TITLE: Walking the tightrope: communicating overdiagnosis in modern healthcare

STANDFIRST: Communication that empowers the public, patients, clinicians and policy makers to think differently about overdiagnosis will help support a more sustainable healthcare future for all.

Authors: Kirsten McCaffery, Jesse Jansen, Laura Scherer, Hazel Thornton, Jolyn Hersch, Stacy Carter, Alex Barratt, Stacey Sheridan, Ray Moynihan, Jo Waller, John Brodersen, Kristen Pickles, Adrian Edwards

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INTRODUCTION

Overdiagnosis and overtreatment have serious implications for individuals, healthcare systems and society (see Box 1)[1 2] and effective strategies are urgently needed to help the public, clinicians, and policymakers address this problem. Communication about overdiagnosis has been highlighted as an essential strategy for moving forward. However, communicating about it presents several challenges, such as the potential to confuse the public, undermine trust and adversely affect those already diagnosed. Various *communication-based* strategies offer real promise; this paper describes what is currently known and what we need to know to communicate effectively, and safely about overdiagnosis and overtreatment.

Box 1.

Overdiagnosis and its consequences[1 2]

- Overdiagnosis occurs when a diagnosis is "correct" according to current professional standards, but when the diagnosis and/or associated treatment has a very low probability of benefiting the person diagnosed:[2] It is caused by a range of factors such as:
    - Use of increasingly sensitive tests that identify abnormalities that are indolent, non-progressive or regressive (*over-detection*)
    - Expanded definitions of disease, for example ADHD and dementia, and lowering of disease thresholds such as hyperlipidemia or osteoporosis (*over-definition*)
    - Creation of pseudo-diseases (also called 'disease mongering') e.g. '*Low T*' and '*Restless leg syndrome*'
    - Clinicians' fear of missing a diagnosis / fear of litigation
    - Patient / public enthusiasm for screening/ testing and desire for reassurance
    - Financial incentives
- *Consequences* of overdiagnosis
    - Psychological and behavioural effects of disease labelling
    - Physical harms and side-effects of unnecessary tests or treatment
    - Quality of life impact of unnecessary treatment
    - Hassles of unnecessary tests and treatments
    - Increased financial costs to individuals
    - Wasted resources and opportunity costs to the health system
    - Over-medicalization of society

What are the key messages to be communicated?

Understanding of overdiagnosis among the general public and health professionals is limited, so it is essential to communicate what overdiagnosis means for individuals, the health system and society. By definition, overdiagnosis will not improve prognosis, and will likely harm individuals (e.g. unnecessary intervention) and/or society (e.g. opportunity costs). For individuals, it is important to communicate the nature (physical and/or psychological), likelihood and duration of the harms. For societies with free public healthcare, the financial strain and opportunity cost is usually borne only at the macro level – the resources, including clinician time wasted by unnecessary tests and treatments hence unavailable for people in greater need. For societies with private healthcare systems, overdiagnosis can be a huge personal financial burden, even for those with insurance.
The financial and opportunity costs and consequences of overdiagnosis to the individual and society need to be clearly explained.

