Ethical issues around clinical research in busy and under-resourced environments

Not if but how

The ethics of research related to healthcare in ~~developing countries~~

Busy clinical environments

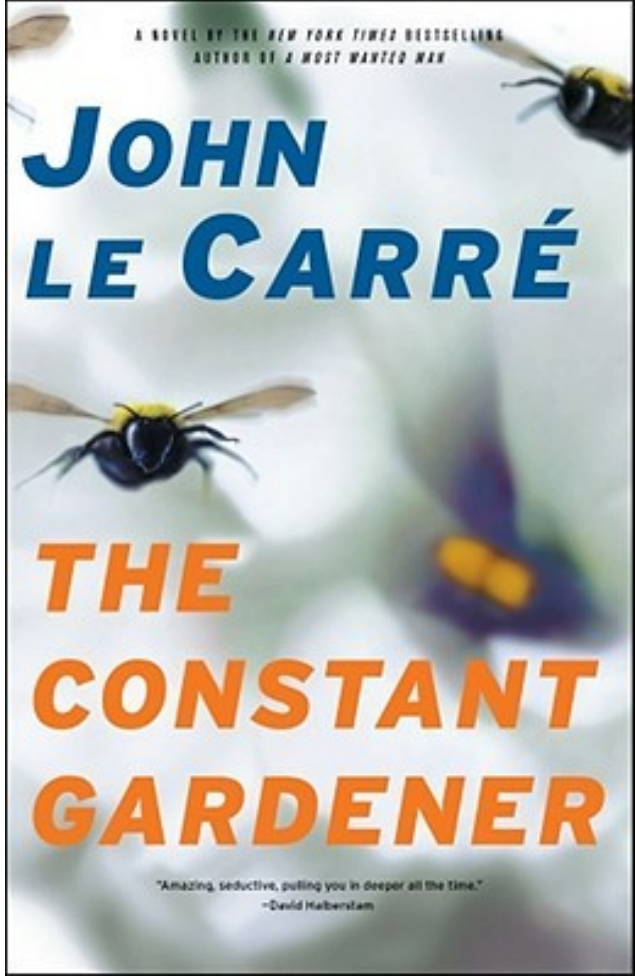
NUFFIELD COUNCIL ON BIOETHICS

Principles

- The duty to alleviate suffering
  - “it matters morally to all of us that effective medical research and research related to healthcare is indeed carried out. There is an inescapable moral duty which must be the basis for public policy in this area.”
- Respect for persons
- Sensitivity to cultural differences
- The duty not to exploit the vulnerable

- Impact of research on the clinical setting
  - Usually positive
  - Beware predatory researchers
    - Under-resourced
    - Time intensive – fixing the poorly envisaged
    - Modest or no local clinical gain

- Impact of an added commitment on busy clinicians



Research participation

- Patients
  - Better outcomes…
  - More attention to detail
- Institution
  - Easier to recruit staff
  - Institutional morale
  - Funding
- Clinicians
  - Knowledge and skills
  - Sense of community/networking
  - Sense of purpose

Clarke and Loudon *Trials* 2011, **12**:16
http://www.trialsjournal.com/content/12/1/16

TRIALS

RESEARCH Open Access

Effects on patients of their healthcare practitioner's or institution's participation in clinical trials: a systematic review

Mike Clarke[1,2*], Kirsty Loudon[1]

Abstract

Background: Systematic reviews have shown uncertainty about the size or direction of any 'trial effect' for patients

Research Activity and the Association with Mortality

Baris A. Ozdemir[1]*, Alan Karthikesalingam[1], Sidhartha Sinha[1], Jan D. Poloniecki[1], Robert J. Hinchliffe[1], Matt M. Thompson[1], Jonathan D. Gower[2], Annette Boaz[3], Peter J. E. Holt[1]

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Abstract

Introduction

The aims of this study were to describe the key features of acute NHS Trusts with different levels of research activity and to investigate associations between research activity and clinical outcomes.

