

Overdiagnosis and overtreatment as a quality problem: insights from healthcare improvement research

Author: Natalie Armstrong, Department of Health Sciences, University of Leicester, UK

Address: Department of Health Sciences, College of Life Sciences, University of Leicester, George Davies Centre, University Road, Leicester, LE1 7RH

Email: Natalie.Armstrong@le.ac.uk

Acknowledgements: Natalie Armstrong is supported by a Health Foundation Improvement Science Fellowship

Overdiagnosis and overtreatment as a quality problem: insights from healthcare improvement research

Overdiagnosis and overtreatment as a quality problem

Overdiagnosis and overtreatment are increasingly highlighted as a significant problem in contemporary healthcare. While not necessarily straightforward to define,^[1] overdiagnosis and any subsequent overtreatment are terms generally used about instances in which a diagnosis is 'correct' according to current standards but the diagnosis or associated treatment has a low probability of benefitting the patient, and may instead be harmful.^[2] While initially used largely in the context of cancer screening, more recently concerns about overdiagnosis and overtreatment have spread to a wide range of clinical activities.^[3,4] The potential consequences of overdiagnosis and overtreatment may be significant and include such harms as the psychological and behavioural effects of disease labelling, physical harms and side effects of unnecessary tests or treatments, unnecessary treatment negatively affecting quality of life, increased financial costs to individuals, and wasted resources and opportunity costs to the health system.^[2, 5, 6]

Overdiagnosis and overtreatment are attracting attention from a range of different disciplines and perspectives,^[7-9] but one way to understand them is as a quality problem, not least because many of these different perspectives arguably reflect dimensions of quality (e.g. the avoidance of harm, waste or inappropriate use). Looked at in this way, a concern with overuse is not so new. Those working in healthcare quality have long been concerned about problems of overuse and inappropriate use; one view being that all quality problems can be categorized in terms of either underuse, overuse or misuse.^[10] One implication from the many studies showing large variations in practice is that for interventions lacking good evidence of effectiveness, a substantial proportion of such activity is likely to have been at best unnecessary and at worst has caused avoidable harm.^[11] Therefore while arguably more attention has been placed on problematic underuse since publication

of the landmark Institute of Medicine reports of the early 2000s and a growing recognition of the frequency with which patients do not receive basic evidence-based processes of care, a concern with potential overuse and practical efforts to ensure appropriate use has nevertheless been present.^[12]
^{13]} The Institute of Medicine's six aims for the healthcare system include that healthcare be patient- or person-centred, and respectful of and responsive to an individual patient's preferences, needs, and values,^[14] both of which are highly relevant to avoiding overdiagnosis and overtreatment.

Insights from healthcare improvement research

If we understand overdiagnosis and overtreatment as a problem of healthcare quality then there are some helpful insights from healthcare improvement research that can be applied and which may help us understand how to give ourselves the best chance of success. In this paper I focus on three of these: i) the need for clear articulation of the problem and the factors driving it; ii) the value of careful, theory-informed design of interventions with clearly articulated and credible proposed mechanisms through which the desired outcomes will be achieved; and iii) the need for robust evaluation of efforts to tackle the problem, including qualitative, process evaluations. While not intended as an exhaustive or comprehensive account of these, what follows are some examples of, often hard-earned, learning.

Clear articulation of the problem, and the factors driving it

Overdiagnosis and overtreatment are acknowledged to be complex and not necessarily easy to define.^[1] Many likely contributing factors have been identified, including: increasingly sensitive tests that identify indolent, nonprogressive, or regressive abnormalities; expanded disease definitions and lowered thresholds for intervention; creation of 'pseudo diseases'; public enthusiasm for screening or testing and the desire for reassurance;^[15] clinicians' fears of missing a diagnosis or of being held to account for decisions not to act;^[16] and financial incentives.^[17] In an effort to develop a comprehensive overview, recent work from Australia has sought to map these possible drivers and link them to their potential solutions.^[18] This mapping suggests drivers of overdiagnosis and

