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Removing the cancer label from low risk conditions

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**STANDFIRST:** Brooke Nickel and colleagues consider the evidence that removing the cancer label in very low risk conditions that are unlikely to cause harm if left untreated, may be one helpful strategy to address issues of overdiagnosis and overtreatment.

There is a growing body of research showing that disease labels can impact people’s psychological responses and their decisions about management options. The use of more medicalised labels can increase both concern about illness and desire for more invasive treatment.\(^1\) For low risk cancers where there is evidence of overdiagnosis\(^2\) and calls to replace the term cancer,\(^3\)\(^-\)\(^6\) we consider the potential implication of removing the cancer label.

**Our changing understanding of the prognosis of cancers**

Some ‘cancers’ are non-growing or so slow-growing that they will never cause harm to patients if left undetected.\(^2\) A prime example of this type of cancer is low risk papillary thyroid cancer. Autopsy studies reveal there is a large reservoir of undetected papillary thyroid cancer that never causes harm\(^7\) and there is now substantial evidence of a dramatic increase in the incidence of thyroid cancer in many developed countries. This increase has been predominantly driven by an increase in small papillary thyroid cancers, with mortality remaining largely unchanged.\(^8\) Detection of these small papillary thyroid cancer has mainly been a result of the advent of new technologies, increased access to health services and thyroid cancer screening.\(^5\) Studies demonstrate that rates of metastases, progression to clinical disease and tumour growth in patients diagnosed with small papillary thyroid cancer who receive immediate surgery are comparable to those who follow active surveillance.\(^9\)\(^10\)

Likewise, for both low risk ductal carcinoma in situ (DCIS) and localised prostate cancer, detection strategies have become controversial as long-term outcomes for both conditions have been shown to be excellent\(^11\)\(^12\) and there is evidence and concern about overdiagnosis and overtreatment.\(^2\) Given
the potential harms of overtreatment of DCIS, active surveillance is now being trialled internationally as an alternative management approach.\textsuperscript{13-15} Active surveillance is also recognised as a safe and desirable management option for localised prostate cancer in current clinical practice, although invasive procedures such as a prostatectomy are still common and conventional treatment options for men diagnosed with localised disease.

Beyond low risk thyroid cancer, DCIS and prostate cancer, there is some evidence and informed speculation that melanoma in situ, small lung cancers and certain small kidney cancers may be considered low risk cancers and subject to similar overdiagnosis and overtreatment.\textsuperscript{2 16-18}

**The cancer label**

For decades ‘cancer’ has been associated with death. This association has been ingrained in society with public health messaging that ‘cancer screening saves lives’. This promotion has been used with the best of intentions, but in part deployed to induce feelings of fear and vulnerability in the population and then offer hope through screening\textsuperscript{19} (Box 1).

While conservative management approaches, such as active surveillance, are becoming an option for some patients with cancer, there is still a strong perception that aggressive treatments are always required.\textsuperscript{20} Recent studies on men diagnosed with localised prostate cancer have found that emotional distress of the diagnosis may motivate men to choose more aggressive treatment.\textsuperscript{21} However, not treating prostate cancer and following active surveillance also increases men’s levels of anxiety, rates of depression and fear of cancer recurrence.\textsuperscript{22} Importantly, almost a quarter of men who initially choose to manage their prostate cancer with active surveillance opt for surgery or radiation therapy within 5 years for non-biological reasons.\textsuperscript{23}
Box 1. Impact of the cancer label

Widespread enthusiasm for cancer screening

- Landmark US survey found that 87% of adults believe routine cancer screening is almost always a good idea and 74% of adults said that finding cancer early (most or all of the time) saves lives.\textsuperscript{24}
- A British survey of 2024 men and women aged 50-80 years found that almost 90% of people believe that screening is ‘almost always a good idea’ and 49% said that they would be tested for cancer even if it was untreatable.\textsuperscript{25}
- In studies on breast and cervical cancer it has been shown that women are often highly resistant to the idea of less intensive screening, with concerns about the frequency of screening intervals and that the changes are being made due to cost cutting considerations rather than on the basis of improved evidence about managing the cancer in question.\textsuperscript{26-28}
- Interviews with more than 10,000 members of the European public demonstrates that 92% of women and 89% of men overestimate (or do not know) the mortality benefit of breast and prostate cancer screening.\textsuperscript{29}

Strong desire for surgery

- In a study including healthy US adults it was found that when treatment was framed as being harmful, participants were significantly more inclined to opt for surgery compared to medication (65% v. 38%, $\chi^2=11.40$, $p=0.001$), even though doing so may increase their chance of death.\textsuperscript{20}
- A study of 394 women found that when ductal carcinoma in situ (DCIS) was described as a non-invasive cancer 47% of women preferred surgery over non-surgical treatment options such as medication or active surveillance, whereas only 34% preferred surgery when it was described as ‘breast lesion’ and 31% when it was described as ‘abnormal cells’ ($p<0.001$).\textsuperscript{30}