Citation: Ozdemir BA, Karthikesalingam A, Sinha S, Poloniecki JD, Hinchliffe RJ, Thompson MM, et al. (2015) Research Activity and the Association with Mortality. PLoS ONE 10(2): e0118253. doi:10.1371/journal.pone.0118253

The impact of the process of clinical research on health service outcomes

P. Selby, P. Autier

Annals of Oncology, Volume 22, Issue Suppl_7, 1 November 2011, Pages vii5–vii9, https://doi.org/10.1093/annonc/mdr419

Published: 01 November 2011

Abstract

Chapter 1 introduces the key questions and context for the work described in the supplement, on the impact of the process of clinical research on healthcare outcomes. The distinction between the influence of research activity on the outcomes for individual patients involved in clinical trials and other well-designed studies when compared to similar individuals cared for within similar healthcare institutions are considered. The evidence is reviewed and broadly the conclusion is that there is little evidence to support the hypothesis that individuals included in randomized trials do better than individuals with the same clinical characteristics in such trials

So what does busy mean?

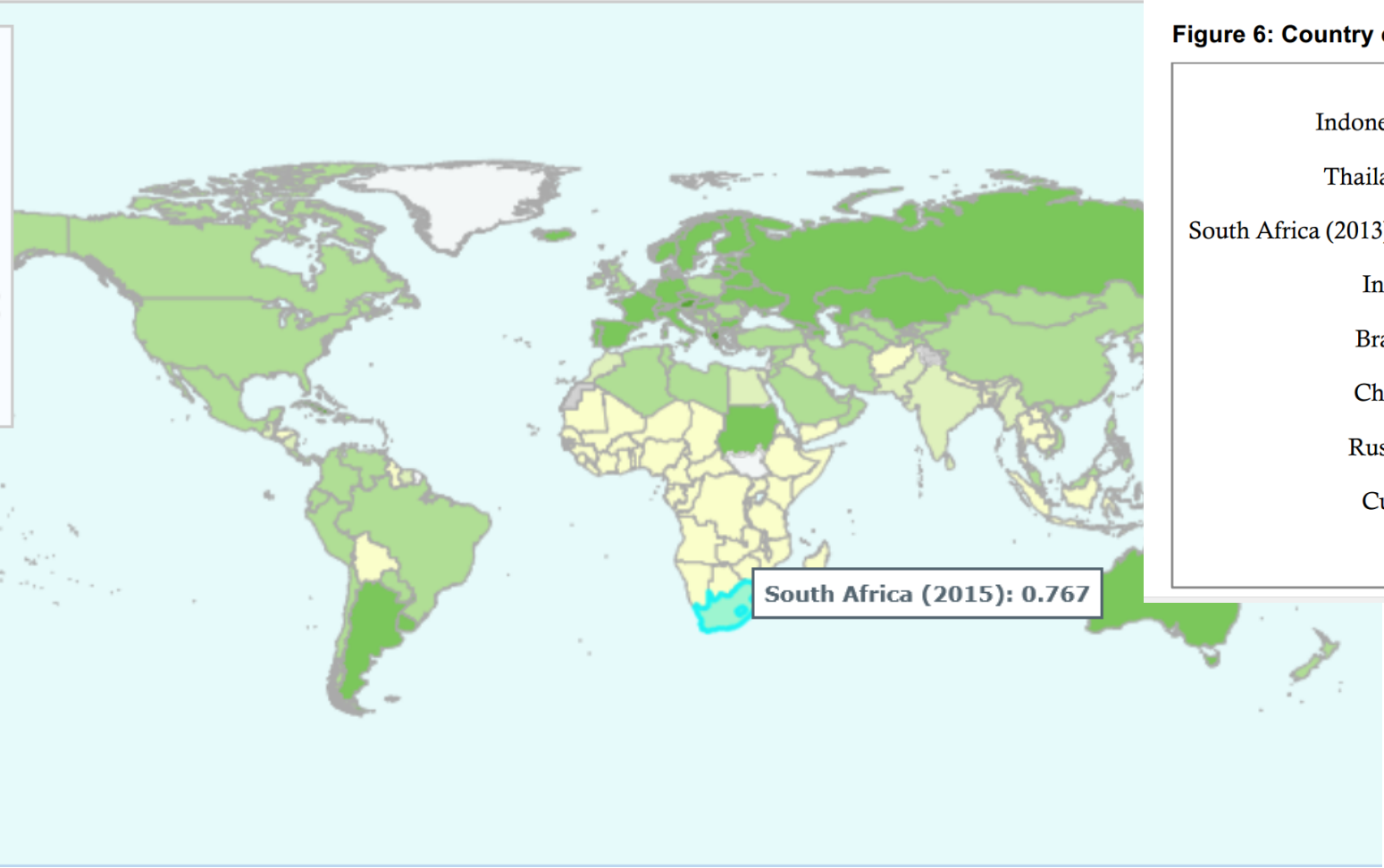


Figure 6: Country comparison – All doctors per 100,000 citizens (2010 or latest year available)

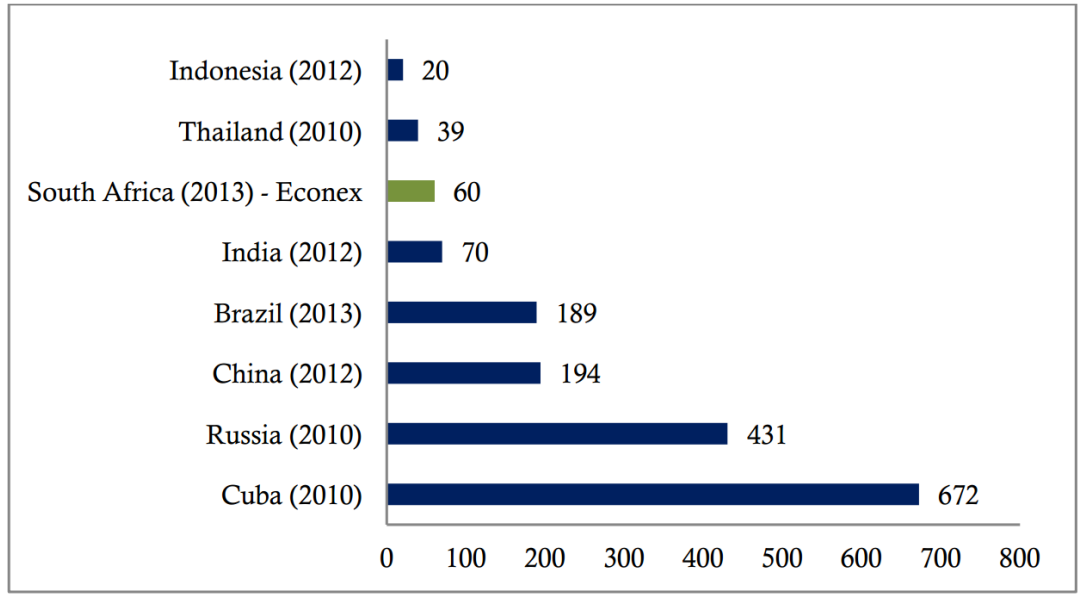


Table 4: Number of medical practitioners per 10 000 population, by province, 2004

Region	Medical doctors per 10 000 population*
Western Cape	14.7
Gauteng	12.6
Free State	5.4
KZN	5.2
Northern Cape	4.2
Mpumulanga	3.0
Eastern Cape	2.7
North West	2.3
Limpopo	1.8
National average	**6.7**