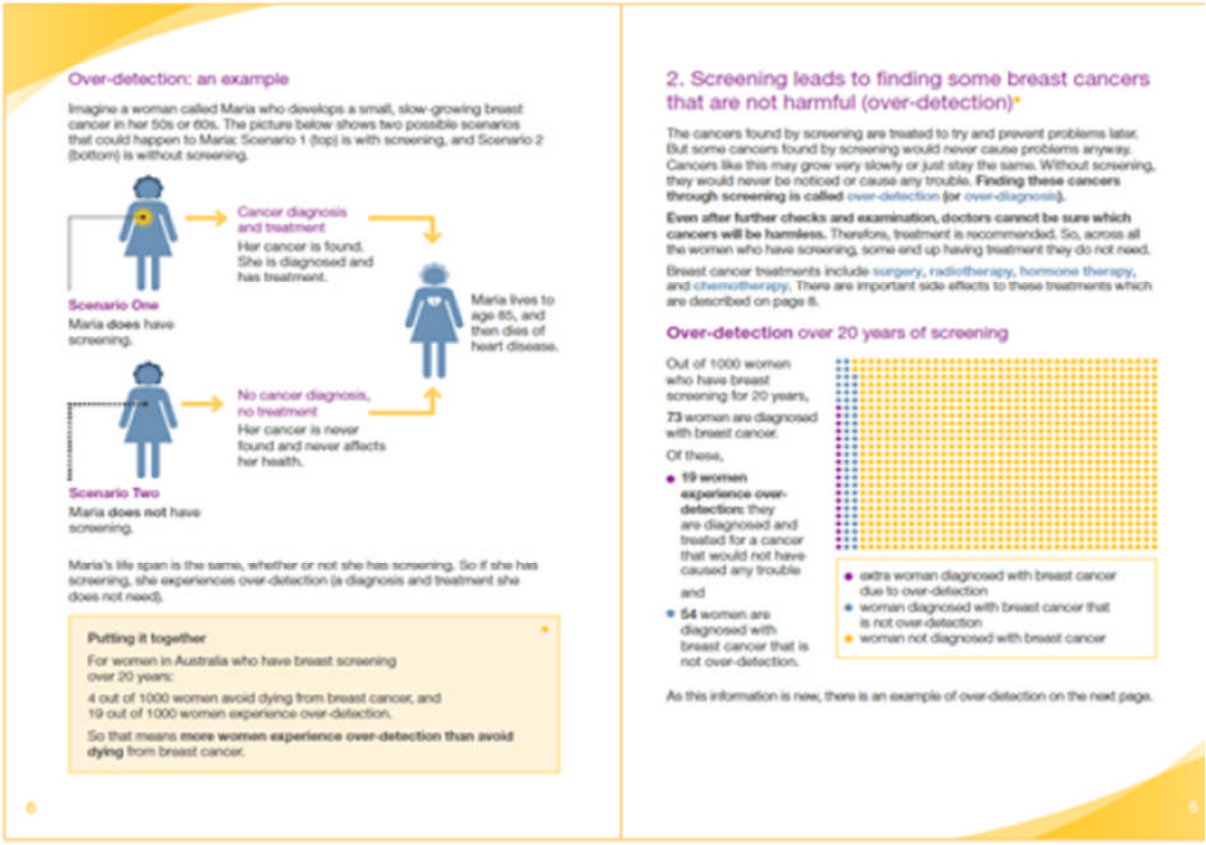
Communication is further complicated because it is usually impossible to know if an individual has been overdiagnosed or benefited from the diagnosis – overdiagnosis can only be observed at the aggregate level. Recent efforts to communicate the concept and likelihood of overdiagnosis in breast screening have found some success albeit still with much room for improvement. Using an infographic and icon array as part of a patient decision aid (Figure 1[3]), 29% of women understood both the concept and quantitative outcomes of breast screening (including deaths avoided, false positives and overdiagnosis); 59% of women understood the conceptual information alone.

Communication-based strategies to mitigate overdiagnosis

Several communication-based strategies have been applied in the areas of overtesting and overtreatment, and directed at individual, community or policy levels (see Box 2).

Strategies for individuals: *Shared Decision Making* (SDM) is a consultation process where a clinician and patient jointly make a health decision. SDM changes the way decisions are framed, firstly by identifying that there is a decision to be made (not an obligatory test or default treatment), and explaining the range of options available and their benefits and harms. Secondly it involves deciding with the patient "what is most important to them", in terms of their values, preferences and circumstances.[4] Importantly, the option of doing nothing or active surveillance can be identified and discussed as a deliberate or positive action[5] to counter people's bias for active tests and treatment, especially in the context of cancer.[6] Some consumer-led question-asking interventions explicitly teach patients to ask about benefits and harms of different options and have shown some success.[7] SDM is increasingly part of clinical training, often combined with evidence-based healthcare,[8] and this should be enhanced further to include understanding and communicating about overdiagnosis.

Figure 1. Infographic and icon array explaining overdiagnosis (*overdetection*) in breast screening in a patient decision aid developed by Hersch et al[3]



Patient decision aids are tools to support SDM. High quality evidence from 115 trials shows they improve patients' knowledge and understanding of options and their risks and benefits, and increase consistency between patients' values and choices[9]. Decision aids have successfully informed women about overdiagnosis in breast screening,[3] reduced men's desire for PSA testing[10] or surgical management for prostate cancer, and reduced preferences for potentially unnecessary elective surgery.[9] The only published decision aid trial explicitly communicating overdiagnosis in breast screening (879 women approaching age 50) showed that detailed information about overdiagnosis increased informed choice compared to controls and did not increase anxiety; worry about breast cancer decreased (see Box 2).[3] A pilot study of a breast screening decision aid for women over 75 years (n=45) including overdiagnosis information had similar findings.[11 12] However, at present, information on the harms of overdiagnosis and overtreatment is rarely presented.[13 14] Consumers consistently overestimate the benefits of screening, tests and treatments and underestimate the harms,[13] and while SDM is widely espoused, it is not often implemented.[15].

