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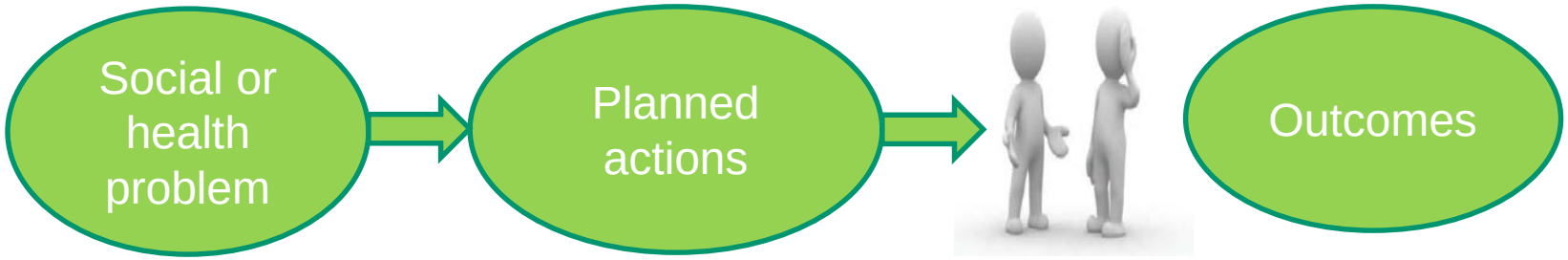
Systematic development and evaluation of complex interventions to improve health:
A route to success?
Sally Wyke
INSPIRING PEOPLE

What is an intervention?

A set of planned actions that are designed to bring about desired changes (outcomes) in a defined population in order to address a social or health problem.



Complex interventions are…..

…. made up of **many components** that act both **on their own** and **in conjunction with each other**

Why does it matter? Research waste

‘Every year, about a third of a trillion dollars (USD) is spent on biomedical research across the world. But there is good evidence showing that much of this investment is wasted because of the way that research priorities are set; the way research is designed, conducted, and analysed; the way research is regulated and managed; the lack of publication of much research; and the poor reporting of research that is published.’

http://www.thelancet.com/campaigns/efficiency/introduction-update

The problem with trials is….

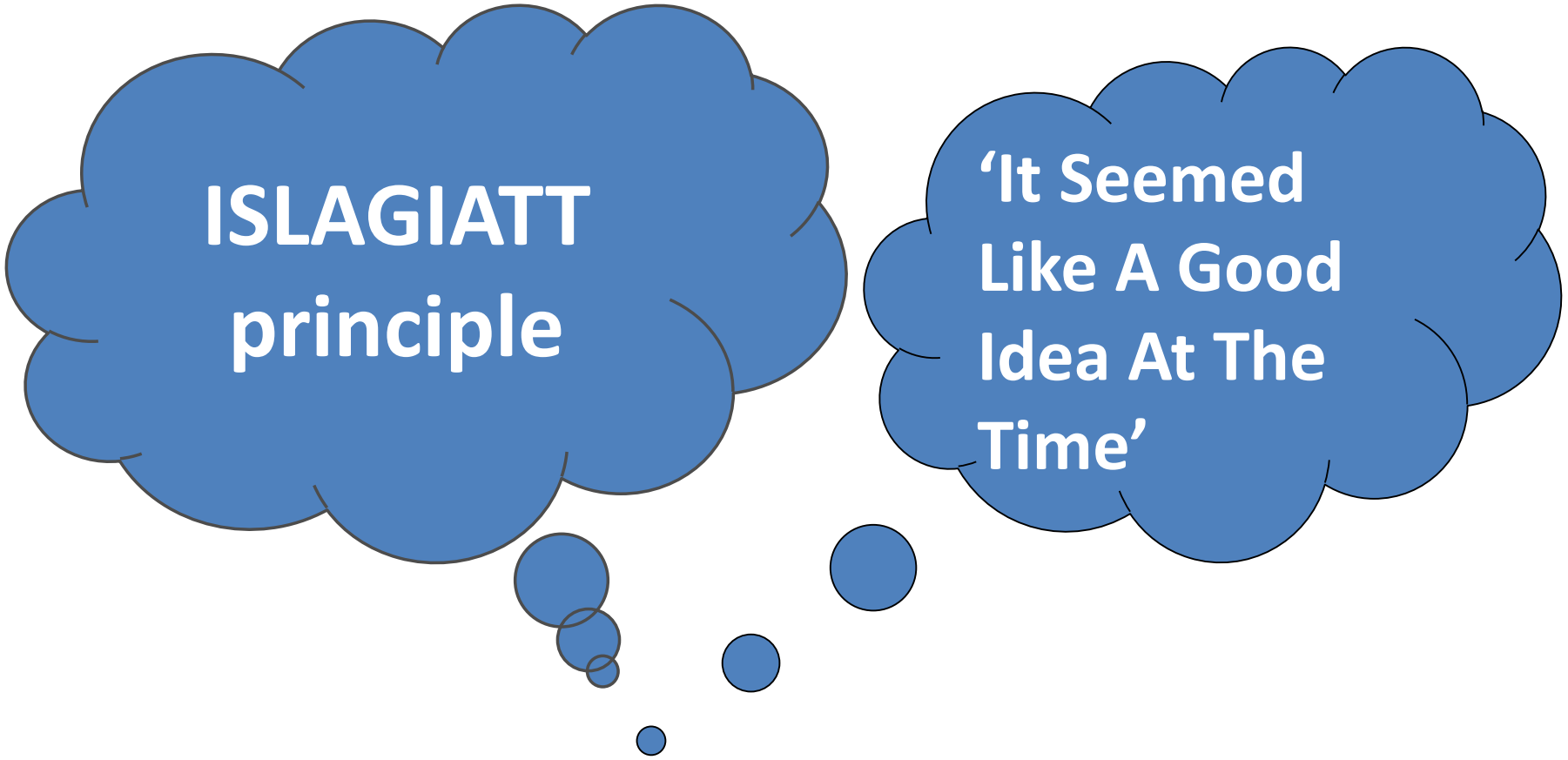
- Only 20% of trials recruit ≥ 80% of target number of participants.*
- Over 60% of HTA-funded trials fail to show postulated statistically significant difference.**

WHY?

- Over-optimism?
- Funding constraints?
- A ‘winner’s curse’ phenomenon? – publication bias***
- Weak evidence base for trial conduct?****
- **Not well enough developed interventions**

*Campbell et al (2007) Health Technol Assess **11**: 1 **Raftery (2013) Lancet **382**: 1278 ***Young et al (2008) PLoS Medicine **5**(10): e201 ****Treweek et al (2015) Trials **16**: 261.

How do you develop an intervention?



Martin P Eccles
Professor of Clinical Effectiveness
Newcastle

The six steps approach to quality intervention development*

1. Define and understand the problem and its causes
2. Clarify which causal or contextual factors are modifiable and have greatest scope for change

3. Identify how to bring about change: change mechanism
4. Identify how to deliver change mechanism

5. Test and refine the intervention on small scale
6. Collect sufficient evidence of effectiveness to justify rigorous evaluation/ implementation

*Wight D, et al (2016) J Epidemiol Community Health 70:520-525.

Living well with multimorbidity: the CARE Plus study

Stewart Mercer
Sally Wyke

Bruce Guthrie
Elizabeth Fenwick
Bridie Fotzpatrick
Alex McConnachie
Rosalind O'Brien
Graham Watt
NHS and Deep End General Practices

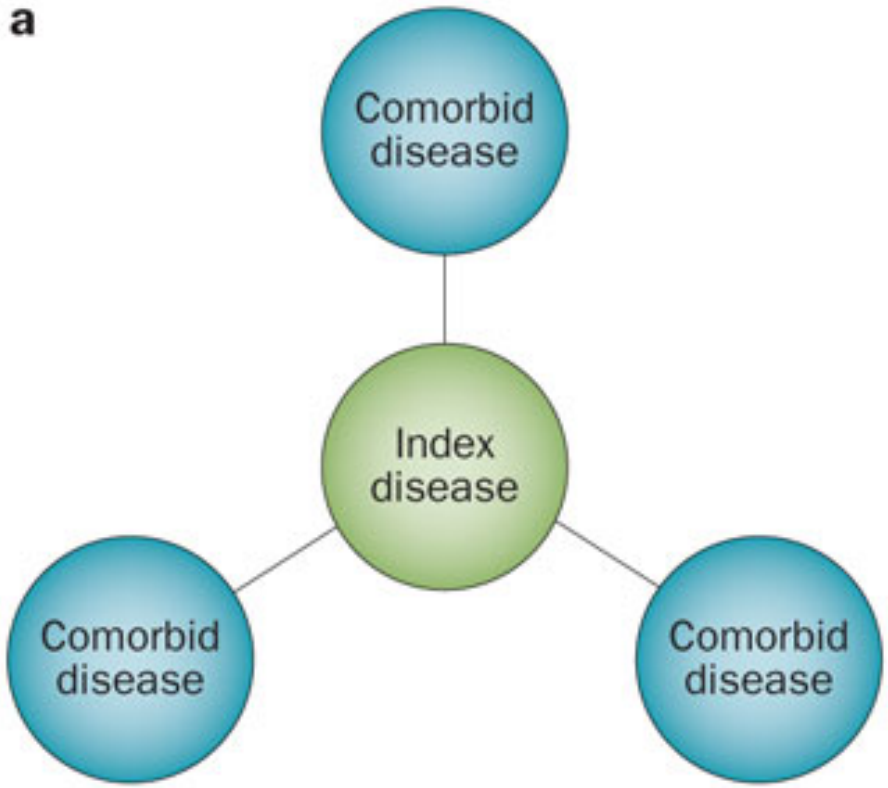
2009- 2013

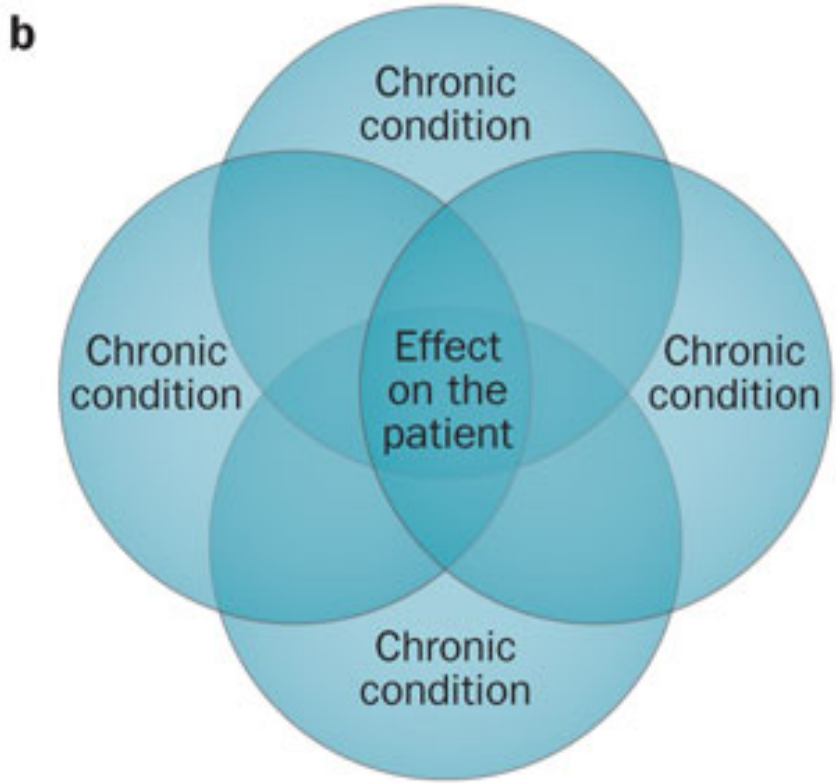
CHIEF SCIENTIST OFFICE

Comorbidity and Multimorbidity

COMORBIDITY

MULTIMORBIDITY





Living well with multimorbidity: Steps and methods

1 & 2. Define the problem and clarify what is modifiable	• 310 general practices -1,754,133 patients • Qualitative interviews - 19 HCPs and 14 patients • Economic analysis: Scottish Health Survey
3 & 4. Identify how to bring about and deliver change	• Co-development in Focus Group Discussions
5 & 6. Test and refine. Gather enough evidence to justify trial	• Pilot study in 2 practices • Exploratory cluster RCT: 8 practices, GPs and nurses; 152 patients • Economic analysis: in-trial and modelling