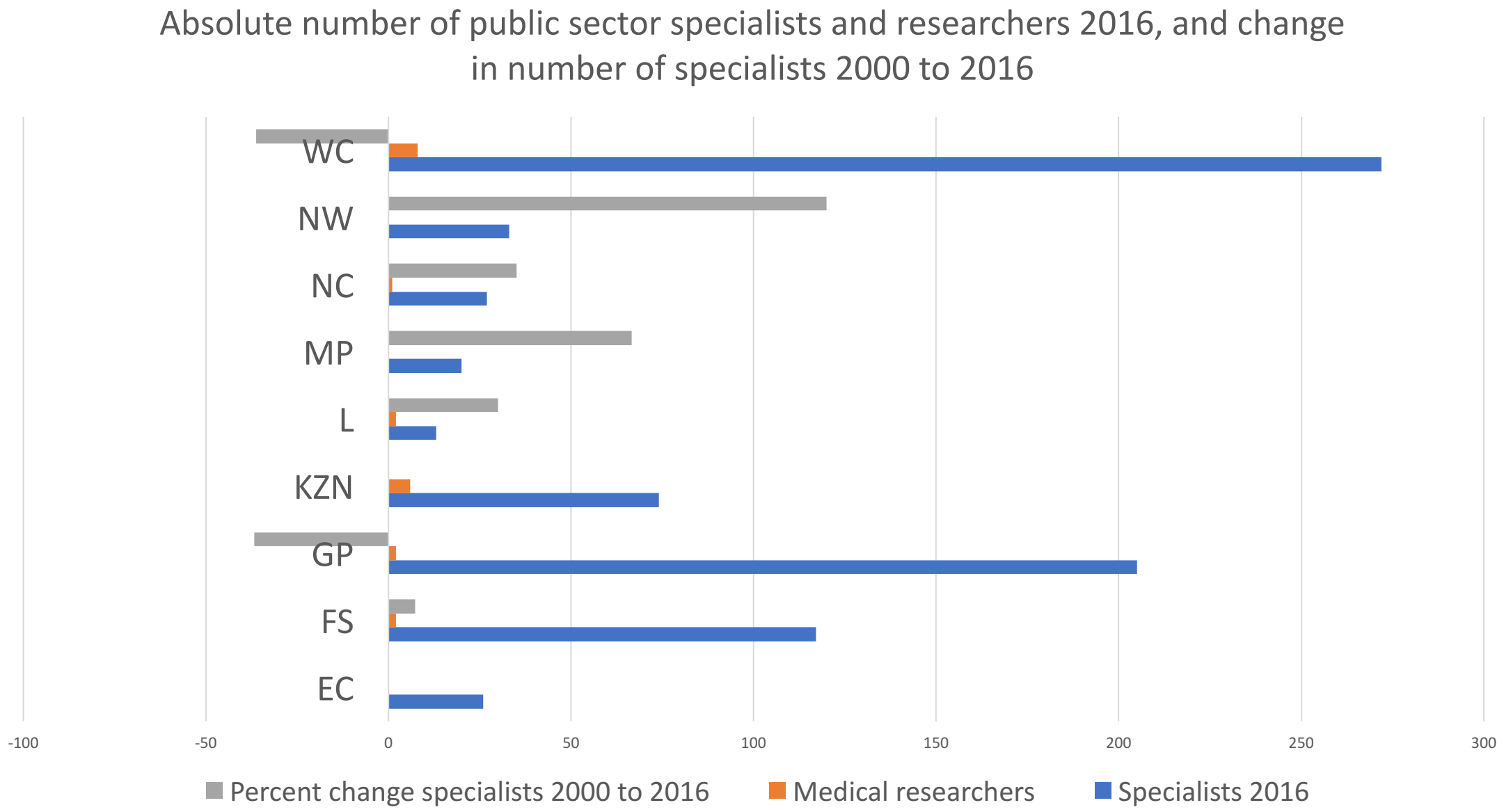
* Based on HPCSA figures for registered medical practitioners and StatsSA population estimates fo 2004.

