

for real-world change in primary care



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I have no conflicts of interest relevant to this presentation



for real-world change in primary care



- Positioning implementation research
- Exemplars of implementation
- The challenge of implementation





Human physiology First in humans (healthy volunteers) Proof of concept Phase 1 clinical trials

Human physiology and the potential for intervention

Findings from basic research are tested for clinical effect and/or applicability

https://catalyst.harvard.edu/pathfinder/





Phase 2 clinical trials Phase 3 clinical trials

Efficacy in optimal settings

New interventions are tested under controlled environments to form the basis for clinical application and evidence-based guidelines

https://catalyst.harvard.edu/pathfinder/





Phase 4 Clinical Trials Health Services Research -Dissemination, Communication -Implementation Clinical Outcomes Research.

Effectiveness in realworld settings

Explore ways of applying recommendations or guidelines in clinical practice.

https://catalyst.harvard.edu/pathfinder/





Public health implementation Population-level outcome studies Social Determinants of Health.

Improved global health

Study factors and interventions that influence the health of populations.

https://catalyst.harvard.edu/pathfinder/





It is not enough to show that an intervention can work under ideal conditions (as in a trial)

The implementation question is 'will it work – or can I adapt it to make it work - in my setting'





Developing and evaluating complex interventions



Pinnock H, et al. Annals ATS 2014;11: S118-S122



Intervention

The evidence-based intervention being implemented

Implementation strategy

The evidence-based strategies used to promote implementation

Report the following:		"Implementation strategy" refers to how the intervention was implemented.		
		"Intervention" refers to the healthcare or public health intervention that is being implemented.		
Checklist item		Implementation Strategy	Intervention	
Title	1	Identification as an implementation study, and description of the methodology in the title and/or keywords)		
Abstract	2	Identification as an intervention implementation study, including a clear description of the implementation		
		strategy, the clinical, healthcare, or public health intervention and the key outcomes.		
Introduction	3	Description of the deficiency in healthcare or public health that the intervention being implemented a		
		address.		
	4	The scientific background and rationale for the	The scientific background and rationale for the	
		implementation strategy (including any underpinning	intervention being implemented (including evidence	
		theory/framework/model, how it is expected to	about its effectiveness and how it is expected to	
		achieve its effects and any pilot work).	achieve its effects).	
Aims	5	The aims of the study, differentiating between implementation strategy objectives and any intervention		
		objectives.		



Pinnock H, et al. Standards for Reporting Implementation Studies (StaRI) statement. BMJ 2017;347:f6753



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Checklist item		Implementation Strategy	Intervention		
Methods:	6	The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting			
description		standards) and any changes to study design/outcomes,	ls) and any changes to study design/outcomes, with reasons		
	7	The context in which the intervention was implemented	. (Consider social, economic, policy, healthcare,		
		organisational barriers and facilitators).			
	8	The characteristics of the targeted 'site(s)'	The population targeted by the intervention and any		
		(locations/personnel/resources etc.) for	eligibility criteria.		
		implementation and any eligibility criteria.			
	9	A description of the implementation strategy	A description of the intervention		
	10	Any sub-groups recruited for additional research tasks, a	\sim		
Methods:	11	Defined pre-specified primary and other outcome(s) of	Defined pre-specified primary and other outcome(s) of		
evaluation		the implementation strategy, and how they were	the intervention (if assessed), and how they were		
		assessed. Document any pre-determined targets	assessed. Document any pre-determined targets		
	12	Process evaluation aims and outcomes (related back to			
		the 'logic pathway').		Standards for reporting implementation studies	
	13	Resource use and costs data for the implementation stra	rce use and costs data for the implementation strategy and / or the intervention (if assessed).		
	14	Rationale for sample sizes (including sample size calcul	lations, budgetary constraints, practical considerations,	tement. <i>BIVIJ</i> 2017;347:f6753	



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Checklist item		Implementation Strategy	Intervention	
Results	17	Characteristics of the recipient population for the implementation strategy.	Characteristics (if appropriate) of the recipient population for the intervention	
	18	Primary and other outcome(s) of the implementation strategy.	Primary and other outcome(s) of the Intervention (if assessed).	
	19	Process outcomes (that relate back to the 'logic pathway').		
	20	Resource use and cost analyses (includes a budget impact analysis, where relevant).		
	21 Reports representativeness and outcomes of subgroups including those recruited to specifi		uding those recruited to specific research tasks	
	22	Fidelity to implementation strategy and adaptation to that process (where applicable).	Fidelity to delivering the core components of intervention and adaptations (where applicable).	
	23	Contextual changes which may have affected results		
	24	All important harms or unintended effects in each group.		
Discussion	25	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications.		
	26	Discussion of policy, practice and research implications of the implementation strategy	Discussion of policy, practice and research implications of the intervention (where applicable)	
General	27	Include statement(s) on regulatory approvals (including as appropriate ethical approval, confidential use of		



ement. BMJ 2017;347:f6753

Outcomes



Pinnock H, et al. Standards for Reporting Implementation Studies (StaRI) statement. BMJ 2017;347:f6753



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This distinction is not only helpful for academics...