Strategies for communities: *Mass media and direct-to-consumer communication* campaigns can influence large numbers of people simultaneously and can promote sustained beneficial behaviour changes.[16] For example, a mass media campaign about back pain, driven partly by concerns about unnecessary back imaging, changed both community and GP beliefs about management, resulting in

reduced imaging, work insurance claims and healthcare utilisation.[17] Scaled down versions of the program have now been replicated in several countries.[16] Other important initiatives include the *Choosing Wisely* Campaign, now operating in 9 countries (www.choosingwisely.org) and UK's *Do not Do*.

Policy directed strategies: *Deliberative democratic methods (e.g. community juries)* support policy decisions by gathering informed public responses about disputed issues, such as what services are available or reimbursed by health funds. Because overdiagnosis is scientifically and politically contested, this topic is ideal for deliberative democratic methods. Deliberative methods must meet exacting standards and are time consuming.[18] Community juries have considered PSA testing in Australia[19 20] and mammographic screening in New Zealand, where participants changed their recommendation at least partly because of potential harms from overdiagnosis.[21] Disseminating findings from juries could enhance community health literacy, leading to better-informed citizens and more transparent decision-making.

Changing 'disease' terminology: Behaviours can be influenced by medical terminology, and changing nomenclature for medical conditions may help reduce the impact of overdiagnosis. In one study, referring to Ductal Carcinoma In Situ as "non-invasive *cancer*" resulted in 13-16% more women choosing surgical treatment—rather than medication or active surveillance—compared to calling it a "breast lesion" or "abnormal cells".[22] Similar findings were reported in Australia.[23 24] Independent experts convened by the US National Cancer Institute[25] and National Institute of Health[26] have proposed dropping the word "cancer" entirely in this case, arguing "to reserve 'cancer' or 'carcinoma' for lesions likely to progress if untreated". Similar arguments exist regarding thyroid and prostate cancer[27] but effects of disease labels extend beyond cancer. Parents were more likely to accept medication when the term "Gastro-esophageal Reflux Disease" (compared to no label) was used to describe excessive irritability in infants, even when told the medications were ineffective for symptom control.[28] Careful use of terminology may be important in mitigating overdiagnosis and overtreatment.

Box 2.

Examples of tested and effective communication strategies for overdiagnosis or overtreatment

Community interventions

- Back pain campaign (3 year campaign 1997-1999)[17]
    - Significant improvements in community (n=4730) beliefs about back pain over 3 years in Victoria (where campaign was run) vs New South Wales (NSW) (not run).
    - GP (n=2556) knowledge improved *e.g.* time when patients can to return to work; not prescribing complete bed rest. Victorian GPs 2.51 times as likely *not* to order tests for acute low back pain and 0.40 times as likely to order lumbosacral radiographs. Insurance claims for back pain reduced 15%.

Individual (public and patients) interventions

- Patient decision aids (ptDAs)[9]
    - Cochrane review of 115 RCTs reported where assessed, ptDAs reduced number of people choosing major elective surgery in favour of more conservative options (RR 0.79) and reduced number of men choosing PSA testing (RR 0.87) in 9 studies.
    - Breast screening ptDA - RCT of a ptDA for women approaching 50 years (n=879) which explicitly explained the concept of overdiagnosis and presented quantitative information on its likelihood found: intervention PtDA increased informed choice by 9% (I=24% vs C=15%), reduced intentions to screen by 13% (I=74% vs C=87%)[3].

Policy

- Changing disease terminology
    - Ductal Carcinoma In Situ (DCIS) – study of 394 women compared the commonly used cancer term for DCIS (non-invasive cancer) with non-cancer terms (breast lesion, abnormal cells). Results showed 47% preferred surgery when cancer term used compared to 34% and 31% respectively.
- Citizen Juries
    - PSA Screening Community Jury[24] 27 men randomly allocated to jury (n=11) or control. The jury concluded the Australian government should not invest in PSA testing, it recommended an education program for GPs with better quality and consistent information about PSA for doctors and patients. After the jury, men had significantly lower intentions to screen compared to controls.