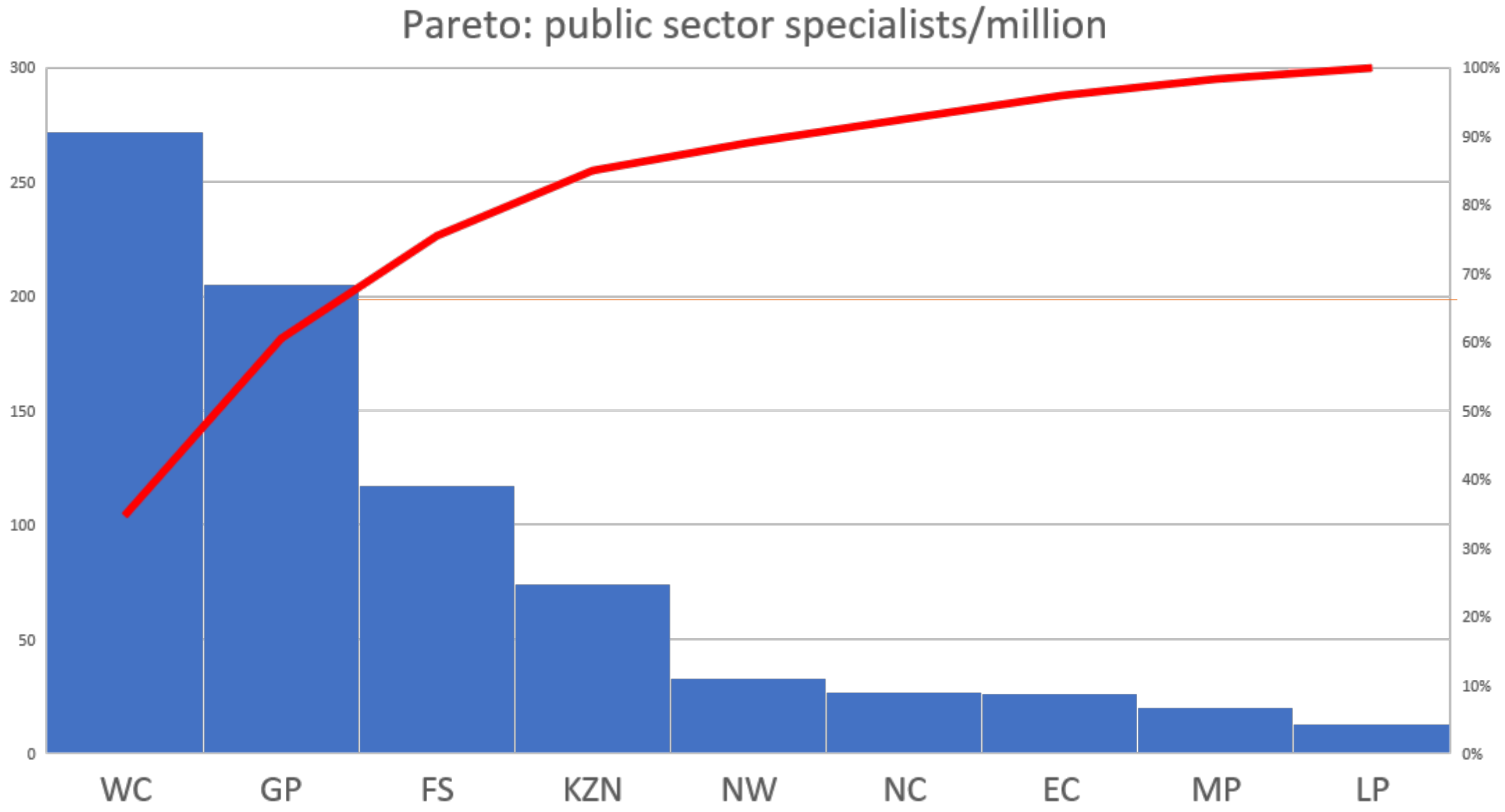
Trends in public sector doctor prevalence/100 000