overtreatment fall into one of five key domains: culture (e.g. an intolerance of uncertainty, or a belief that prevention is better than cure); health system (e.g. quality measures that encourage doing more, or financial incentives for tests, treatments and diagnoses); industry and technology (e.g. industry promotion of tests and treatments to both professionals and public, or diagnostic tests with increased sensitivity); professional (e.g. fear of litigation and associated defensive medicine, or lack of knowledge of potential harms); and patient and public (e.g. reliance on tests for reassurance, or lack of understanding of potential harms). Of note though, is that the vast majority of articles included in this mapping exercise were analyses or commentaries rather than empirical studies (although the authors state that many of the analysis pieces were informed by empirical work). Therefore, while there is no doubt much merit in the drivers proposed, further empirical work to really understand whether and importantly how these work in practice, and how they may be interconnected and mutually reinforcing, is still needed. Overdiagnosis and overtreatment are terms that tend to be used rather imprecisely, meaning different things to different people, and in different contexts.^[1] Given this complexity, it is unlikely that the same drivers will be relevant in all cases or that they will function in the same ways even if they are.

Careful, theory-informed design of interventions

There is growing recognition within healthcare improvement research of the gains to be had from ensuring that the design and execution of improvement efforts are appropriately theoretically informed, and that while a more intuitive approach to solution design may be effective in some cases, this is often biased, distorted and limited in scope.^[19] Articulating a clear theory of change, an account of how and why the planned activities are credible as a means through which the desired outcomes can be achieved, is an important early step in improvement work. A good example of this is Leviton et al's thoughtful approach to increasing the use of antenatal corticosteroids for fetal maturation.^[20] Here, an 'active, focused dissemination effort' on the benefits of using corticosteroids drew directly on research about adoption of medical practices and significantly increased the odds of

corticosteroid use. Engaging in this form of interrogation is important for, amongst other things, making the necessary shift from implicit to explicit thinking about how interventions are supposed to work and, relatedly, surfacing any weakness or incoherence in the proposed causal links.^[19]

Achieving clarity about and shared understanding of the outcomes sought is an important part of intervention design. In the case of tackling overdiagnosis and overtreatment the outcomes sought may vary. One objective may be to seek to reduce the use of particular tests or procedures which are regarded as in some way unnecessary in at least some cases. The number of tests or procedures carried out is likely to be quite straightforward to measure, but likely to be less clear is whether and how it is possible to discern which are truly not necessary. Another objective may be to reduce the rates of harms such as invasive treatment of anomalies that were unlikely to cause problems, but again being able to identify to which cases this applies is not straightforward. Another objective may be to facilitate more informed decision making on the part of patients about whether they wish to participate in interventions which may bring harms as well as possible benefits, such as participation in screening or taking preventive medication such as statins, or to achieve more meaningful use of approaches such as shared decision making in these types of cases. The challenges here are possible differences of opinion about what constitutes a harm or a benefit, and how to most appropriately trade these off against each other.^[1]

Numerous possible approaches to tackling the problems of overdiagnosis and overtreatment are starting to emerge, including the development of decision aids for people invited to take part in population-based screening programmes,^[21] shared decision making as a means through which to ensure that decisions about both diagnosis and any potential treatment are person-centred,^[22] awareness raising campaigns and educational programmes,^[23] and changes to financial and other incentives that are embedded within healthcare systems and which influence healthcare professionals' behaviour.^[18] Some initiatives encompass several of these strategies and may be understood as a form of complex intervention. The Choosing Wisely initiative is one such example,

combining the development of lists of tests and procedures that providers and patients should question, materials to help patients engage with healthcare professionals and ask questions,^[24] and educational resources for healthcare professionals to facilitate their engaging more effectively with patients.^[22] While appealing in principle, efforts to drive change through the facilitation of such ‘bottom up’ approaches can be deceptively difficult to achieve in practice.^[25]

