of the population, but not to 50%*’ (Macintyre, 2011).

Barriers – costs

- Costs seen as prohibitive, particularly in current financial climate.
- Recent push to emphasise that policy trials can be undertaken cheaply using administrative data (e.g. Behavioural Insight Team, 2012; CEBP, 2012).
- Possibly no more expensive than equivalent (quasi-experimental) designs with some form of control.
- Policy trials more efficient at reducing causal uncertainty, so cheaper in long run (Cook, 2002).
- Important to assess cost relative to that of potentially implementing ineffective policy i.e. policy trial as an investment (to save).
  - e.g. US National Job Training Partnership Act trial cost $50m but annual spend was $1.8bn (Burtless, 1995).

But there are levers as well!

- ~~Research-policy interaction.~~
- Advocates within and outwith government.
- Independence of evaluation team from policy makers/politicians.
- Outcomes and potential for economic analysis.
- Departure from describing well established problems.
- Ease of presentation of trial findings.
- Body of evidence emerging that policy trials are possible, can estimate outcomes and inform theory/practice i.e. explore ‘black box’.

ERS - evidence and policy

- Inconsistent RCT evidence due to heterogeneity and quality of schemes. Need for rigorous RCTs of theoretically informed approaches, clear description of content and subgroup effectiveness (Pavey et al, 2011).

- Rapid expansion encouraged by DoH with policy defined as a *''success''* (DoH 2006).

- ERS evolved in parallel to and with little reference to evidence base (Snowden and Raine 2008).

- National Institute for Health and Clinical Excellence (NICE 2006) guidance *''"Practitioners, policy makers, and commissioners should only endorse exercise referral schemes to promote physical activity that are part of a properly designed and controlled research study to determine effectiveness"* .

Challenges to building evidence based ERS policy

- Widespread assumptions of effectiveness,
- Perceived withdrawal of service and lack of clinical equipoise
- Possible low recruitment and impaired retention for randomisation
- Adverse consequences of dismantling schemes - partnership working and delivery systems
- Difficulties in obtaining research funding for non randomised designs and intervention costs from partners
  - (Snowden and Raine 2008; Simmons et al, 2009)

The evaluation of NERS in Wales

- WG commissioned independent evaluation of effectiveness for mental health and / or CHD risk referrals
- Rolled out in 3 phases, first phase (12 LHBs) within a randomised controlled trial, with nested economic and process evaluations
- Pragmatic randomised controlled trial with nested process and economic evaluations for CHD risk and mental health patients.
- NERS (16 weeks) –Motivational Interviewing, £1 cost and post scheme relapse strategies. Control – normal care and advice booklet.
- Primary outcome 7-day physical activity by telephone interview [Blair 1985]. Secondary outcomes - Hospital Anxiety and Depression Scale by post (HADS)

Key aims

- To estimate the effect of NERS on physical activity, anxiety and depression, compared to the provision of an information leaflet and normal care.
- To understand **why** it may be effective, for **whom**, under what **circumstances** and at what **cost** [Pawson, 1997] – reflects REAIM framework.

Strategies and structures to facilitate a trial

- Development of high quality schemes a key action area [WAG, 2005]
- Existing local funding arrangements ending and Welsh Assembly Government (WAG) steps in.
- Policy development coincided with publication of NICE guidelines recommending future roll-out should only proceed as part of RCT.
- Existing good practice assessed and standardised in Wales-wide protocols in collaboration with practitioners [WAG 2006]. Local buy in
- WAG funds an Exercise Co-ordinator (EC) and one to two Exercise Professionals (EP) in each Local Health Board (LHB) and national support for a standardised programme.
- NERS rolled out - replaced local schemes in three phases from 2007.

Commissioning the trial

- Embedded governmental social researchers – lobbying for policy evaluations to encourage evidence culture.
- Ministerial commitment to evidence and long term funds dependent on effectiveness.
- Timetable challenging to fit in with Ministerial funding decision.
- Research call –included period of consultation between policy, gvt social researchers, practice and academia.
- Research bid – costed for a number of scenarios.
- Substantial pre trial development phase - Early engagement between government researchers, policy co-coordinator, local implementers and evaluators = promote and negotiate scientific and practical considerations for rigorous design.
- Opportunity to revisit research costs in light of decisions.
- Gvt social researchers as key link.

Significant barriers to randomisation and recruitment

- PH workforce belief in effectiveness of local schemes. Concerns re reduced throughput for schemes
- Significant GP resistance – lack of clinical equipoise. Perception of change or withdrawal of service [Sowden and Raines, 2008].

Implementing policy trials - on going strategic “hearts and minds” activity

- Practice/policy/evaluators implementation group – developing research literacy, addressing initial and on going concerns
- Briefing sessions for GPs by the evaluation and national policy team. BMA approval, GP on team and CMO promotion DVD
- Senior policy support for random allocation = access to NERS only through study
- Advantage of number of areas.
- Trial recruitment ends once areas have met recruitment targets

Implementing policy trials - recruitment and retention

- Briefings and distribution of trial information by NERS co-ordinators
- Opportunistic referral by health professionals
- Trial recruitment undertaken by the evaluation team after clinicians had provided basic information to patients = low research burden on health professionals who promoted but did not recruit to the trial.
- Minimal baseline data collection – demographics, GPAQ
- Data collection resources concentrated on 12 month telephone interview

Recruitment and 12 month follow up rates

- During trial recruitment period
  - 4,779 health professional referrals received
  - 3,286 were eligible and sent full informed consent
  - 2,160 recruited (890 non response & 236 not consenting)

- At 12-month
  - 1479 (68.5%) for 7D-PAR , 992 (45.9%) for HADS, 798 (55%) for HE
  - Response rates were similar in the two groups

- Of those allocated to the intervention trial arm
  - 43.8 % (n=473) completed the 16 week programme,
  - 41.3% (n=446) started the programme but did not complete
  - 14.9% (n=161) failed to attend.