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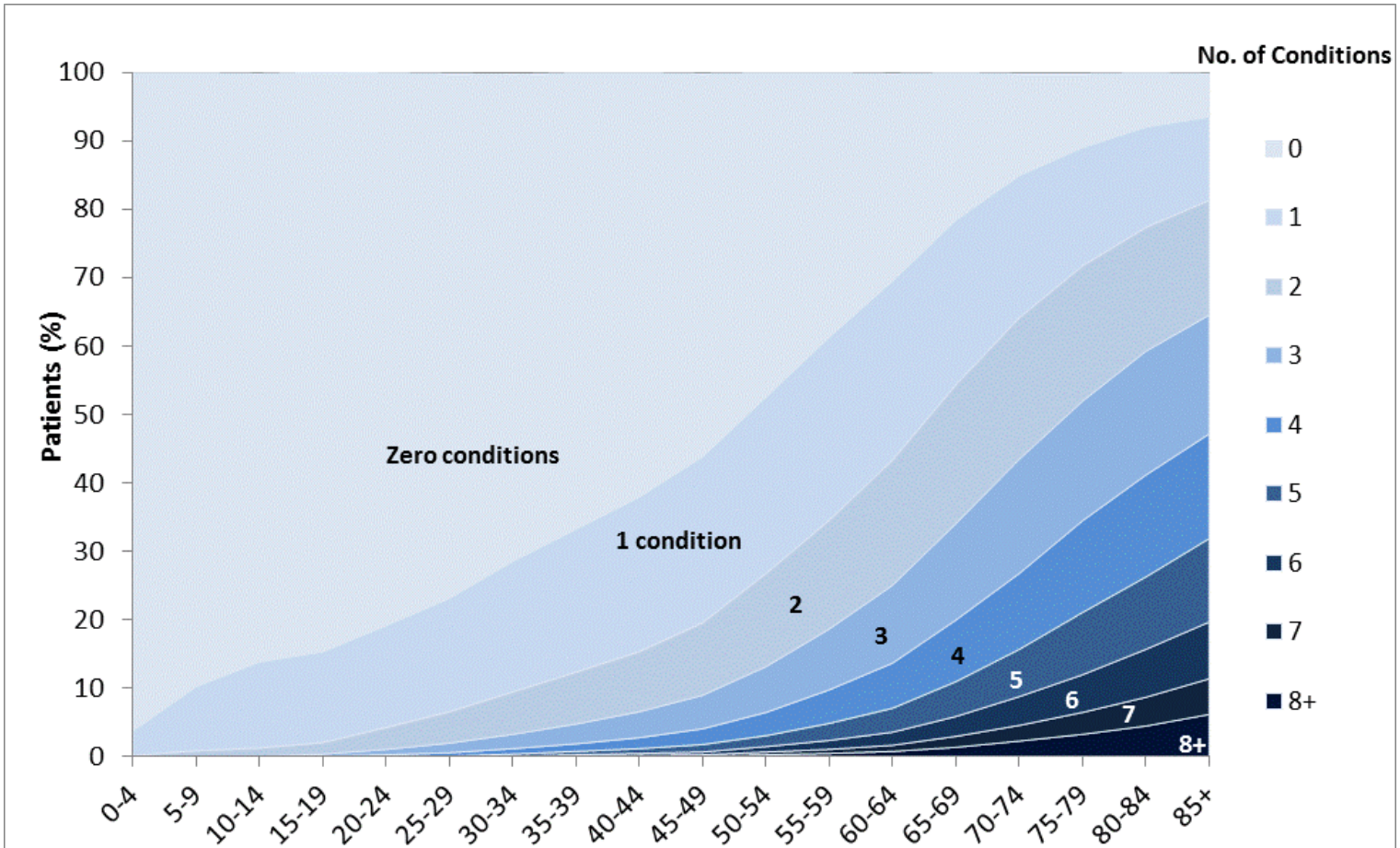
MULTIMORBIDITY

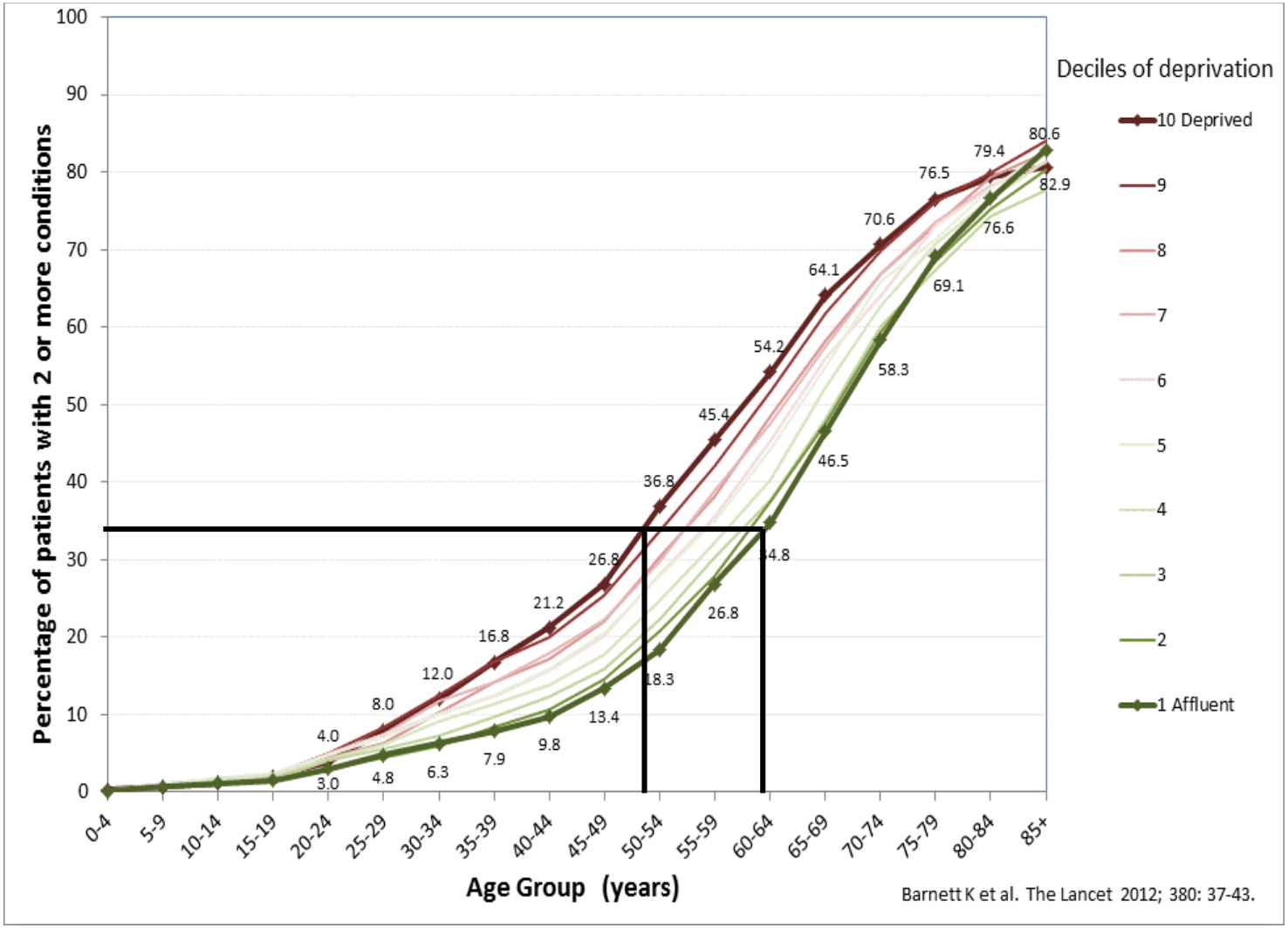
1. UNDERSTAND THE PROBLEM

Multimorbidity is very common

- The majority of over-65s have 2 or more conditions, and the majority of over-75s have 3 or more conditions
- More people have 2 or more conditions than only have 1

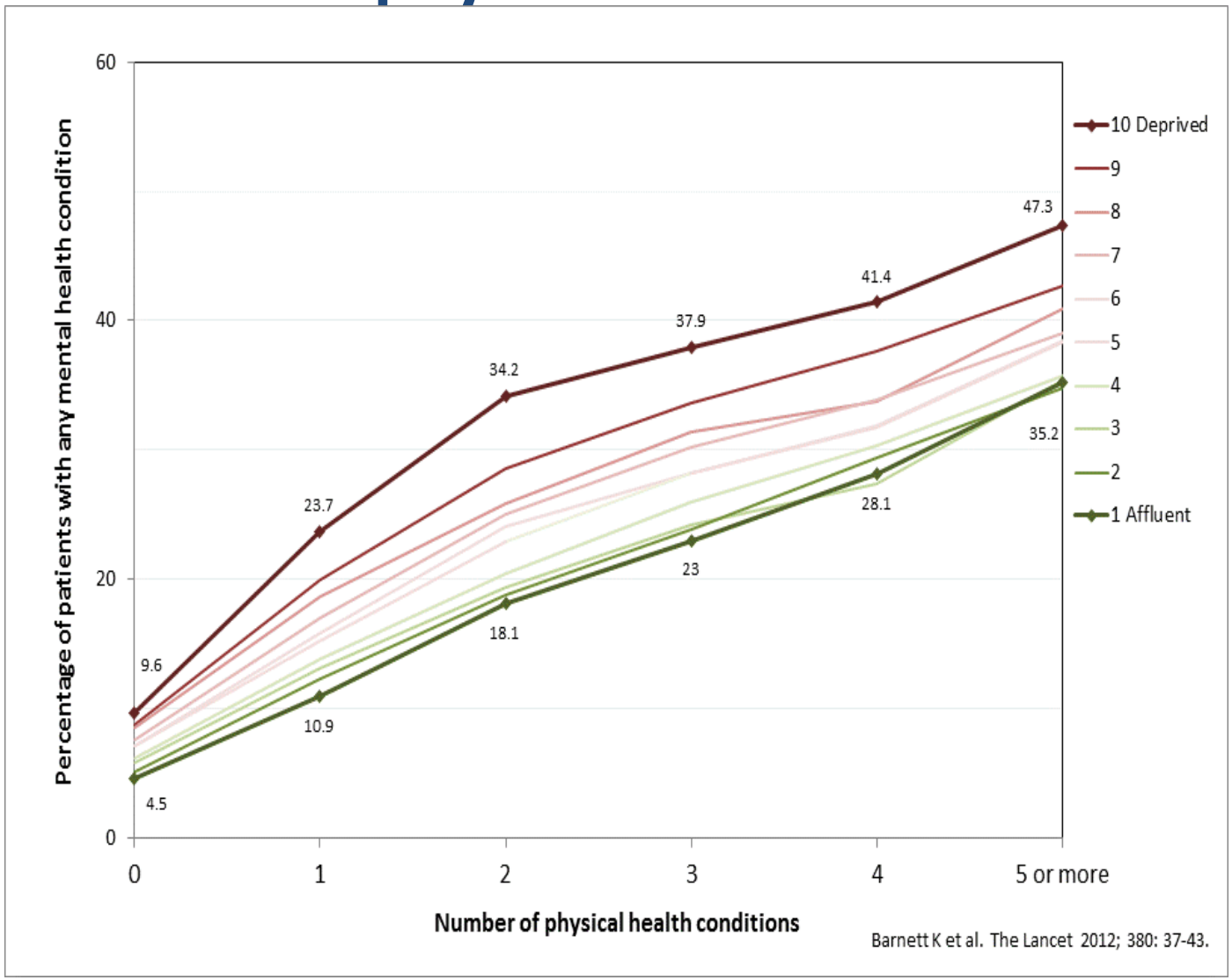


People living in most deprived areas develop multimorbidity 10-15 years before those living in the most affluent areas