Ensure robust evaluation of efforts to tackle the problem

The importance of evidence-based improvement is becoming ever clearer, with healthcare improvement research all too often showing that efforts to bring about change are either not effective at all or that those that appear effective in one place either cannot be sustained or fail to reproduce the same impact elsewhere. While overdiagnosis and overtreatment may be worthy problems to seek to address, robust evaluation of the impact of having done so is important. One reason for this is that the reward may turn out to be smaller than anticipated,^[26] with some studies of the likely gains to be made through targeting so called ‘low value’ care raising questions about the magnitude of any likely impact.^[27, 28] A second reason that robust evaluation is needed is that these issues may be trickier to gain traction on than might be anticipated. For example, Kullgren et al’s recent study of the impact of clinicians’ precommitting to follow Choosing Wisely recommendations with decision supports showed only a small, unsustainable decrease in potentially low value activity for one of three targeted conditions and a small increase in alternative orders.^[29] This is an interesting example as seeking to draw on the behavioural economics strategy of precommitment (committing one’s future self to a course of action) makes intuitive sense given its apparent success in changing other behaviours. Kullgren et al’s study provides sobering evidence of the apparent lack of effect in practice, however.

While efforts to develop integrated frameworks for evaluating the impact of some kinds of interventions are starting to be developed,^[30] these tend to focus on quantitative measurement of things like provider attitudes, patient experience and outcomes, and rates of use of different tests or

procedures. What tends to figure less prominently, but which healthcare improvement research increasingly shows to be vital, is process evaluation using qualitative methods such as observations, interviews and documentary analysis.^[31] Such an approach allows the depth of exploration and analysis necessary in order to ensure a comprehensive understanding of how implementation has happened in practice, why and how processes give rise to particular consequences, and why the same intervention may play out differently in different contexts.

Using such an approach to critically reflect on the underpinning theory of change for any intervention, and how this played out in practice, can be particularly useful. This is likely to be especially valuable for interventions seeking to achieve de-implementation rather than implementation,^[32] as professionals' practice is often deeply influenced by historical, social, cultural and economic forces, requiring complex interventions that take account of context. Even with seemingly adequate theorisation of change mechanisms, efforts to improve care can still fall prey to the sometimes bewildering complexity of healthcare systems and their challenging contextual features.^[33] Returning to the example of precommitting to follow Choosing Wisely recommendations, while Kullgren et al's study is valuable it does little to help us understand *why* the approach taken did not work in the ways hoped, what the flaws in the underpinning theory of change and/or the operationalisation of this in practice may have been, and what strategies may be more successful.

Conclusion

Understanding overdiagnosis and overtreatment as a problem of healthcare quality suggests some helpful insights from healthcare improvement research that can be applied. In this paper I have focused on three of these in particular. First, the need for clear articulation of the problem and the factors driving it, and recognition that these may vary in different cases according to features of, for example, the particular clinical context, or the professional or patient groups concerned. Second, the value of careful, theory-informed design of interventions with clearly articulated and credible

proposed mechanisms through which the desired outcomes will be achieved. Third, the need for robust evaluation of efforts to tackle the problem, including qualitative, process evaluations capable of producing in-depth and nuanced accounts of whether and how interventions have worked in practice.

Achieving improvements in healthcare quality is rarely straightforward; the challenges of tackling issues in practice and achieving meaningful and sustained change can be formidable. Overdiagnosis and overtreatment are problems that are often tricky to define, with suggestions that there may be much politics at play in deciding which problems are targeted^[34] and differing approaches to the significance attached to any possible harms that might be incurred or benefits that might be achieved.^[9] This is not to suggest that overdiagnosis and overtreatment are not worthy issues to seek to tackle, but rather to highlight that doing so in practice may be harder and more complex than anticipated.