Uncertainty around active surveillance of cancer

- In a 5-year nationwide follow-up study it was found that 23% of men discontinued active surveillance for their low to intermediate risk prostate cancer diagnosis for non-biological reasons (20% patient preference and 3% other reasons).\textsuperscript{23}

Psychological repercussions

- Across a sample of 1521 men diagnosed with localised prostate cancer it was found that men who were more emotionally distressed at the time of diagnosis were more likely to choose surgery over active surveillance (RRR 1.07; 95% CI 1.01, 1.14; $p=0.02$).\textsuperscript{21}
- A population-based prospective cohort study of 341 men demonstrated that at 9-11 years after diagnosis men who started active surveillance and/or watchful waiting for their low risk localised prostate cancer had higher levels of distress and hyperarousal than men who had radiation or high-dose-rate brachytherapy (AMD=5.9; 95% CI [0.5, 11.3] and AMD=5.4; 95% CI [0.2, 10.5], respectively) and higher levels of distress and avoidance than men who had low-dose-rate brachytherapy (AMD=5.3; 95% CI [0.2, 10.3] and AMD=7.0; 95% CI [0.5, 13.5], respectively).\textsuperscript{22}

One potential strategy to calibrate expectation and to avoid unnecessary testing and treatment for these low risk cancers may be to remove the cancer label from conditions unlikely to cause harm if left untreated. This strategy has been proposed by several international experts,\textsuperscript{3,6} including a
National Institutes of Health state of the science conference panel and a National Cancer Institute working group. In line with this, the chief medical officer of the American Cancer Society Otis W. Brawley has stated: “We need a 21st-century definition of cancer instead of a 19th-century definition of cancer, which is what we’ve been using.”31 Notwithstanding the challenges, we agree there is now a clear need to re-label a number of precancerous conditions and low risk cancers (Table 1).

**Evidence about labelling supports move to change**

There is now evidence from several studies that describing a condition using more medicalised labels, including the use of the term ‘cancer’, can lead to an increased preference for more invasive management options (Table 2),1 and this supports calls to remove the cancer label, where appropriate. The increased desire for more invasive management may be particularly important to consider in cancers which have a high public profile such as DCIS and prostate cancer. In DCIS it has been shown that women are increasingly opting for more aggressive treatments such as mastectomy and bilateral mastectomy rather than lumpectomy,32 33 even though these treatments do not improve breast cancer-specific survival.34 Similarly, in localised prostate cancer where active surveillance has been a recommended management option for a number of years, studies have shown that the majority of men still prefer to opt for radical prostatectomy or radiation therapy (external-beam radiation or brachytherapy) to manage their diagnosis.23 35

How clinicians categorise conditions and recommend treatments may also be influenced by labels.36 37 For clinicians a number of factors may drive them to overdiagnose and overtreat, albeit unconsciously and unintentionally. According to a recent review of the literature,38 potential drivers of overdiagnosis in the professional domain include fear of litigation or missing disease, an overemphasis on the need to diagnose, a lack of awareness of potential iatrogenic harms, and the challenge of doing nothing rather than something. Removing the cancer label from low risk
conditions may help shift clinician perspectives and enable them to feel comfortable recommending less invasive treatment options to patients.

**Examples where the cancer label has been removed**

Removing the cancer label from conditions has occurred previously when there is clear evidence that tumours are largely indolent and very unlikely to cause harm (Table 3). An early example of this was when the World Health Organisation and International Society of Urological Pathologists jointly decided to remove the cancer label from bladder tumours. It was agreed by a multidisciplinary group of experts that a condition known to rarely progress to invasive cancer should not be called ‘cancer’. In this change papilloma and grade 1 carcinoma of the bladder were reclassified as papillary urothelial neoplasia of low malignant potential. Similarly, a change in the description of cervical abnormalities found during a Pap smear from cervical intraepithelial neoplasia (ie. cancer), to squamous intraepithelial lesions, using the Bethesda System, has helped support more women to follow active surveillance. This change reflected important advances in the biological understanding of cervical neoplasia as well as advances in cervical screening technology and was driven by a motivation to help provide more uniform, evidence-based, clearer and less anxiety-provoking terminology.