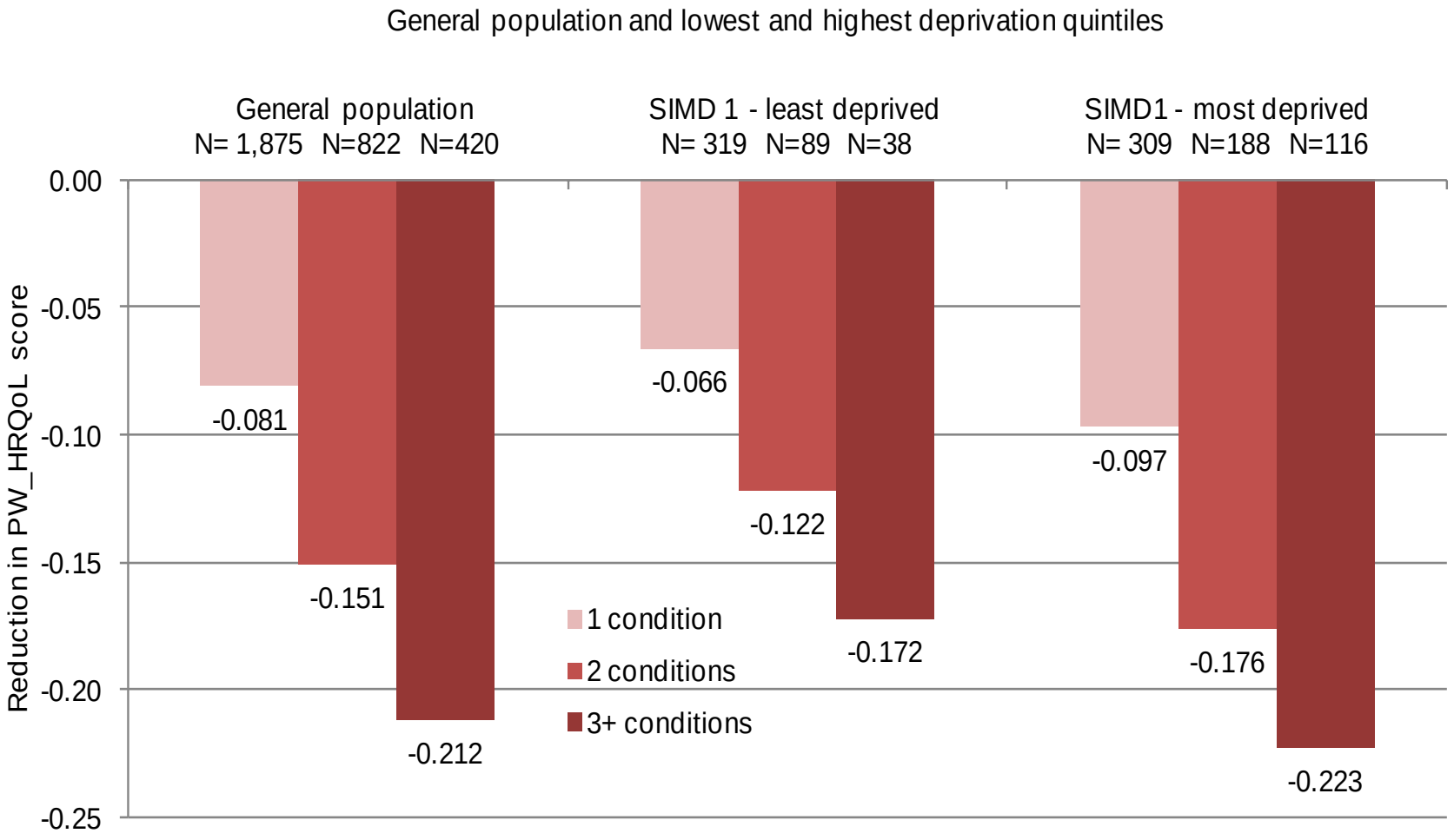
Barnett K et al. The Lancet 2012; 380: 37-43.

Mental health problems are strongly associated with number of physical conditions



Barnett K et al. The Lancet 2012; 380: 37-43.

Multimorbidity is associated with poorer quality of life, particularly in deprived areas



•Lawson KD, Mercer SW, Wyke S ,et al: Int J Equity in Health 2013, 12:67

Health and social problems can seem overwhelming

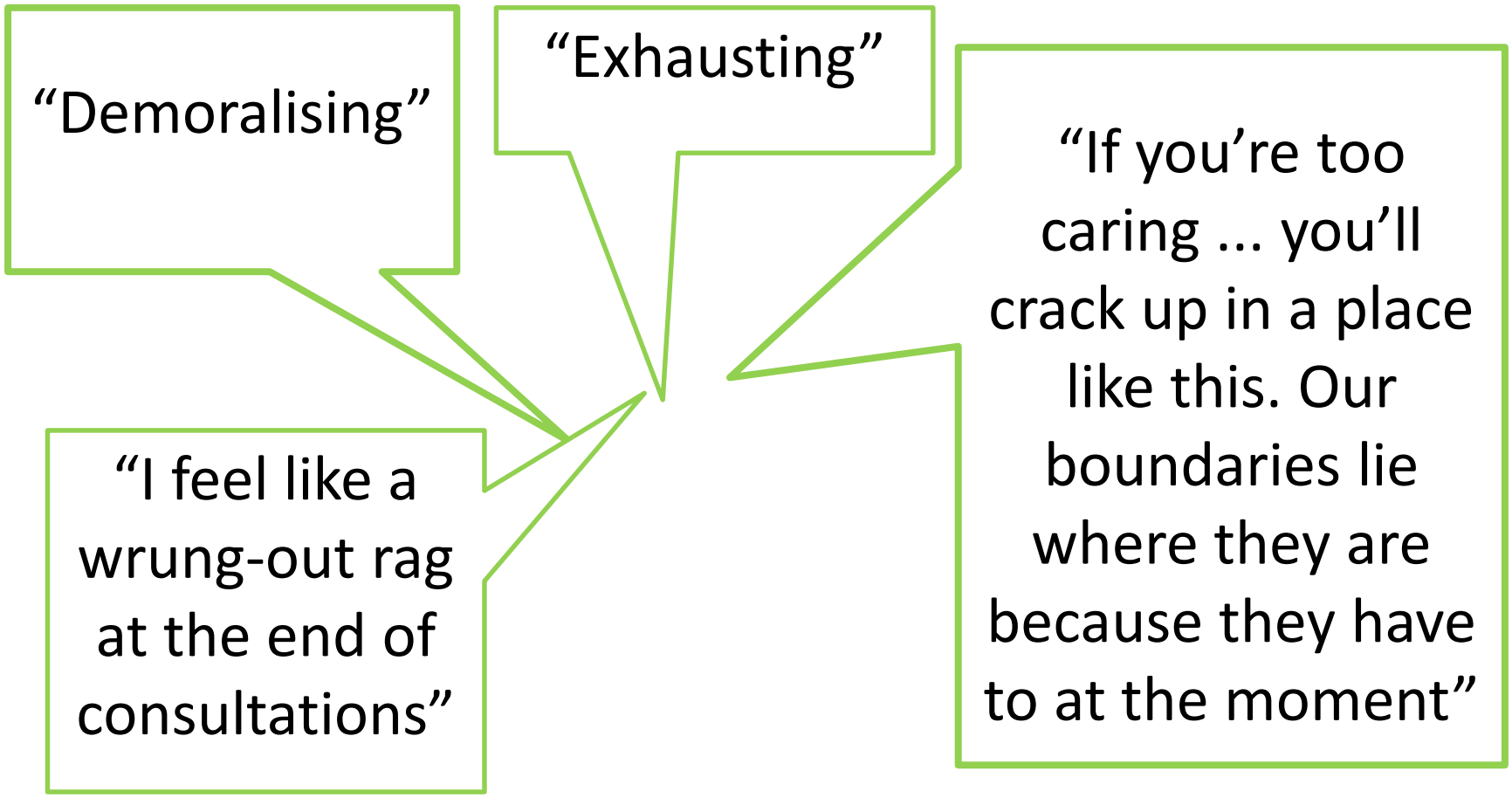
"There's nowhere round here…there's nothing to do"

"every day, week, month is the same"

"Sometimes I sit and cry. I do. I sit and cry 'cause I think 'God's sake, you're only 50. How did it come to this?"

O'Brien et al Journal of Comorbidity 2014; 4: 1-10.

Clinical staff in deprived areas struggle too…



O'Brien R et al. Chronic Illness 2011;7(1):45-59.