References

1. Carter SM, et al. The challenge of overdiagnosis begins with its definition. *BMJ* 2015;350.
2. Moynihan R, Doust J, Henry D. Preventing overdiagnosis: how to stop harming the healthy. *BMJ* 2012;344.
3. Welch HG, Schwartz LM, Woloshin S. *Overdiagnosed: Making People Sick in the Pursuit of Health*. Boston: Beacon Press, 2011.
4. Hofman B, Welch HG. New diagnostic tests: more harm than good. *BMJ* 2017;358:j3314
5. Heath I. Role of fear in overdiagnosis and overtreatment - an essay by Iona Heath. *BMJ* 2014; 349.
6. Hicks LK. Reframing overuse in health care: time to focus on the harms. *Journal of Oncology Practice* 2015; 11:168-170.
7. Carter SM, et al. A definition and ethical evaluation of overdiagnosis. *Journal of Medical Ethics* 2016;42:705-714.
8. Hensher M, Tisdell J, Zimitat C. "Too much medicine": Insights and explanations from economic theory and research. *Social Science & Medicine* 2017;176:77-84.
9. Carter SM. Overdiagnosis, ethics, and trolley problems: why factors other than outcomes matter—an essay by Stacy Carter. *BMJ* 2017;358.
10. Chassin MR, Galvin RW. The urgent need to improve health care quality. Institute of Medicine National Roundtable on Health Care Quality. *JAMA* 1998;280:1000-5.
11. Wennberg JE. Time to tackle unwarranted variations in practice. *BMJ* 2011;342.
12. Bernstein SJ, et al. The appropriateness of use of coronary angiography in New York State. *JAMA* 1993;269:766-9.
13. Shiffman RN, Leape LL, Greenes RA. Translation of appropriateness criteria into practice guidelines: application of decision table techniques to the RAND criteria for coronary artery bypass graft. *Proc Annu Symp Comput Appl Med Care* 1993:248-52.
14. Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington DC: National Academy of Sciences, 2001.
15. Chen JY, Eborall H, Armstrong N. Stakeholders' positions in the breast screening debate, and media coverage of the debate: a qualitative study. *Critical Public Health* 2014;24:62-72.
16. Armstrong N, Hilton P. Doing diagnosis: Whether and how clinicians use a diagnostic tool of uncertain clinical utility. *Social Science and Medicine* 2014;120:208-214.
17. Moynihan R, Henry D, Moons KGM. Using evidence to combat overdiagnosis and overtreatment: evaluating treatments, tests, and disease definitions in the time of too much. *PLoS Medicine* 2014;11.
18. Pathirana T, Clark J, Moynihan R. Mapping the drivers of overdiagnosis to potential solutions. *BMJ* 2017;358:3879.
19. Davidoff F, et al. Demystifying theory and its use in improvement. *BMJ Qual Saf* 2015;24:228-238.
20. Leviton L, et al. Methods to encourage the use of antenatal corticosteroid therapy for fetal maturation. A randomized controlled trial. *JAMA* 1999;281:46-52.
21. Hersch J, et al. Use of a decision aid including information on overdetection to support informed choice about breast cancer screening: a randomised controlled trial. *The Lancet* 2015;385:1642-1652.
22. Berger ZD, et al. Patient centred diagnosis: sharing diagnostic decisions with patients in clinical practice. *BMJ* 2017;359.
23. <http://www.choosingwisely.org/>
24. Born KB, et al. Engaging patients and the public in Choosing Wisely. *BMJ Qual Saf* 2017;26: 687-691.

25. Aveling EL, et al. Optimising the community-based approach to healthcare improvement: comparative case studies of the clinical community model in practice. *Social Science and Medicine* 2017;173:96-103.
26. Willson A. The problem with eliminating 'low-value care'. *BMJ Qual Saf* 2015;24:611-614.
27. Colla CH, et al. Use of non-indicated cardiac testing in low-risk patients: Choosing Wisely. *BMJ Qual Saf* 2015;24:149-153.
28. McAlister FA, et al. Frequency of low-value care in Alberta, Canada: a retrospective cohort study. *BMJ Qual Saf* 2017.
29. Kullgren JT, et al. Precommitting to choose wisely about low-value services: a stepped wedge cluster randomised trial. *BMJ Qual Saf* 2017.
30. Bhatia RS, et al. Measuring the effect of Choosing Wisely: an integrated framework to assess campaign impact on low-value care. *BMJ Qual Saf* 2015;24:523-531.
31. Portela MC, et al. How to study improvement interventions: a brief overview of possible study types. *BMJ Qual Saf* 2015;24:325-336.
32. van Bodegom-Vos L, Davidoff F, Marang-van de Mheen PJ. *Implementation and de-implementation: two sides of the same coin?* *BMJ Qual Saf* 2017;26:495-501.
33. Armstrong N, et al. Taking the heat or taking the temperature? A qualitative study of a large-scale exercise in seeking to measure for improvement, not blame. *Soc Sci Med* <http://www.sciencedirect.com/science/article/pii/S0277953617307773>
34. Morden NE, et al. Choosing Wisely — the politics and economics of labeling low-value services. *N Engl J Med* 2014;370:589-592.