Healthcare professionals, managers and policymakers will find it helpful to distinguish between:

- the planned service improvement (eg, treatment, management, core components, resources)
- and the evidence based implementation strategies used to embed the intervention into health systems (eg, adaptation to local context and routines, engaging stakeholders, training, incentives).



Pinnock H, et al. Standards for Reporting Implementation Studies (StaRI) statement. BMJ 2017;347:f6753





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Home-monitoring for hypertension





As an asymptomatic condition, hypertension has traditionally been managed by clinicians measuring blood pressure at intervals. This has limited patients to passively complying with the clinicians' instructions.

Shahaj et al. J Hypertension 2019, 37:264–279

Home-monitoring for hypertension



Meta-review: 98 qualitative studies (in 6 reviews) 446 quantitative studies (in 29 reviews)



For some patients, symptoms acted as a guide for the seriousness of their hypertension and guided their medication use:

- stopped treatment if symptoms disappeared.
- used medication to manage worry or anxiety

Review

Supporting self-management for people with hypertension: a meta-review of quantitative and qualitative systematic reviews

Orjola Shahaj^a, Diarmuid Denneny^{b.c}, Anna Schwappach^d, Gemma Pearce^e, Eleni Epiphaniou^f, Hannah L. Parke^g, Stephanie J.C. Taylor^b, and Hilary Pinnock^a

Home-monitoring for hypertension

Self-monitoring with feedback from healthcare professionals vs usual care



Meta-review: 98 qualitative studies (in 6 reviews) 446 quantitative studies (in 29 reviews)





Foster a therapeutic alliance

- changing the patient's perceptions of the significance of symptoms
- fostering a sense of self-control, motivation, and increased confidence in managing hypertension.

Review

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Tele-monitoring for hypertension





Reduced BP compared with control

- ≈ 4mm drop in systolic BP
- ≈ 2mm drop in diastolic BP

McKInstry et al. BMJ 2013;346:f3030

RCT in Edinburgh, Lothian:

- 401 people with uncontrolled BP
- Outcome ambulatory BP

Cost-effective because of impact on cardiovascular

disease

Stoddart et al. BMJ Open 2013;3:e002681

Trusted, convenient for patients Received positively by healthcare professionals

Hanley et al. BMJ Open 2013;3:e002671



T2









Lack of confidence in IT skills (patients or professionals)

The trial system needed separate log-in

Implementation strategy

Training and helplines

Feedback to practice via 'Docman'



Implementation challenges ...

Mark Florence	DOB:01/10/1990	CHI:1903444659
1 High Street, Bonnyrigg	EH19 3PU	
Mobile: 07898767652		

BP Readings				
Date	Time	Systolic	Diastolic	Alert
18/08/2015	10:01	135	84	BP Above Desired Range
25/08/2015	18:00	130	90	BP Above Desired Range
08/09/2015	12:03	130	98	BP Above Desired Range
15/09/2015	11:25	130	95	BP Above Desired Range
22/09/2015	08:06	280	100	
22/09/2015	08:07	195	100	BP Above Desired Range
22/09/2015	12:43	80	56	BP Below Desired Range
22/09/2015	12:44	260	80	Critical
22/09/2015	12:49	100	60	
22/09/2015	15:06	195	80	BP Above Desired Range
22/09/2015	15:06	171	100	BP Above Desired Range
22/09/2015	15:06	169	80	BP Above Desired Range
22/09/2015	15:07	171	80	BP Above Desired Range



ALERT

READINGS SUGGEST THAT BLOOD PRESSURE IS NOT CONTROLLED. CONSIDER ADHERENCE OR CHANGE IN THERAPY.



PDF sent via normal practice systems:

- No need to change routines
- No need to scroll down
- Interval set by the general practitioner

Feedback to practice via 'Docman'



Implementation challenges ...

- Lack of confidence in IT skills (patients or professionals)
- The trial system needed separate log-in
- Initial registration was time-consuming
- Potential increase inequities
- Could be difficult to contact patient
- Patients vary in their clinical needs



Implementation strategy



Training and helplines Feedback to practice via 'Docman' NHS Lothian funded support

NHS Lothian provided equipment

Promote asynchronous consulting

Flexible BP targets and review regimes

Awareness, local champions; feedback of uptake, encouraging adaptation

Outcomes: routine data

Implementation outcomes

75/126 practices in Lothian signed up over 45 months, each recruiting between 6 and 400 patients



Why go down to the surgery when I can do it sitting at the kitchen table? [Patient]



"I think there is a clear vision of not having patients coming in for routine hypertension, and that must be the way forward." (GP)

Health outcomes



Detailed routine data from eight of the practices



Aware of raised BP

"Couldn't bear looking at a 150/110 and I wanted to just be able to see better readings in a way". [Patient]

Improved adherence

Increase in number of prescriptions/patient from 9.63 to 10.69 scripts/year

Adherence by whom...???