The Inverse Care Law

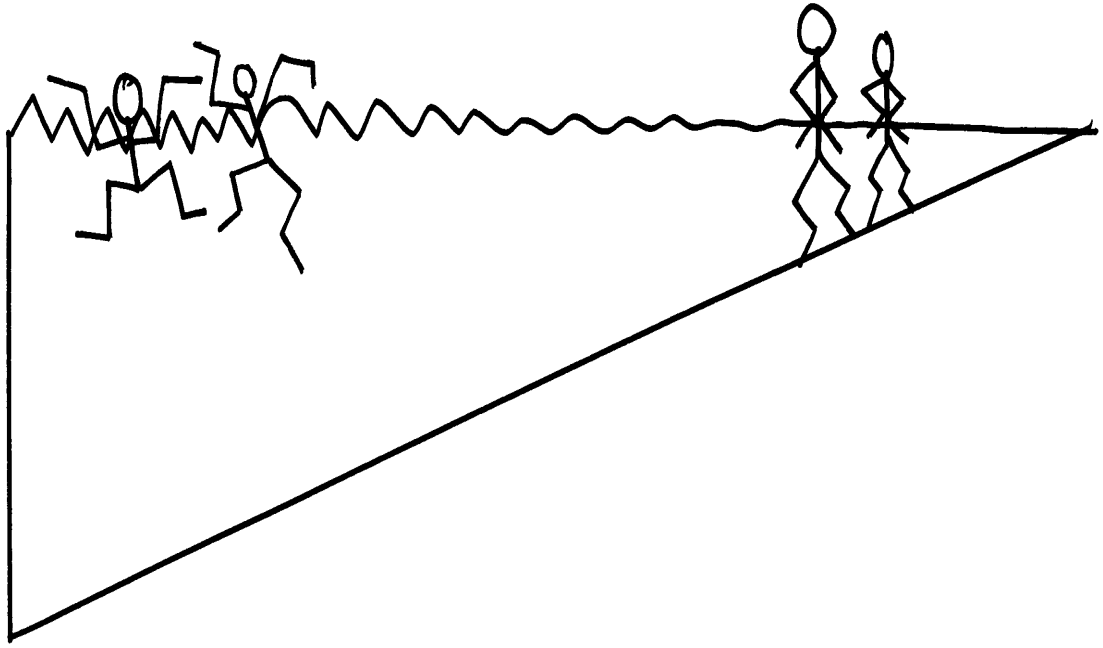
- ‘The provision of good medical care tends to vary inversely with the need for it in the population served.’
- Health care is not available on an equitable basis even in the NHS…….there is an inverse care law
- General practices in the most deprived areas have 20% more consultations, consultations that are more complex and no more funding*

General practice funding underpins the persistence of the inverse care law:

cross-sectional study in Scotland

*McLean et al. *British Journal of General Practice 2015;* ***65(641): e799-e805.***

General Practitioners at the Deep End



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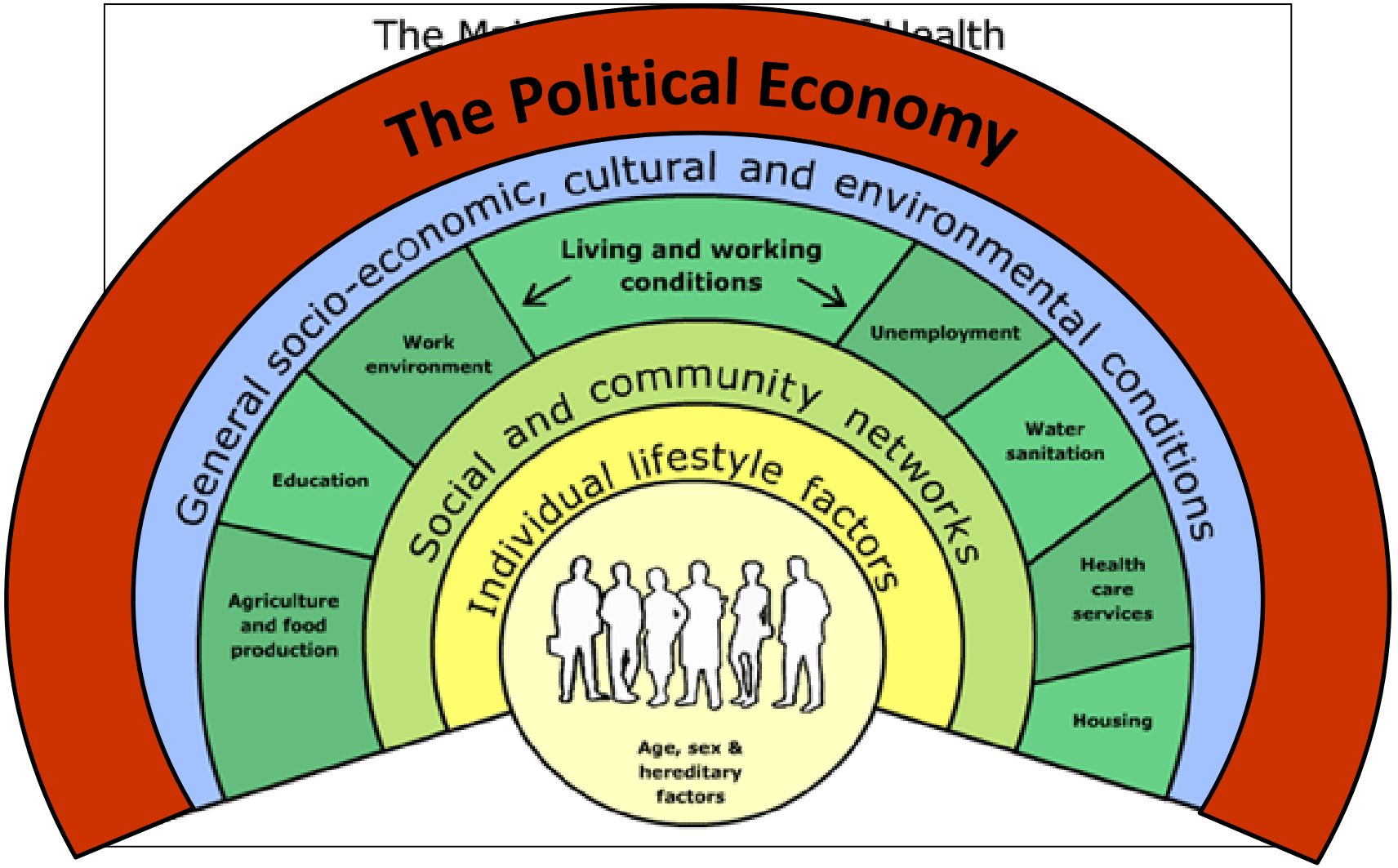
MULTIMORBIDITY

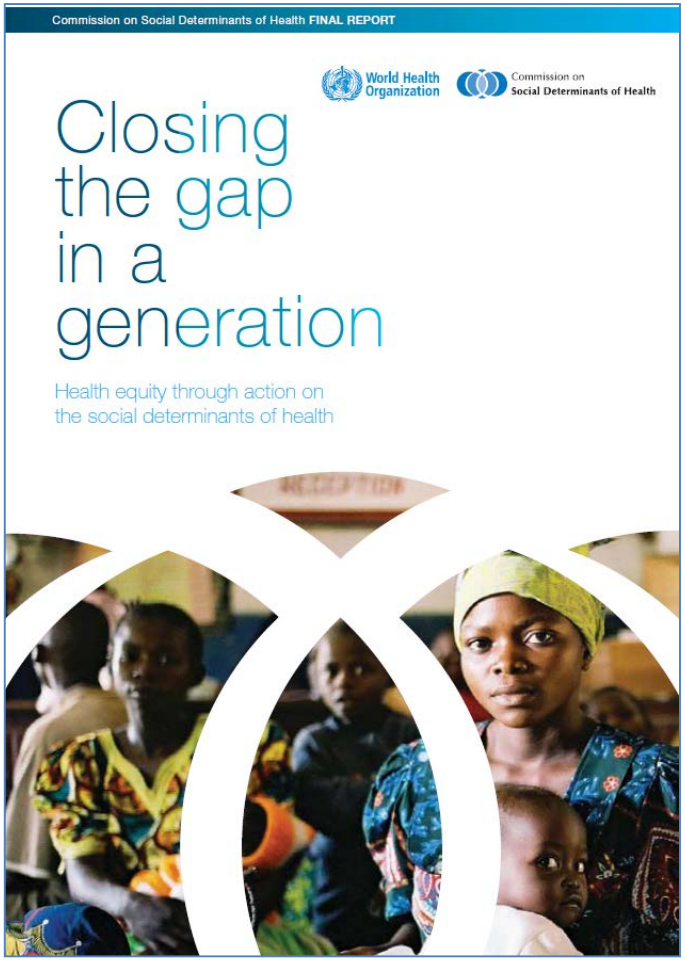
2. IDENTIFY WHAT IS MODIFIABLE

What determines health in a population



Source: Dahlgren G, Whitehead M. European strategies for tackling social inequities in health: levelling up, Part 2. Copenhagen: WHO Regional Office for Europe, 2007

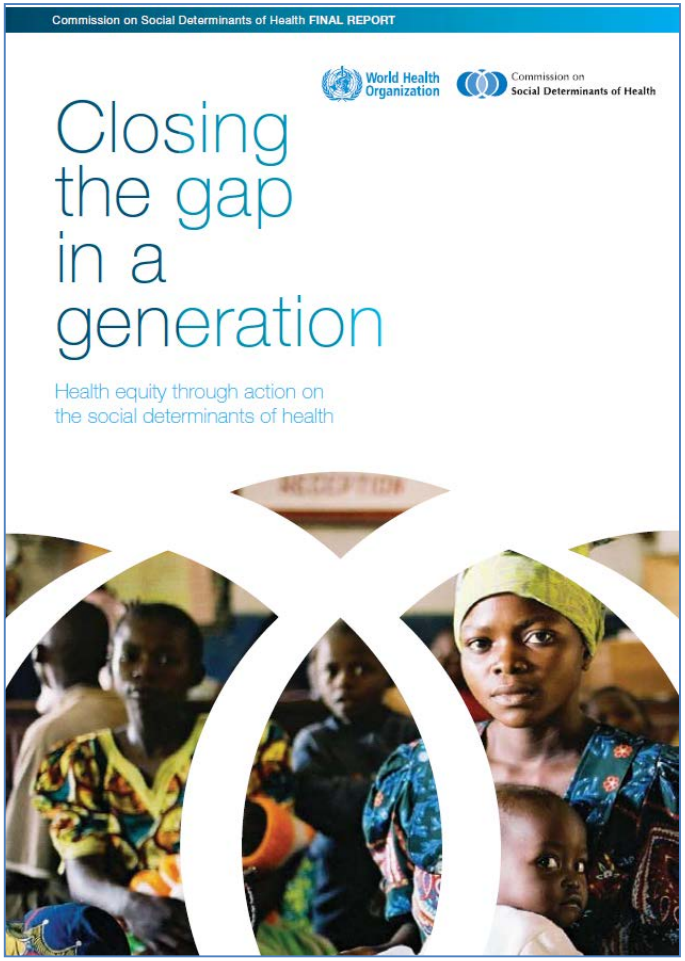
World Health Organisation (WHO)



"It does not have to be this way and it is not right that it should be like this… Social injustice is killing people on a grand scale"

WHO Commission on Social Determinants of Health, 2008.