HST 2017

Table 48: Public and private sector health personnel per 100 000 target population by province

Indicator	Year	Subgroup	EC	FS	GP	KZN	LP	MP	NC	NW	WC	SA	Ref
			12								40		
Medical practitioners per 100 000 population	2000	public sector	12.3	24.3	36.6	24.0	12.5	16.4	28.9	11.9	39.7	21.9	a
	2005	public sector	16.3	20.3	24.3	23.5	15.8	19.8	25.5	15.8	32.2	21.6	a
	2010	private sector										37.0	b
		public sector	22.4	24.1	31.5	33.2	20.1	22.5	32.9	16.0	34.2	27.3	a
		public sector adjusted										35.0	b
	2015	public sector	26.1	23.3	34.6	35.9	24.4	22.9	45.5	21.3	34.2	30.3	a
	2016	both sexes public sector	25.9	23.9	34.8	36.0	24.3	25.6	46.6	22.4	31.4	30.4	a
			25								30		


Absolute number of public sector specialists and researchers 2016, and change in number of specialists 2000 to 2016
WC
NW
NC
MP
L
KZN
GP
FS
EC
-100
-50
0
50
100
150
200
250
300
Percent change specialists 2000 to 2016
Medical researchers
Specialists 2016


Pareto: public sector specialists/million
300
250
200
150
100
50
0
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
WC
GP
FS
KZN
NW
NC
EC
MP
LP