Prescribing by the healthcare professional?



Patient adherence to medication?



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- **Exemplars of implementation**
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Supported self-management for asthma

Variable condition

Action plan

Pinnock et al. BMC Medicine 2017;15:64





All people with asthma should be offered selfmanagement education which should include a written personalised asthma action plan and be supported by regular professional review

Supported self-management for asthma

Variable condition

Action plan

Pinnock et al. BMC Medicine 2017:15:64



loctor: Hospital/Clinic:	Personal best PEr Until Date of Plan
Crese: Doing Med. Second Access that Byltness or shortness of brash or skyright ANO Second Statution (ANO Can do sust activities OFFbbmin (87% to 150% of personal best)	Take these conclusion medications everyday. Controller medications New Mach New Other New Other Take spacer when possible
Velocie: Gesting Warse • - Cough, shines: chen trabaines or shorhees of broath CR - Wake up at right dae to attrive sorgetons CR - Can do some, bind at usual activities CR - Caddin - Order Dim. - PGF:b	Take pair regular medicitions and rise up relever medication for 1 hood Toke pair regular medicitions and rise takes Toke pairs Toke Toke pairs Toke
Rect: Avert - Simptoms are worsen; caroot do usual adeletes OF worstness of breach, caroot do usual adeletes OF - envry 2 the 1 boars CR - more than 1 boars a day - PEF: belandLrinin (Less than 50% of personal best)	

What to do if...

Effective written action plans:

- ✓ Symptoms or peak flow (using personal best PF)
- \checkmark 2 to 4 action points
- ✓ Increasing ICS and commencing oral steroids
- ✓ When to seek help

















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Supported self-management for asthma

An effective intervention

HOSPITALISATIONS

Bailey 2009 Boyd 2009 Gibson 2002 Tapp 2007 RECURSIVE

A&E ATTENDANCES

Boyd 2009

Gibson 2002

Tapp 2007

RECURSIVE

UNSCHEDULED CONSULTATIONS

Boyd 2009 Jibson 2002

ibson 200

Relative risk Favours self-management





Meta-review: 27 SRs (270 RCTs)

Pinnock et al. Systematic metareview of supported selfmanagement for asthma: a healthcare service perspective. *BMC Medicine* 2017;15:64

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T2

"As far as possible patients should be trained to manage their own treatment rather than be required to consult their doctor before making changes".

BMJ 1990;301;651-653



т2 А

All people with asthma (and/or their parents or carers) should be offered self-management education which should include a written personalised asthma action plan and be supported by regular professional review



6% had a self-management discussion in the clinical record

Systematic review of implementation studies

Supported selfmanagement can be implemented effectively in routine practice



Actively engaging patients

Training and motivating professionals

Supporting the organisation to prioritise and proactively support self-management.



18 studies

Pinnock H et al. BMC Medicine 2015; 13:127

Total estimated asthma population of 800,000 people in six countries



Systematic review of implementation studies



Supported selfmanagement can be implemented effectively in routine practice



IMP²ART

T3

Pinnock H et al. BMC Medicine 2015; 13:127

IMPlementing IMProved Asthma

self-management as RouTine

Programme of work

Explore current practice Develop and pilot strategies Evaluate in UK-wide cluster RCT Understand the process and sustainability







Patient-facing strategies and resources







T3

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Professional motivation and education

Systematic review: 15 educational interventions (18 papers)





Team building

Local opinion leaders Addressing beliefs about consequences Based on guidelines

Skill development: motivational interviewing

Behavioural regulation

McCleary et al for the IMP²ART team: npjPrim Care Respir Med 2018;28:42







McClatchey K, et al. Trials 2022;23:350



Organisational strategies and routines

Qualitative interviews with general practices

Improve template









Implementation is at least as complex as the intervention... and needs a cycle of development, feasibility testing, refining strategies and evaluation

Consider strategies to address the needs of the patient, professionals and the organisation

The context will strongly influence whether the implementation is successful...

There is a spectrum of trial design from efficacy \rightarrow pragmatic effectiveness \rightarrow implementation - and other approaches to evaluating implementation



Broader inclusion criteria (Selected participants → populations) Increased flexibility for clinical judgement (Tightly controlled → embedded in routine care) Outcomes reflect patient perspectives and/or impact on health services.





Thank you for listening! Any questions?