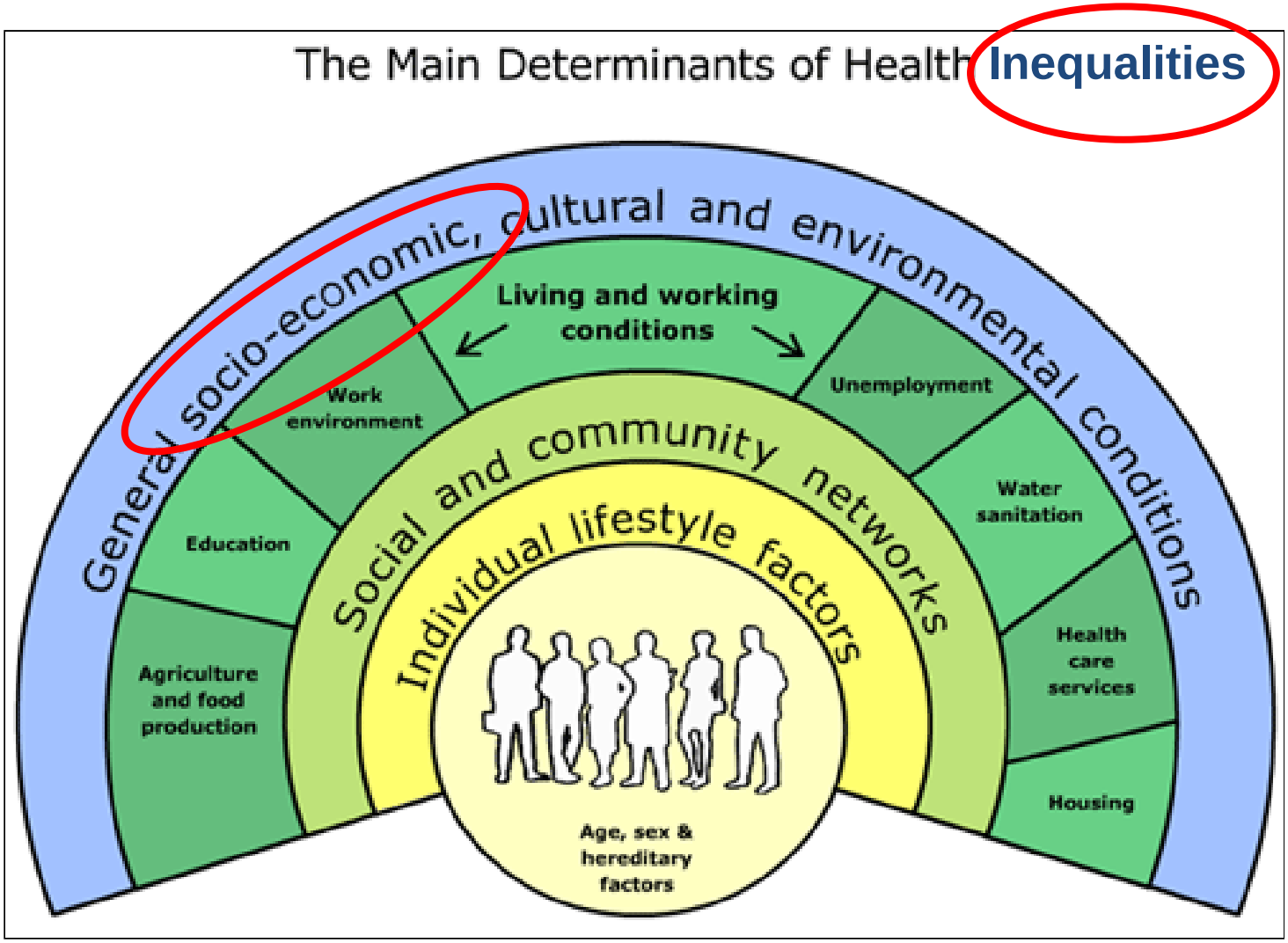
Political economy



"It is not inequalities that kill people, as the report states, it is those who are responsible for these inequalities that kill people"

Navarro V. What we mean by social determinants of health. International Journal of Health Services 2009; 39 (3): 423–441

What determines health in a population



Source: Dahlgren G, Whitehead M. European strategies for tackling social inequities in health: levelling up, Part 2. Copenhagen: WHO Regional Office for Europe, 2007


Maybe we should build a boat instead...

Some problems CAN be addressed in primary care. How?

What sort of intervention?

Can it focus on people and the inverse care law?

Can we recruit practices to deliver and patients to receive it?

Can hard pressed GPs and Nurses deliver it?

Is there a chance that it could help people ‘live well’ with multimorbidity in deprived areas?

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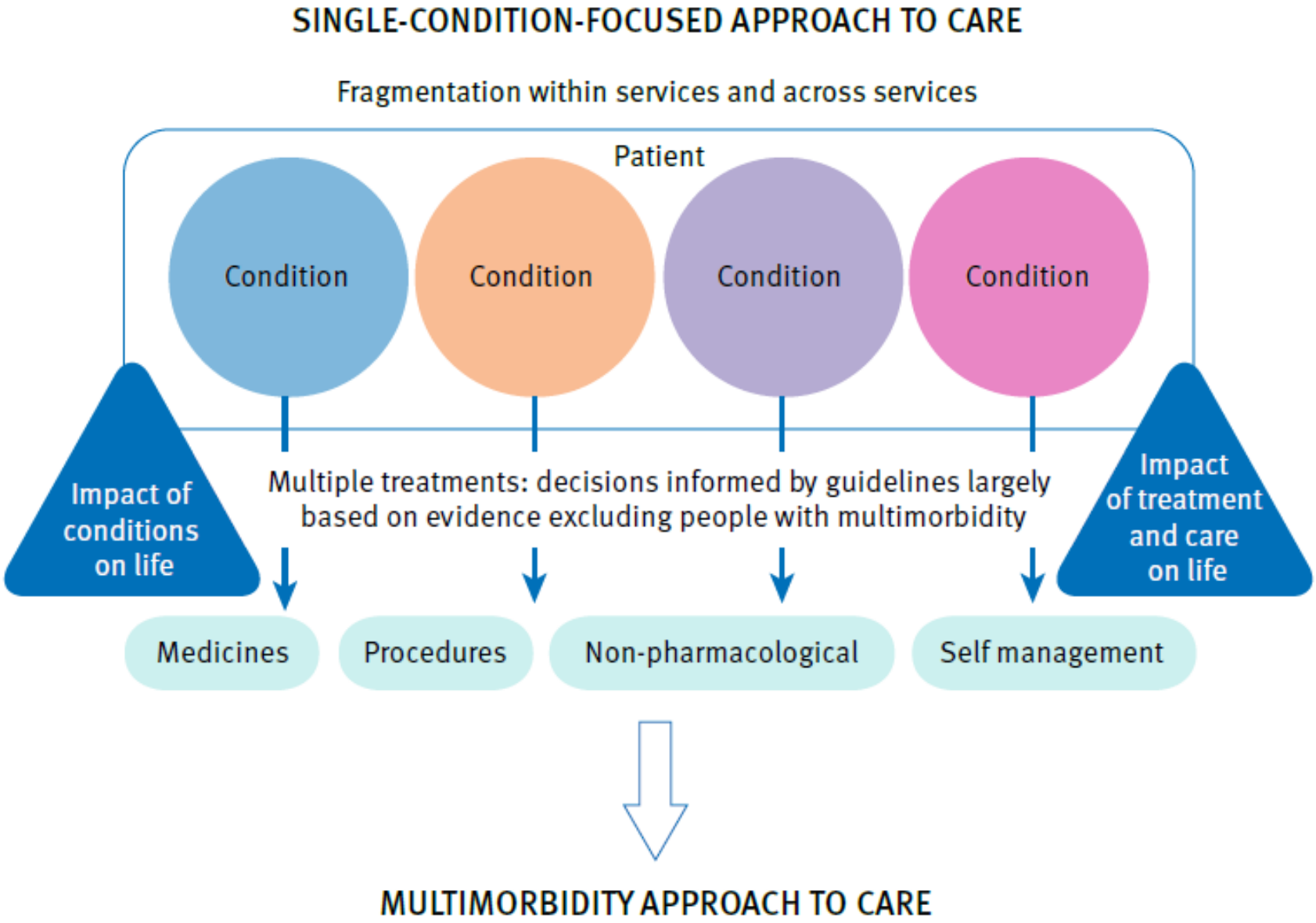
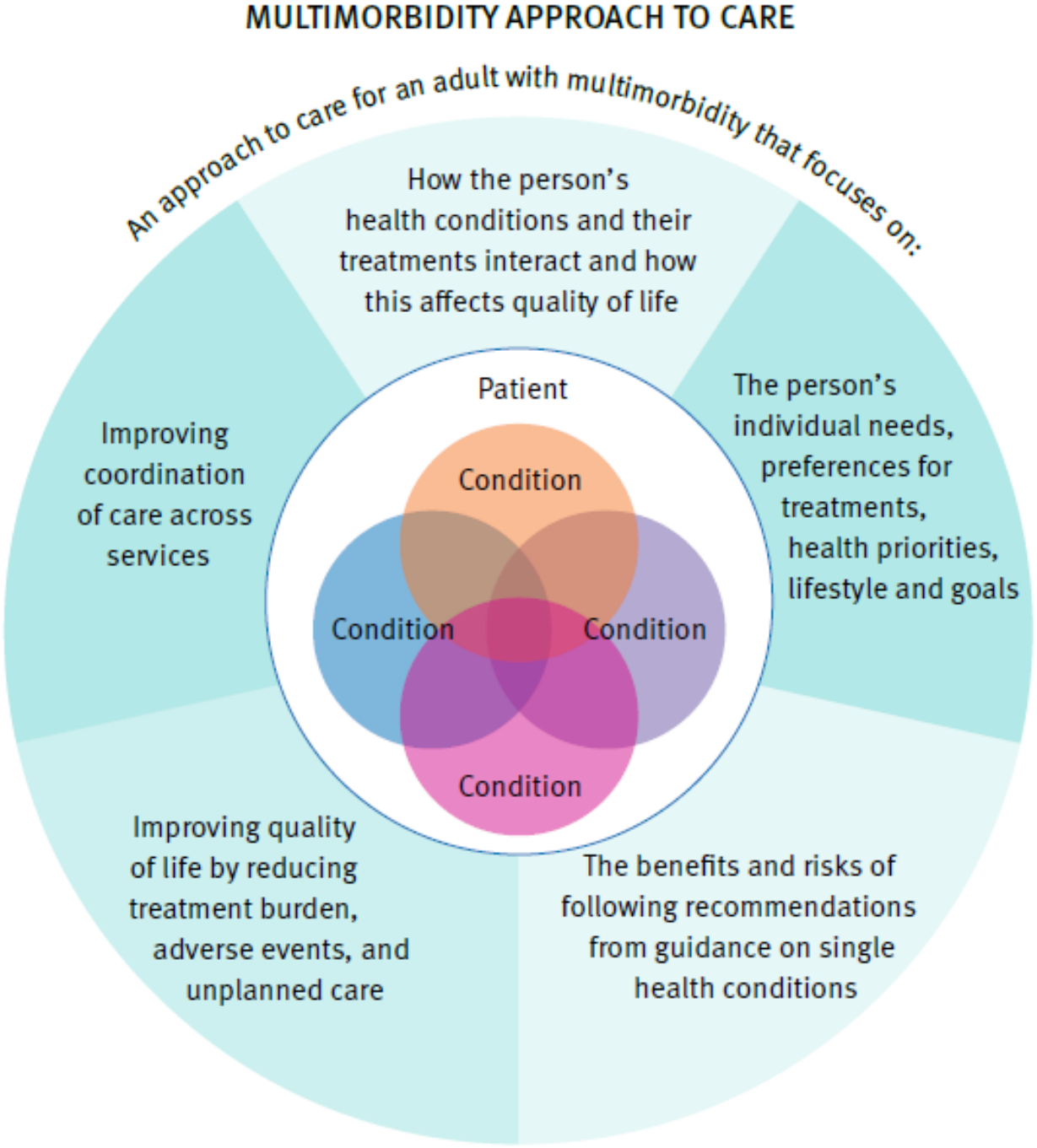
3 & 4. IDENTIFY HOW TO BRING ABOUT AND DELIVER CHANGE

What sort of intervention? Is there an evidence base?