Effectiveness

- **CHD risk factor referrals**
- NERS demonstrated higher levels of activity (OR 1.29, 95% CI: 1.04 to 1.60) compared to normal care.

- **CHD with mental health or mental health referrals**
- NERS demonstrated significantly lower levels of anxiety (-1.56, 95% CI -2.75 to -0.38) and depression (-1.39, 95% CI -2.60 to -0.18) but no significant effect on physical activity (1.06, 95% CI: 0.73 to 1.55).

Effectiveness

- **Level of adherence**
- Greater effects for scheme completers compared to partial or non attenders – activity (1.46, 95% CI 1.17 to 1.84), depression (-1.24, 95% CI -1.88 to -0.61) and anxiety (-1.12, 95% CI -1.80 to -0.44).

- **Gender**
- Mental health benefit only apparent among females - depression (2.10, 95% CI 0.98 to 3.23) and anxiety (1.93, 95% CI 0.72 to 3.14).

- **Welsh Index of Multiple Deprivation**
- No significant differences.

- **Cost effectiveness**
- Assuming referral to the scheme was at a routine GP consultation = £12,111 per QALY, well within the NICE threshold of £20,000-£30,000.

Implementing policy trials – maintaining external validity and understanding process

- **Pragmatic effectiveness RCT** - no influence on scheme other than randomisation at step one of referral.
- **Established common programme database and protocols for data collection and assessment.** Substantial collaboration with national and local coordinators = comparable and reliable data on *uptake, reach*, and *fidelity.*
- **Exercise coordinators** as key link – maintenance of databases written into job descriptions.
- **Importance of process evaluation in pragmatic RCTs – REAIM framework**

Implementation of NERS

Limited delivery of several aspects of one-to-one consultations:

- Motivational interviewing
  - Mean fidelity - 8%. All below 25%. Dominated by structured assessment
- Goal setting and reviewing
  - Only 1 in 3 goals contained a measurable and time-bound element.
  - Most were non-specific (i.e. 'lose weight', 'get fitter')
- Four week follow up of non-attendees
  - 20.1% of non-attendees contacted
  - A third of those contacted returned to the scheme, but most areas didn't do this
- Patient follow-up after scheme exit
  - Most scheme completers (76%) contacted at 8 months
  - Only 56% contacted at 12 months
- Patients – social support group important

Reach

44% of referred patients completed NERS, so it didn't work for everybody

Qualitative data, particularly from professionals, offered insights into patterning

- Access issues perceived as limiting participation in more rural areas
- Class times cited as inconvenient for some working age patients
- Perceived as more effective for patients who actively sought referral, and were already highly motivated to change
- Mental health patients perceived as requiring greater support to assimilate into exercise environment
- Social context perceived as most beneficial for older patients and women

Conclusions

- Policy trials are feasible and can be facilitated.
- Current focus in government of picking the low hanging fruit but don't underestimate the complexity of conducting policy trials.
- Policy officials will not always understand the implications of planned roll-out for study design so early engagement is key.
- 'Winning hearts and minds' is critical but can be time consuming.
- Serendipity is important but so are formal structures to maximise the chance of sustaining ways of working beyond individual relationships.
- Need for on going partnerships and pragmatism to work around the numerous political and operational challenges to maintain rigour

References

- Murphy S, Raisanen L, Moore G, Tudor Edwards R, Linck P, Williams N, Ud Din N, Hale J and Moore L (2010) A pragmatic randomised controlled trial of the Welsh National Exercise Referral Scheme: protocol for trial and integrated economic and process evaluation BMC Public Health, 10:352 http://www.biomedcentral.com/1471-2458/10/352

- Moore, GF., Moore, L. & Murphy, S. (2011). Integration of motivational interviewing into practice in the National Exercise Referral Scheme in Wales: a mixed methods study. Behavioural and Cognitive Psychotherapy Oct 3:1-18. [Epub ahead of print]

- Moore, GF., Moore, L. & Murphy, S. (2011) Facilitating adherence to physical activity: exercise professionals' experiences of the National Exercise Referral Scheme in Wales. BMC Public Health 11:935 http://www.biomedcentral.com/1471-2458/11/935

- Murphy S, Tudor Edwards R, Williams N, Raisanen L, Moore G, Linck P, Hounsome N, Ud Din N and Moore L An evaluation of the effectiveness and cost effectiveness of the National Exercise Referral Scheme in Wales UK: a randomised controlled trial of a public health policy initiative Journal of Epidemiology and Community Health (in press)

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Workshop questions

- For policy/practice/academia – what are the key research questions that need answering in your area of work?
- To what extent can RCTs answer these questions?
- What are the barriers to developing and risks in implementing RCTs?
- Panel questions