Potential challenges to effective communication

Low levels of awareness: Awareness of overdiagnosis is generally low, particularly about cancer screening.[29 30] In one study, 18% of Australian men and only 10% of women said they had been told about overdiagnosis in screening for prostate and breast cancer respectively.[31] Similarly, a US survey reported only 9.5% of men and women (aged 50-69 years) had been informed about overdiagnosis when discussing cancer screening.[32] Further US and UK studies reported that only about half of respondents had heard of 'cancers that grow so slowly that they are unlikely to cause [you] problems in [your] lifetime'.[33 34] There are few publications reporting clinician awareness but one recent survey among 126 university-affiliated clinicians in the US found 28% listed overdiagnosis as a potential harm of PSA testing, and 56% listed unnecessary treatment.[35]

Cognitive biases and counter-intuitive messages: Amid longstanding, prominent public health messages emphasising benefits and ignoring the harms of early diagnosis across for many diseases, [36 37] the concept of overdiagnosis is unfamiliar, counter-intuitive and difficult to understand. There is

widespread faith in the importance of 'early detection,[38 39] and people may continue to choose cancer screening tests because it is the apparent default decision, even if their own informed preferences would be different.[40-42] Furthermore, when people are positively predisposed towards an intervention, they may perceive benefits to be high and risks low, even when explicitly told otherwise.[43] Suggesting a reduction in tests that are popular with the public can provoke emotionally charged, even hostile responses,[44] reflecting potential 'cognitive dissonance' in reaction to one's pre-existing beliefs and feelings.[45]

Uncertainty and trust: Intolerance of uncertainty and anxiety about missing rare cases underpin much medical excess.[46] Communicating about overdiagnosis involves acknowledging the inherent uncertainty in the size and extent of the problem and its consequences. These issues are often hotly contested.[47] Communicating uncertainty adds complexity, may lead to confusion and avoidance of decision making,[48] can undermine trust in the healthcare provider,[49]and is usually avoided by clinicians in conversations with patients[48]. Information about overdiagnosis has potential to erode trust especially for interventions that have been heavily promoted.[29] However, distrust may also be experienced when it is discovered that information about harms has been withheld. People feel information about overdiagnosis should be made available, as shown in both breast and prostate screening studies.[19 29]

Vested interests and persuasive communication: Vested interests may influence how information is presented in the media and the scientific arena. Pharmaceutical and device manufacturers have direct interests in maximising product sales. Industry-funded disease-awareness campaigns often increase the numbers of people portrayed as patients.[50] Narrowing the boundaries that define disease or raising diagnostic thresholds is a threat to turnover, profit and professional interests.[51] Similarly patient advocacy groups, often also industry-funded, can have interests in portraying their condition as widespread, severe and treatable to optimise media, professional and policy attention, and to attract resources.[52] Politicians too have seen mileage in supporting screening programs which touch the lives of many voters, without offering more nuanced assessments of their benefits and harms, including risks of overdiagnosis (e.g. https://www.gov.uk/government/speeches/innovation-and-efficiency).

Further research directions

We need studies about what the public, patients and clinicians currently know, understand, and want to know about overdiagnosis, and their attitudes, reactions and choices made when provided with such information. Then we can research effective communication itself – how to increase understanding among all parties through mass media and the effectiveness and acceptability of such strategies; the effects of altered terminology; the best formats for presenting information; how to best achieve shared decision making, and finding ways to support active surveillance as a positive management option when viable. Once identified, we need to understand how to implement such interventions within healthcare systems that currently reward overdiagnosis. However, research must also consider potential harms of communicating overdiagnosis, and herein lies the tightrope. Possible harms include cognitively overburdening and confusing the public, adversely affecting patients already diagnosed and treated, and creating distrust in conventional medicine.[29] A careful evidence-based approach is essential.

CONCLUSIONS:
Communication lies at the heart of the problem of overdiagnosis, but is also integral to its solution. Despite the challenges, we have some tools to move forward. Achieving widespread understanding about overdiagnosis will take time. The medical/health community must be patient and compassionate with those who do not currently share our concern about overdiagnosis, given that high health anxiety is in large part a consequence of the health system itself. Successful communication that empowers the public, patients, clinicians and policy makers to think differently about overdiagnosis will help support more sustainable healthcare for all.

Key Messages
• Overdiagnosis provides no benefits for patients and presents a major challenge to the sustainability of modern healthcare systems, and effective strategies are needed to tackle this growing problem. • *Communication-based* strategies could help reduce overdiagnosis and its negative impact on individuals and the health system. • Mass media education, shared decision making, terminology changes for disease states, and deliberative methods (juries) all have potential. • This paper considers what is currently known and what we still need to know to communicate this complex topic to the public, patients, clinicians and policy makers.

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and expert in quantifying the harms of screening, KP is a PhD student with expertise in clinicians' understanding of overdiagnosis.

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