Clinical service load

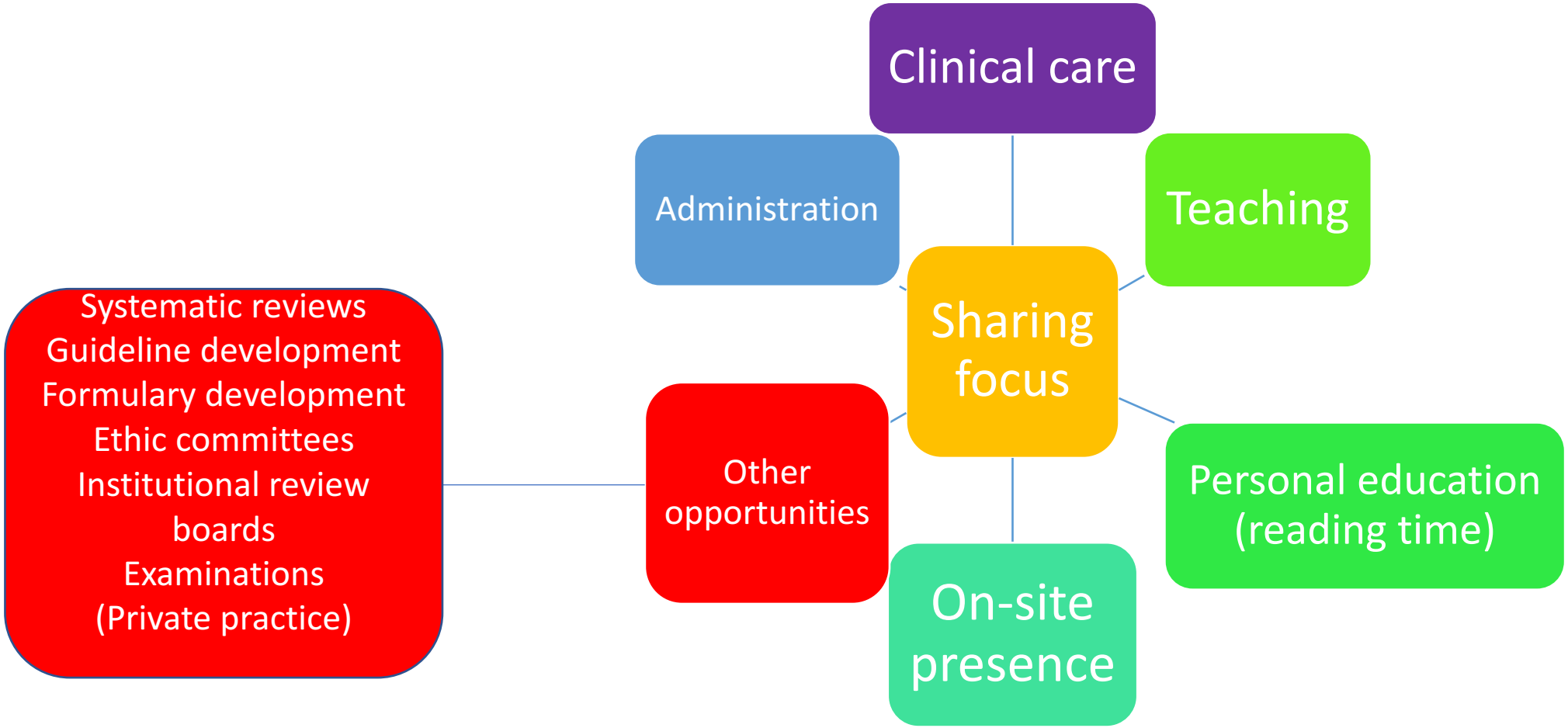
Administration

Teaching

Outreach

Research

The ethics: opportunity costs of research

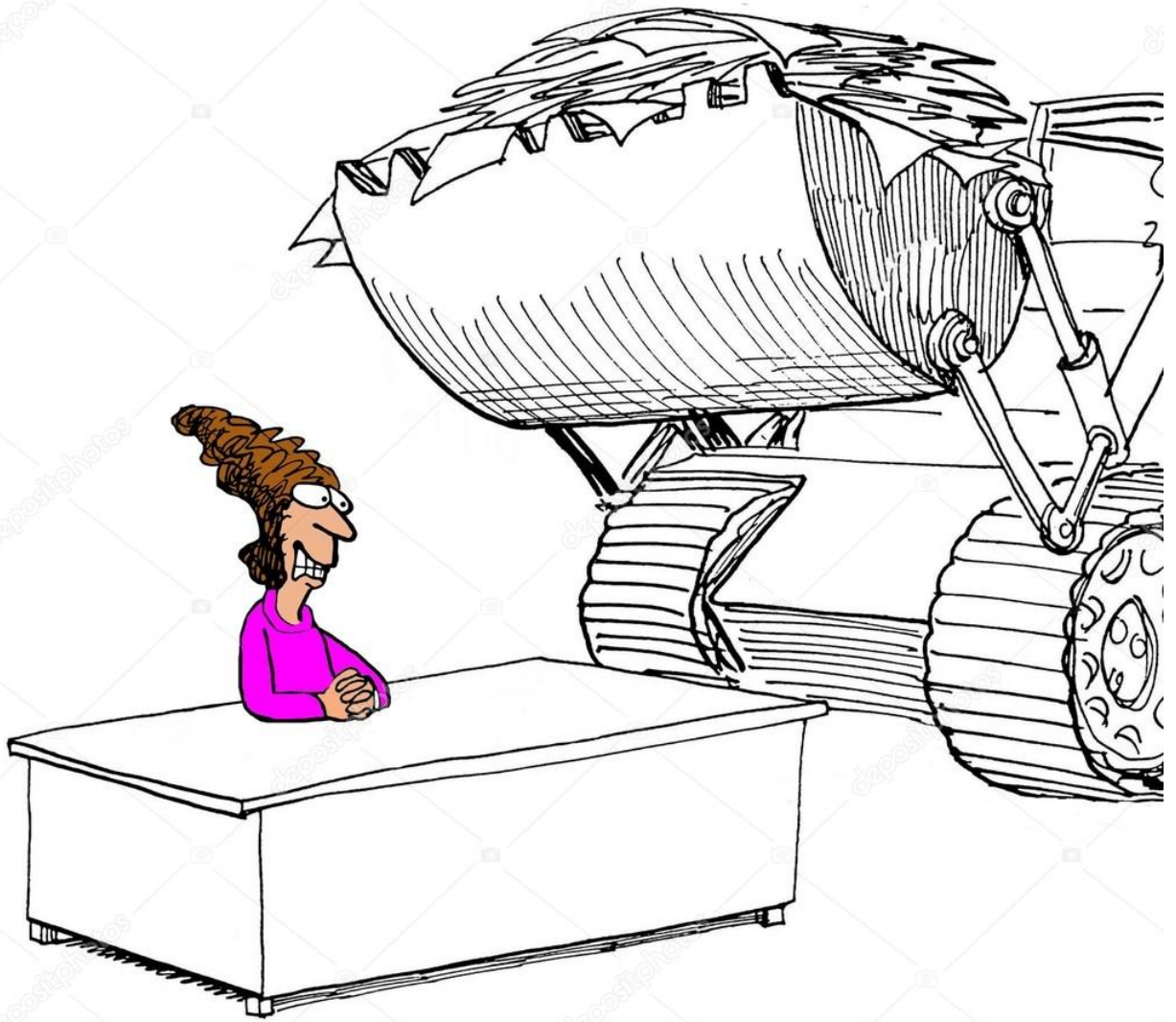


Coal face perspectives on research

- Too busy
- Too irrelevant
- Too drawn out
- Too expensive

- Doing it anyway
- Daily questions without answers
- Lost opportunities
- Research as quality improvement

The added admin

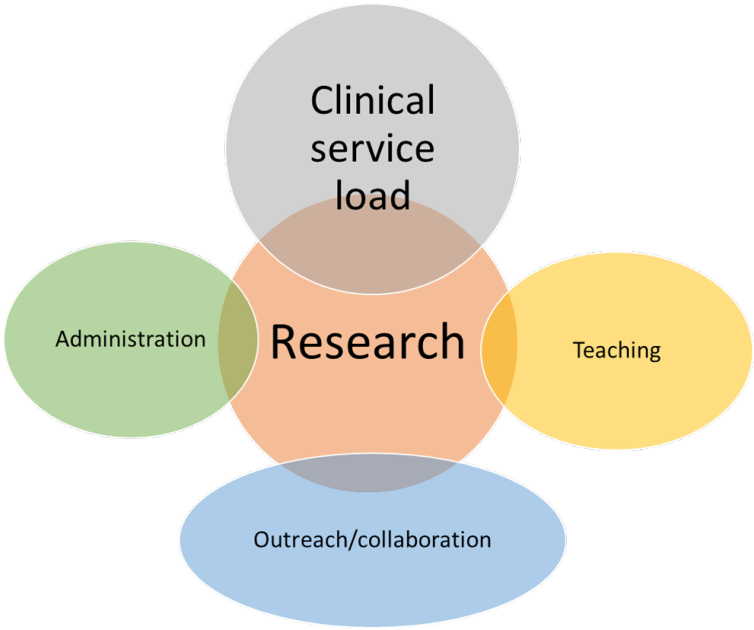


Opportunities

- More people and developing critical mass
- More money – non-linear issues around grant application success versus cautious incremental start-up in busy environments - sharing
- More enthusiasm and work-site appeal (clinical recruitment)
- More collaboration – joining the ‘team’ versus academic isolation
- More administrative buy-in
- More local academic ownership
- Mindset change –not if but how

Research in a busy environment - ethics

- Adds value if planned carefully
- Can be done, with external resources
- Opportunity costs management
- Moral duty to get involved in local research…



- Practically:
  - Ring-fenced research posts
  - Imaginative solutions to reduce impact on other commitments
    - Clinical manager appointments
    - Education posts
    - Locums/post for clinical service load and outreach