- Cochrane Review 2016 Smith et al
  - 18 RCTs worldwide
  - 9 comorbidity / 9 multimorbidity
  - Mostly organisation change in the delivery of care rather than patient-centred
  - Mostly elderly
  - No focus on SES
  - Limited evidence of benefit

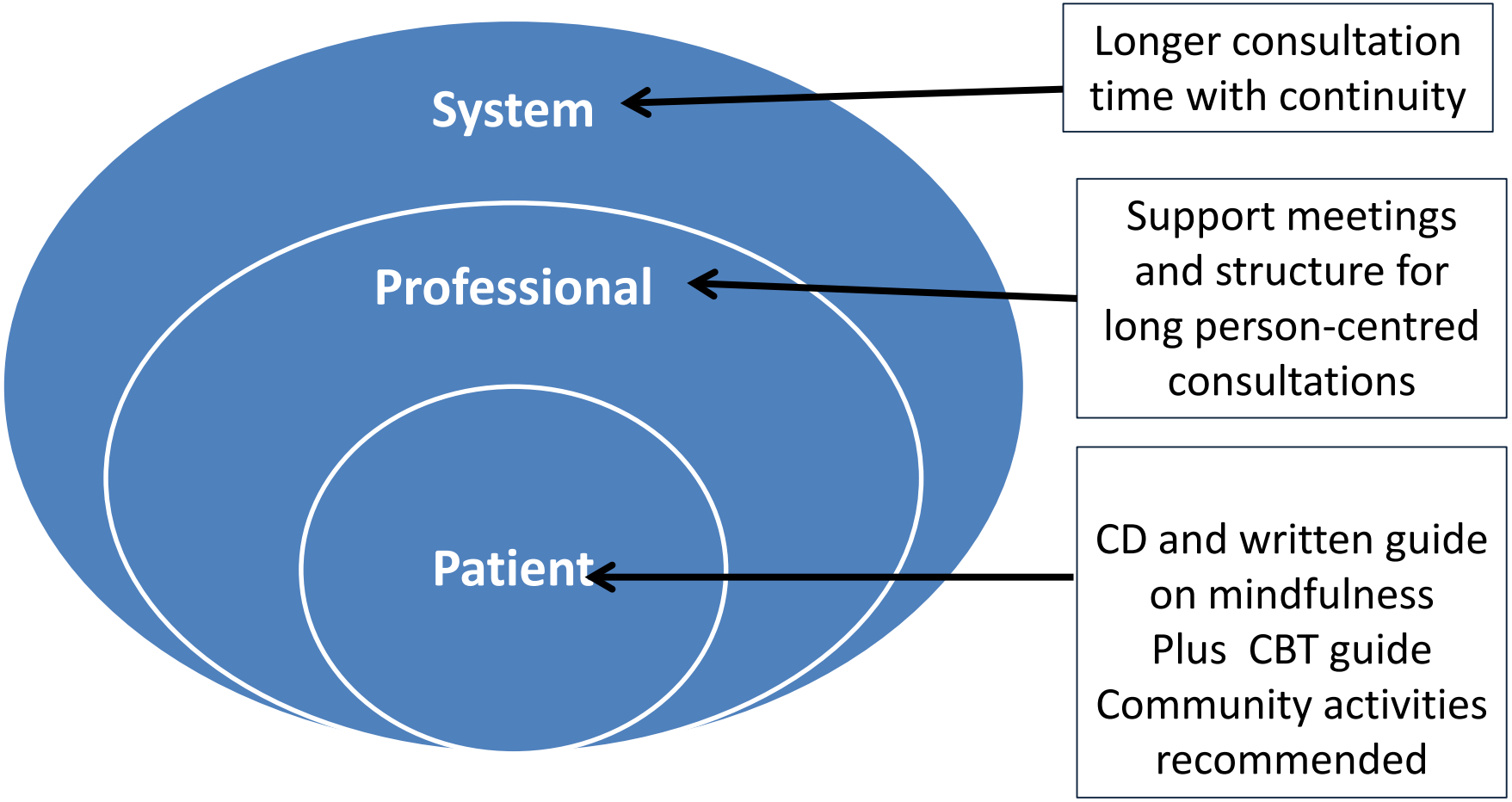
Management approaches: single-condition-focused v multimorbidity




MULTIMORBIDITY APPROACH TO CARE
An approach to care for an adult with multimorbidity that focuses on:
How the person's health conditions and their treatments interact and how this affects quality of life
The person's individual needs, preferences for treatments, health priorities, lifestyle and goals
The benefits and risks of following recommendations from guidance on single health conditions
Improving quality of life by reducing treatment burden, adverse events, and unplanned care
Improving coordination of care across services
Patient
Condition
Condition
Condition
Condition

CARE PLUS: a whole-system approach

Time, continuity, person centredness and self-management support



A whole system approach?

Within **consultations**:

1. Establish and maintain therapeutic relationships (**C**onnect)
2. Focus on 'whole person' in assessing health problems (**A**ssess)
3. Respond in an empathetic and validating way (**R**espond)
4. Empower patients to achieve realistic goals (**E**mpower)

CARE Plus

Article

chronic illness

Chronic Illness
2016, Vol. 12(3) 165–181

DOI: 10.1177/1742395316644304
chi.sagepub.com
SAGE

The development and optimisation of a primary care-based whole system complex intervention (CARE Plus) for patients with multimorbidity living in areas of high socioeconomic deprivation

Stewart William Mercer, Rosaleen O'Brien, Bridie Fitzpatrick, Maria Higgins, Bruce Guthrie, Graham Watt and Sally Wyke

System: Time and relational continuity

Practitioner: Practitioner training and Support

Self management: Support between consultations

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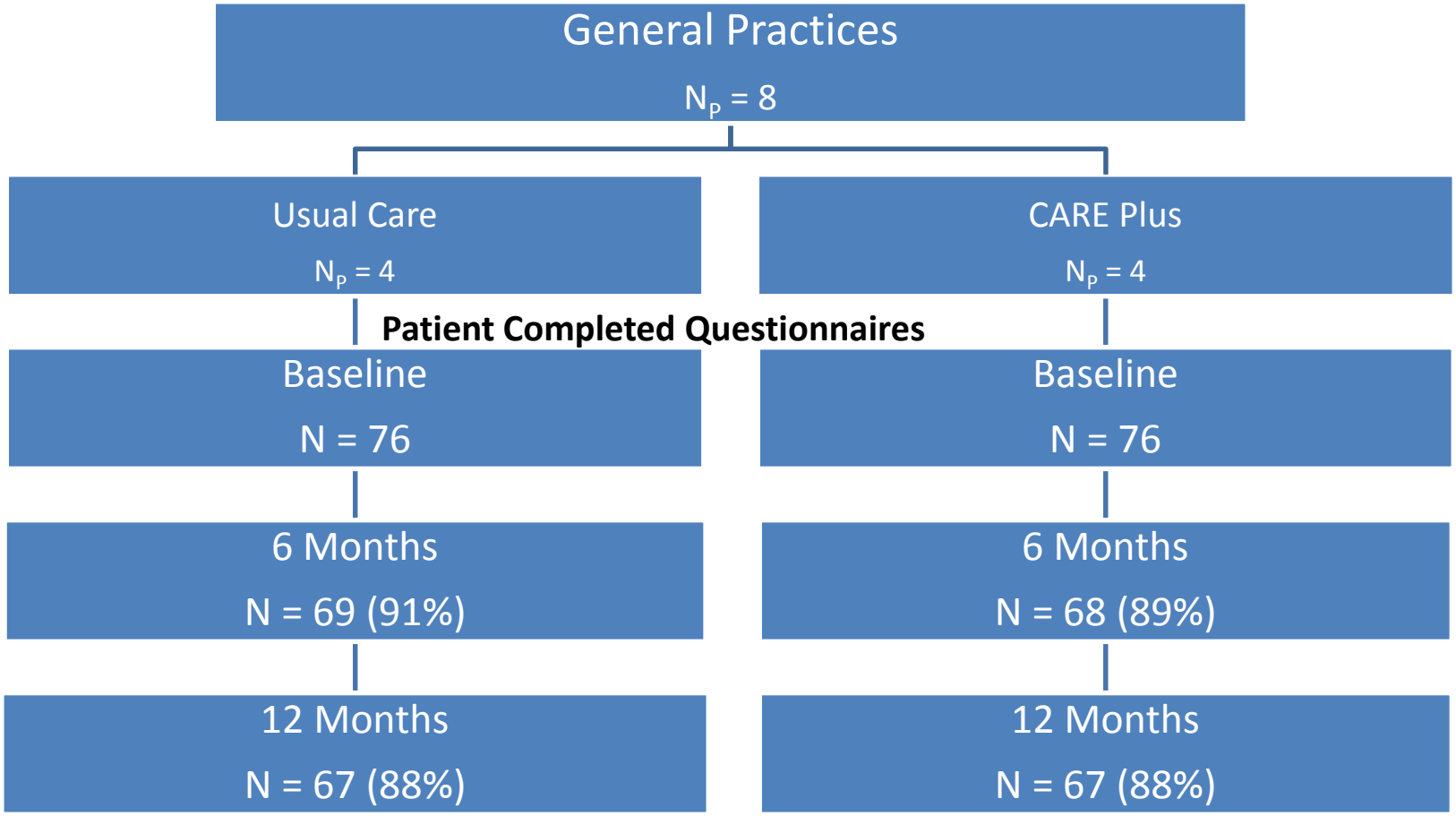
5 & 6. TEST AND REFINE, GATHER ENOUGH EVIDENCE TO JUSTIFY A LARGER EVALUATION

Developed in FGD; tested in 2 practices

Phase 1	Changes made
Practices varied in who should do long consultations, GPs or Nurses	Let practices choose
Varied on how long consultations should be	Let practices and practitioners choose
How many consultations? Depend on pts	Let clinicians decide at the time
Practitioners would need training and support	Offer as many meetings as they wanted
Practitioners could benefit from stress management	Offer mindfulness training to clincal staff
Phase 2	Changes made
On the whole it worked	
Took long time to complete CARE Plus Plan	Care Plus Plan shortened
Practitioner support valuable	Streamlined to include peer support, training, personal and group goals, mindfulness

Pilot cluster RCT: Can we recruit practices and patients?

