RCGP Standing Group on Overdiagnosis

For shared decisions in healthcare

Aim

Some current or proposed areas of Primary Care Activity may have relatively small gain for patients, and little evidence base for benefits. Additionally, there is a pressing need to consider the needs of people with multi-morbidities.

This paper examines policy making in relation to overdiagnosis and overtreatment in general practice, and makes recommendations for the future examination of policy, either presented to or created within the RCGP, in order to prevent avoidable harm, via the use of 'tests' to be applied to new policies being considered. This can be done by any member of College. Members of the Over-diagnosis group are willing to assist on request.

Introduction

Overdiagnosis and overtreatment can be defined as the application of diagnoses and treatments which are of little or no value to patients, or cause net harm. (1)

Additionally, this diverts resources from more effective interventions and potentially impacts on worsening inequalities, by creating disadvantage for patients, producing waste, and increasing the ineffective workload of primary care. Concerns include:

- the unintended consequences of overdiagnosis in screening (e.g. Ductal Carcinoma in Situ in breast screening) (2) ,
- Lowering of thresholds for cardiovascular risk management (e.g. hypertensive treatment) out with evidence for benefit (3)
- Risks of polypharmacy especially in regard to multi-morbidity (4)
- Guidelines which may not always apply to the population they are recommended for. (5)
- Individual patient values should be integral to decision making, but may conflict with standard recommendations for risk management (6)
- The need to encourage shared decision making as in Good Medical Practice (7) may not always be promoted
- Opportunity costs of well meaning interventions may lead to less time with patients with higher needs.

It is not usually possible to determine the individual who has been over-treated except in trials, in retrospect, and on a population basis. However, doctors have a duty to share known uncertainties, and assist shared decision making to enable patients and carers to make informed choices based on their priorities. There is evidence that given high quality information, patients and carers can make better informed decisions (8,9).

Information such as Number Needed to Treat (NNT), Number Needed to Harm (NNH), and information such as absolute risk is commonly included in shared decision aids in order to facilitate high quality choices.

Aligned policy

This work aligns with other RCGP policy in inequalities, because overdiagnosis and overtreatment may lead to an exacerbation of health inequalities via the reduction of resources available. It builds on the work the RCGP is already doing for patient involvement and leadership, because much overtreatment is avoided by shared decision making, where doctor and patient reach individual decisions about what risks and benefits are acceptable.

It aligns with strategies on care planning with especial regard to multi-morbidity, because overtreatment is frequently linked to polypharmacy, including low value treatments with risks of

drug interactions. In addition, this policy is aligned with the recent Supreme Court judgement "to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment and of any reasonable alternative or variant treatment" (10).

Further, priority for 2015/16 within the RCGP is for "Measures that will incentivise the provision of patient-centred care to those living with multiple-morbidities and their carers", which this policy will strongly support.

Tests for new policies

It is recommended that when policies, statements or guidelines are generated by the RCGP or come to the RCGP for approval or comment, they should be subject to the tests below to ensure the risk of over-diagnosis and over-treatment are minimized, while concurrently ensuring that informed choice is promoted through transparent presentation of evidence and uncertainties.

1. **Shared decision making and patient involvement.**
    - When statements, policy or guidelines are produced, the RCGP recommends that, where relevant, statistical information which helps GPs to assist decision making, such as absolute risk, NNT, and NNH are referred to or included along with representation of hazards and uncertainties. To assist patients in making decisions, decision aids, or representation of choices suitable for different types of literacy are recommended.

2. **Population.**
    - Where statements, policy or guidelines are produced, the RCGP recommends that the populations the statements are applicable and not applicable to - with special regard to frailty and multi-morbidity – are clear.

3. **Evidence.**
    - Where statements, policy or guidelines are produced, the RCGP recommends that, where relevant, they should be based on high quality evidence. A statement describing current (un)certainty should be included, along with comment, if necessary, on how to reduce avoidable uncertainties (for example, through recommending that interventions are performed 'only in research'). Opportunity costings should be stated, or the absence of opportunity costings should be highlighted.

4. **Screening.**
    - If the policy, statement or guideline is a screening or risk management screening programme, the RCGP recommends that it should be made clear whether it has been verified, or not, by the independent UK National Screening Committee.

5. **Declarations of interest.**
    - The RCGP recommends that declarations of interest should be made public and clear to professionals, patients and carers. Conflicts of interest can create biases in medical practice, and, as the GMC recommends, doctors and researchers should be open about declaring them.