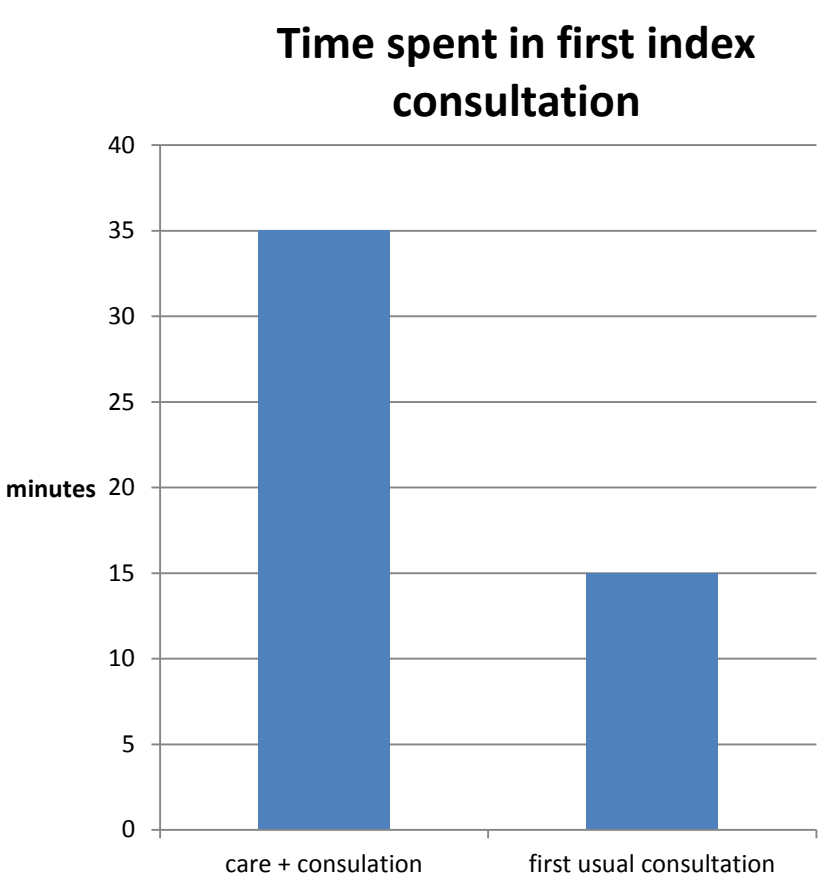


Can hard pressed GPs and Nurses deliver it?

I think that's is where the extra time comes in that you can listen you are not stressed by going through your head 'I need to do five issues ...'. You can let them address their needs ... You can listen connect and then bring (your) agenda in as well because I think at the end of the day I still feel quite .. .yeah, I am a doctor and I need to make sure that I get something through, which is important and not forgotten. (Practice A, Meeting 2, GP Participant 1)

Patients are very positive about it. I think I haven't had single ones who has turned down the suggestion. (Practice A, Meeting 1, GP Participant 3

Can it work I?: Longer consultations let to higher patient satisfaction



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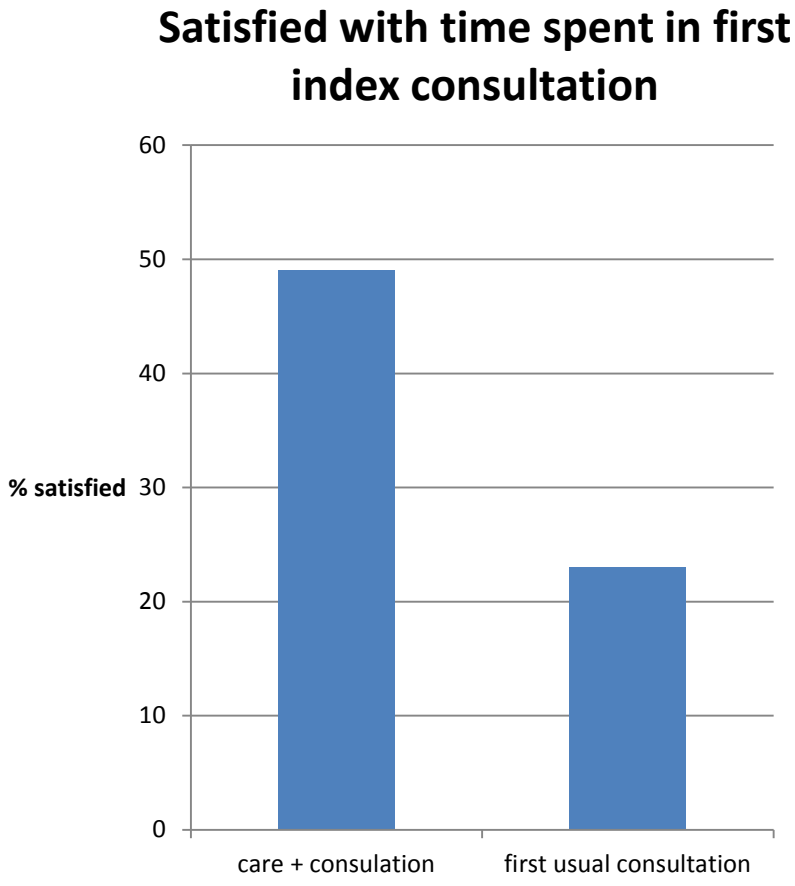

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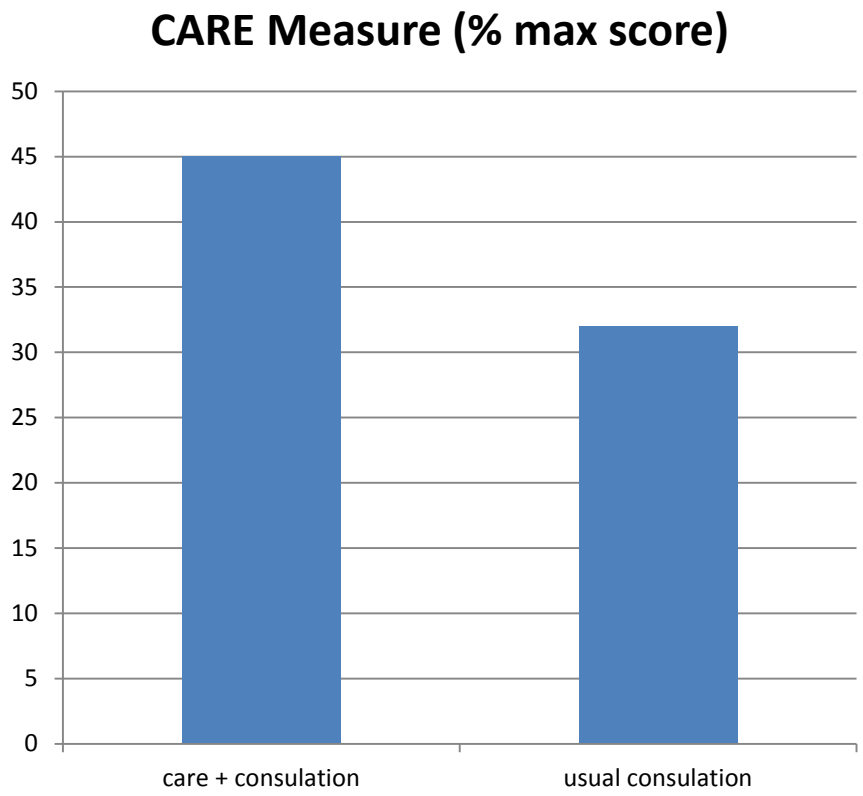
Can it work II? Consultations were seen as ‘better’



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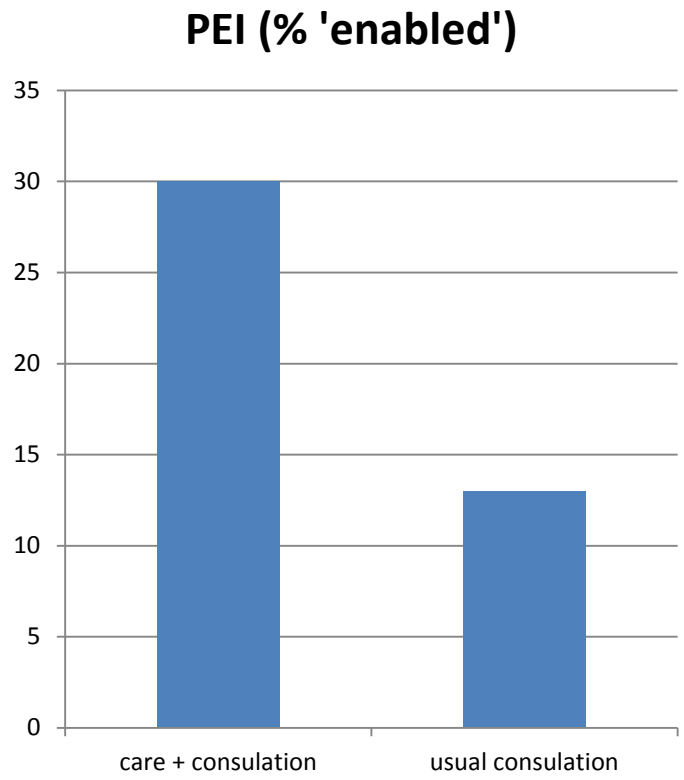