Historical examples when these tests could have been used

Locally Enhanced Service (LES) for Dementia Screening

In 2013 a LES for the screening of people aged over 75, or people aged over 65 with one or more risk factor for dementia (such as hypertension) was enacted. The expected outcomes were, that if 7 in 100 people aged over 65 would have dementia, screening would detect 6 new cases, give a false positive result to 12, and miss 1 (11). 13 in every 100 patients it was applied to will have had false positive or false negative results.

- NNT/NNH (numbers needed to treat / numbers needed to harm), false positive and false negative rates was not centrally created when the LES (locally enhanced service) was produced and was thus not available systematically to all patients to allow shared decision making
- screening for dementia had not been approved by the UKNSC (The UK National Screening Committee)

Type II Diabetes HbA1c

In 2009/10 the Quality and Outcomes Framework (QoF) targets were set for patients with HbA1c readings of less than 7%, less than 8%, or less than 9%. The lowest threshold had been lowered from the previous 7.5%.

In the 2012/13 contract, the thresholds were HbA1c of 59mmol/l or less, 64mmol/mol or less, and 75mmol/mol or less.

The latter thresholds were maintained in the 2014/15 contract.

However the ADVANCE study in 2008 and the Action to Control Cardiovascular Risk in Diabetes (ACCORD) study follow up suggested that aiming for tighter control caused an increased risk of death and no significant advantage to morbidity and a higher risk of hypoglycemic episodes (12, 13).

In 2010 it was found that patients' values regarding HbA1c level were crucial for effective management, and that for most patients over 50 with an HbA1c under 9%, any further lowering had little gain in quality or quantity of life. However it generated unintended harms such as hypoglycemia. (14) This target was therefore likely to have increased the burden of treatment for many without decreasing the risk of earlier death or substantially impacting on morbidity.

- there was significant uncertainty of outcomes of tighter HbA1c control when recommendations were initially made
- the unintended outcomes of lower treatment targets may have included avoidable hypoglycaemia,
- evidence based information for patients and carers regarding these uncertainties was not made clear when the targets for treatment were set, and the need for patient values was not made clear

Healthchecks (similar KeepWell programme in Scotland)

Healthchecks must be commissioned for each adult without a chronic disease between the ages of 45-75 in England. A systematic review of health screening in adults in 2012 found no evidence that they lead to reductions in mortality or morbidity (15) A trial of screening for Type 2 diabetes in England published in 2012 found that it did not improve mortality or morbidity (16), as did the Inter-99 study of a very similar intervention in Denmark (17) The process has not changed prevalence rates (18) and is less acceptable to populations with higher deprivation (19). The Keep Well programme in Scotland has not been found to reduce cardiovascular outcomes (20).

- there were significant uncertainties regarding the evidence for the programme at inception
- high quality decision aids at the point of invitation were not available, and recent statin decision aids are in the main online, and not therefore available to people without an internet connection or with poor literacy
- the programme has not been instigated or overseen by the UKNSC (UK National Screening Committee)

Declarations of interest

There are many gaps in the evidence around the impacts of conflicts of interest. However there is evidence that conflicts are associated with bias (21, 22) . In accordance with GMC (General Medical Council) Good Medical Practice (23), declarations of interest should be made accessible, so that prescribers and patients can decide for themselves whether the declaration constitutes an actual conflict of interest. The RCGP, leading the way in transparency, should include permanent DOI statements of authors of policy or guideline documents, speakers at RCGP events, clinical champions, and speakers at educational and conference events.

Conclusions

In conclusion, ensuring that uncertainties and potential for harm are factored into policy creation or requests for approval of the RCGP through the use of the proposed tests:

- has the potential to reduce waste, through reducing unnecessary and low value interventions;
- will promote patient involvement and shared decision making;
- will improve communication around declared interests to professionals, patients and carers
- which in turn will lead to improved quality of patient care.

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Addendum

Number needed to treat: How many patients would need to be treated in order for one to benefit

Number needed to harm: How many patients would need to be treated in order for one to be harmed

Absolute risk: The observed or calculated risk (or benefit) expressed in percentage form.

For example, the absolute risk of an intervention may be in reducing risk by 5%, from 10% to 5%. However the relative risk reduction is 50% (half of 10 is 5).