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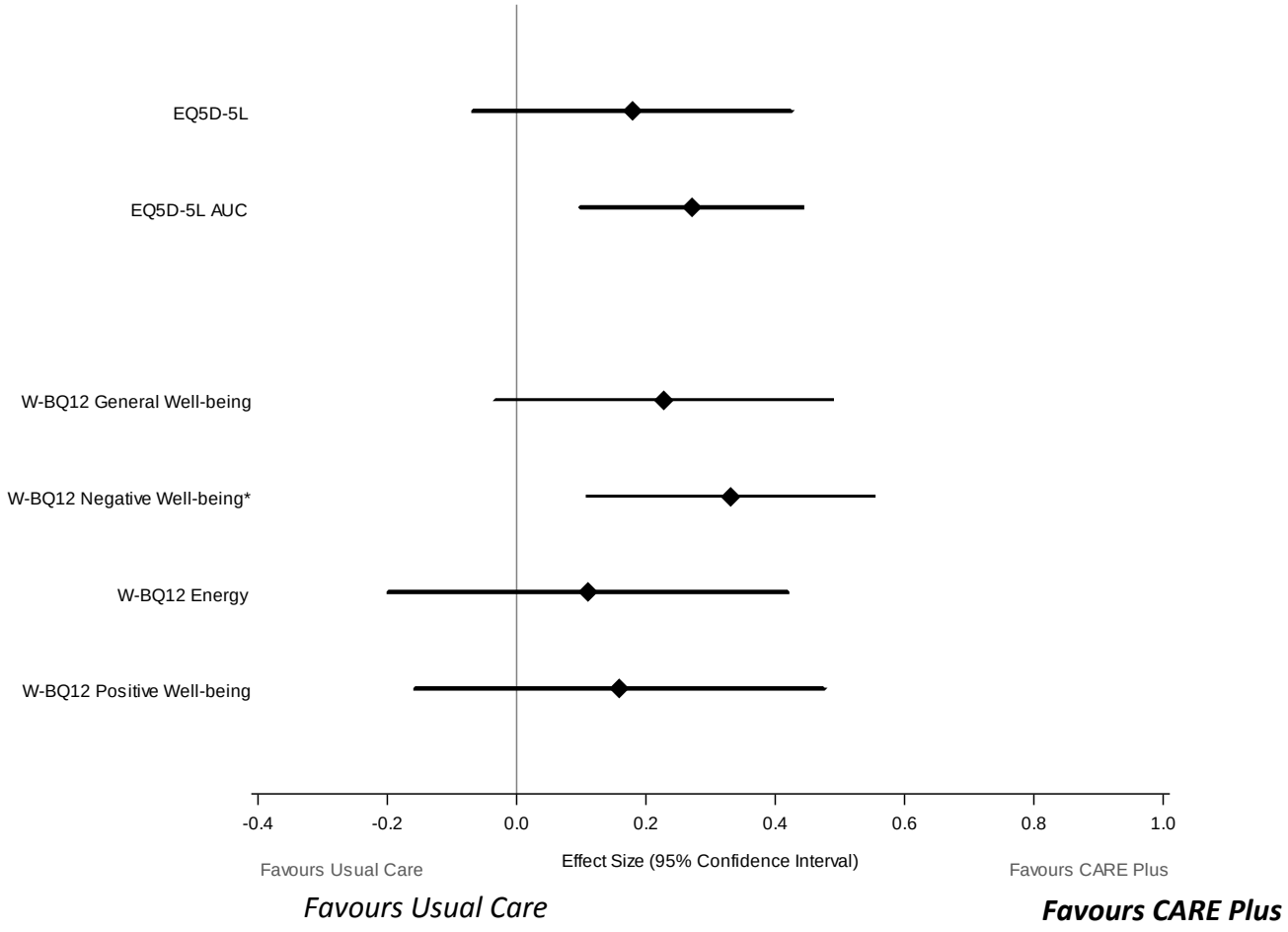
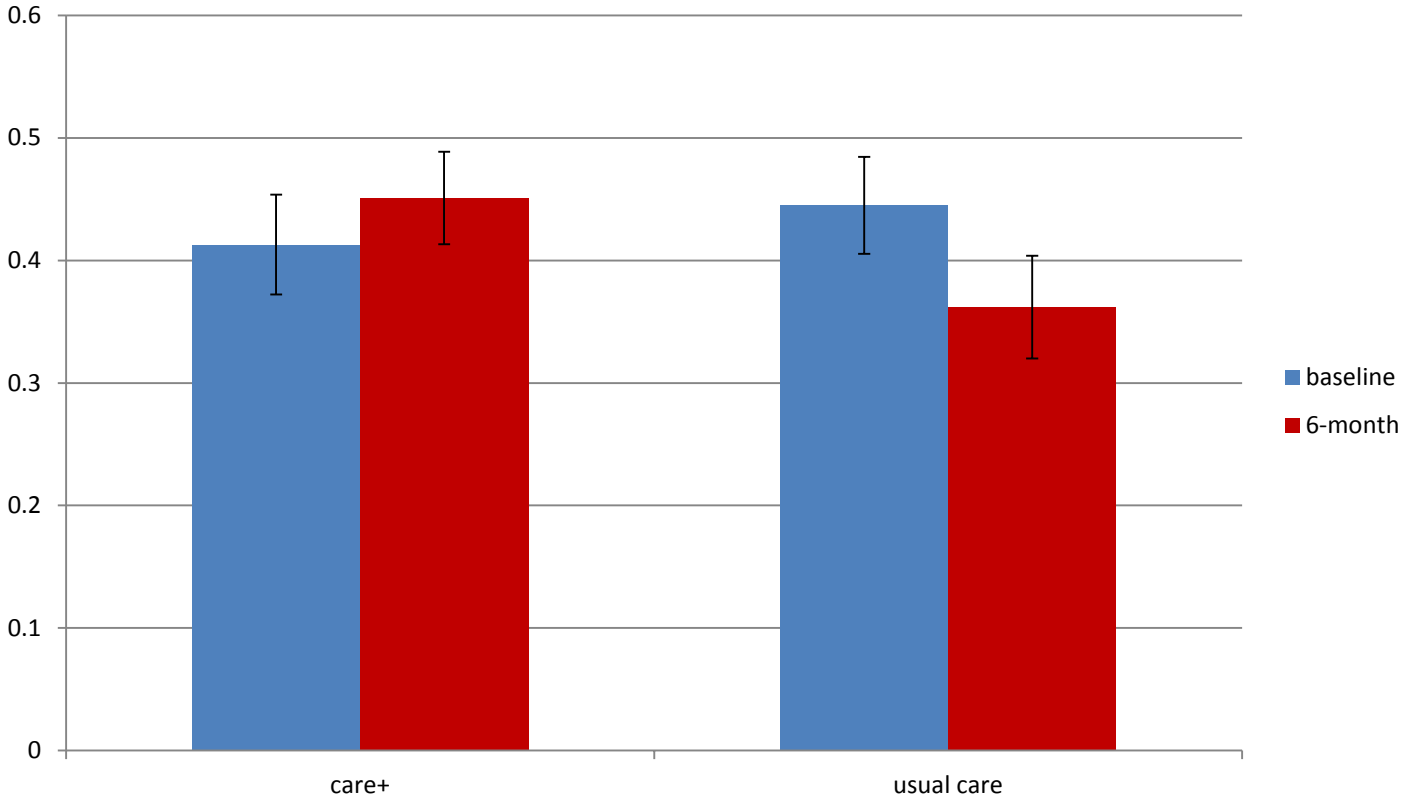
Can it work III? Patients in the CARE Plus group had improvements in quality of life and wellbeing at 12 months



Can it work IV? CARE Plus prevented decline in QOL (EQ5-DL)



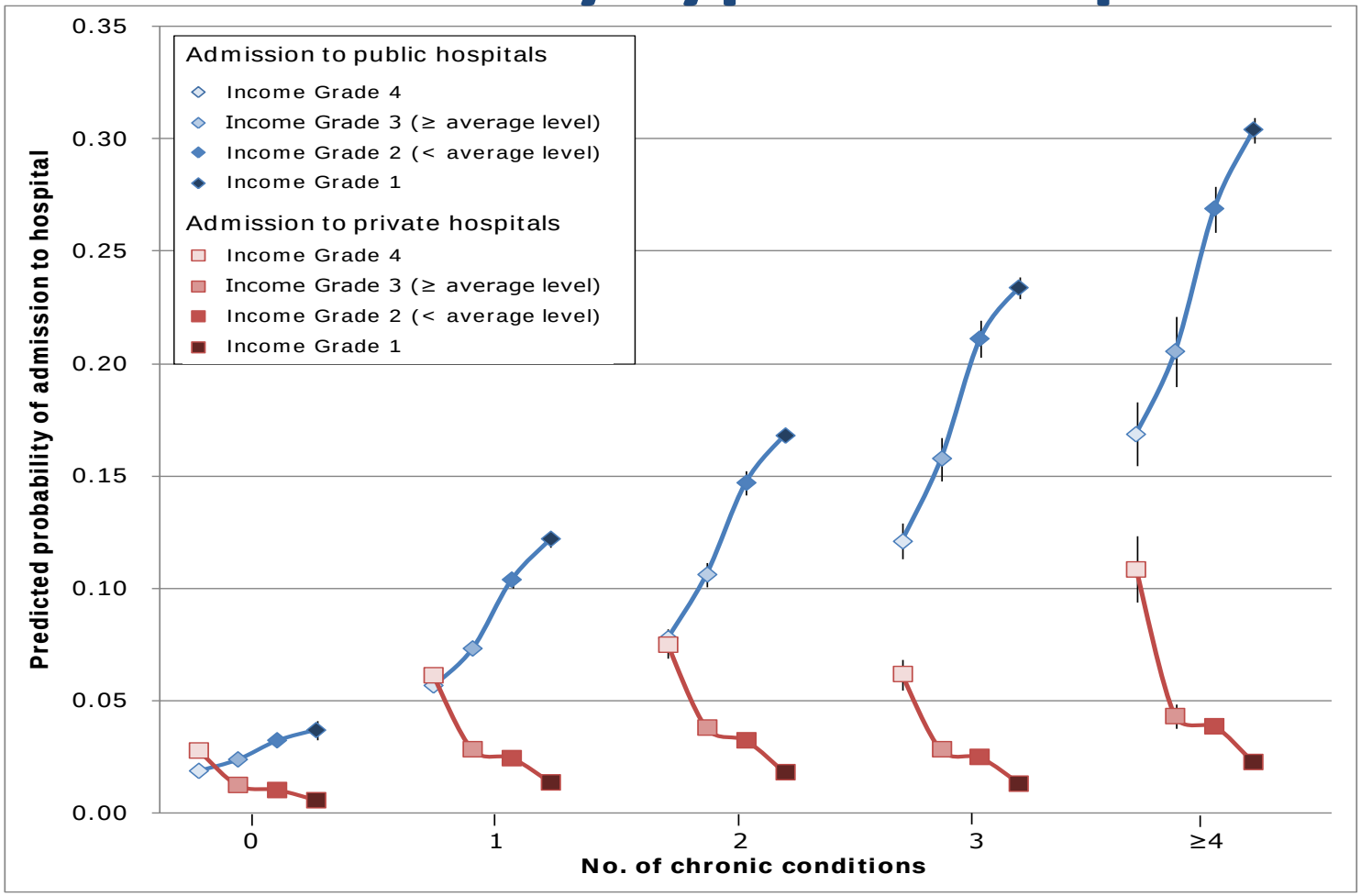
Effect size = 0.35

Cost effective?

In the pilot, CARE Plus was also very cost-effective :

- Cost < £13,000 per QALY
- NICE currently supports a cost of £20,000 - £30,000 per QALY

Hong Kong: MM associated with hospitalisation but pattern by income varies by type of hospital



Wang et al 2015. *Ann Fam Med 13; 2 164-167*

Summary and Conclusion: multimorbidity in areas of deprivation

- Multimorbidity is a major challenge globally
- Complex interventions are required to make an impact on these challenges
- Complex interventions need to be targeted and require substantial development and optimisation before moving to a full RCT
- We are applying for funding for a full trial of CARE Plus

Conclusion: Six steps to quality intervention development

- To avoid research waste and the ISLAGIATT principle, we must more carefully develop our interventions before trial
- The Six Steps approach can help structure the work
- It can be applied successfully

Key Publications

- Wight D, et al (2016) J Epidemiol Community Health 70:520-525
- Mercer SW, Fitzpatrick B, Guthrie B, Fenwick E, Grieve E, Lawson K, Boyer N, McConnachie A, Lloyd SM, O'Brien R, Watt GCM, Wyke S. The Care Plus study- a whole system intervention to improve quality of life of primary care patients with multimorbidity in areas of high socioeconomic deprivation: cluster randomised controlled trial. *BMC Medicine 2016, 14:88*
- Mercer SW, O'Brien R, Fitzpatrick B, Higgins M, Guthrie B, Watt G, Wyke S. The development and optimisation of a primary care-based whole system complex intervention (CARE Plus) for patients with multimorbidity living in areas of high socioeconomic deprivation. *Chronic Illness. 2016, 12: 165-181*
- O'Brien R, Wyke S, Watt G, Guthrie B, Mercer SW. The 'everyday work' of living with multimorbidity *in socio-economically deprived areas of Scotland. Journal of Comorbidity 2014,9:62*
- Lawson KD, Mercer SW, Wyke S, Grieve E, Guthrie B, Watt GCM, Fenwick EAE. Double trouble: The impact of multimorbidity and deprivation on preference-weighted health related quality of life a cross sectional analysis of the Scottish Health Survey. *International Journal for Equity in Health 2013, 12:67*
- Barnett B, Mercer SW, Norbury M, Watt G, Wyke S, Guthrie B. The epidemiology of multimorbidity in a large cross-sectional dataset: implications for health care, research and medical education. *The Lancet 2012, Jul 7;380(9836):37-43*
- Mercer SW, Gunn J, Bower P, Wyke S, Guthrie B. Managing patients with mental and physical multimorbidity *BMJ 2012;345:e5559*
- Mercer SW, Guthrie B, Furler J, Watt GCM, Hart JT. Multimorbidity and the inverse care law in primary care. *BMJ 2012, ;344:e4152.*
- O'Brien R, Wyke S, Guthrie B, Watt G, Mercer SW. An "endless struggle": a qualitative study of GPs' and Practice Nurses' experiences of managing multimorbidity in socio-economically deprived areas of Scotland. *Chronic Illness 2011, 7; 45-59*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