A more recent example of removing the cancer term occurred with ‘non-invasive encapsulated follicular variant of papillary thyroid carcinoma’ (EFVPT). This condition was shown to behave indolently and rarely exhibit metastases, and was thus reclassified to ‘non-invasive follicular thyroid neoplasm with papillary-like nuclear features’ (NIFTP). Under the auspices of the Endocrine Pathology Society working group a panel of international experts largely made up of pathologists reviewed the current criteria of hundreds of cases of patients who had been followed for at least 10 years. Findings demonstrated that none of the patients whose tumours stayed within their capsules had any evidence of cancer and this resulted in agreement to change the label, a decision endorsed
numerous leading professional societies internationally. To provide simplified and reproducible criteria to assist in the pathological diagnosis of NIFTP the six main consensus nuclear features were grouped together and scored.\textsuperscript{41} The aims of removing the cancer label in this condition were to highlight the indolent nature of the tumour, decrease unnecessary additional therapies\textsuperscript{42,43}, reduce the potential psychological and financial burden associated with being diagnosed with cancer, and change how clinicians counsel their patients.

Significant as these changes almost certainly have been, we were unable to find any formal evaluation of their impact on practice, clinician behaviour or patient outcomes.

**Removing the cancer label**

To help make progress on removing the cancer label from potential low risk conditions, we suggest a number of concrete actions within clinical practice, medical education, and research (Box 2). To start the major reform process of removing the cancer label, we propose an initial global Round Table which could potentially include involvement from key cancer classification and staging groups such as the World Health Organisation (WHO) Classification of Tumours Group, the International Collaboration on Cancer Reporting (ICCR), and the American Joint Committee on Cancer (AJCC), as well as government health agencies and leading professional cancer societies including the National Cancer Institute (NCI) in the United States, the American Cancer Society (ACS), and similar organisations from other nations. We also strongly endorse the inclusion and engagement of both citizens/consumers in initial Round Table discussions and in any subsequent policy decision-making process. Since the identification and treatment of cancer impact the lives of both the public and patients their input and preferences are vital when reaching decisions. In line with contemporary community expectations of independence, formulation of any recommendations for reform would be undertaken in a process free of conflicts of interest.
Box 2. Actions to help make progress on removing the cancer label

**Clinical practice**
- Clinicians should initiate discussions about the likely benign nature of low risk conditions, the possibility of overdiagnosis and overtreatment, and the option of less invasive management such as active surveillance, both before and after diagnostic interventions.
- Clinicians should convey risk information using event rates (or absolute risks) in order to show the long-term outcomes for people with low risk conditions, for both active surveillance and immediate treatment, over relevant timeframes such as 10 or 20 years.

**Medical education**
- Implementation of new medical education curricula can help students and working clinicians gain a deeper understanding of overdiagnosis and strategies to communicate about low risk conditions.
- Information should be designed and widely promulgated for the public about overdiagnosis and the benign nature of some low risk conditions.

**Research**
- Calculation of precise estimates on the proportions of patients affected by changing terminology.
- More studies of long-term outcomes of less invasive management options for low risk conditions.
- Testing possible alternative labels.

Removing the cancer label from some of the low risk candidates (e.g. low risk thyroid cancer and localised prostate cancer) will pose a more challenging task as they display evidence of invasion under the microscope whereas others have no invasive elements (e.g. DCIS). Bringing together a broadly representative multidisciplinary group, such as the one we propose, could start the process of re-labelling by addressing these challenges, as well as current uncertainties and disagreement. Discussions could start by reviewing current evidence on the risk of progression of each of the identified low risk conditions, establishing standardised agreement in pathology reporting and diagnostic criteria across each condition, and then identify – where appropriate – an alternative label that would address the biological and clinical characteristics of the lesion. This process may also have a supplementary effect of enabling pathologists to address and resolve currently concerning levels of disagreement around important thresholds.

As history demonstrates change and innovation in medicine are often resisted. Changing something as fundamental as our shared understanding of the nature and meaning of cancer,
including a change in nomenclature, will therefore face many challenges and barriers, underscoring the need for a multi-stakeholder process. For example, recent qualitative evidence suggests clinicians treating low risk papillary microcarcinomas do not currently see the merits of removing the cancer label.\textsuperscript{37} Similarly focus groups with a random sample of community members found resistance to removing the cancer label from some participants, although a strong openness among many others.\textsuperscript{50}

Following a collective approach that involves informed citizens and consumers will provide input and insights – both positive and negative – about how a new label might help recalibrate expectations for detection, follow-up and treatment. For current patients already diagnosed, the impact of a change in a label might have unexpected results. Downgrading a conditions’ label may cause patients to revise the nature and extend of follow-up, and question the need for additional treatments which could potentially reduce overtreatment, and any associated harmful psychological effects.\textsuperscript{1} On the other hand, current patients might perceive that a new label undermines their current care, including changing what support they have access to.\textsuperscript{51} Thus, any re-labelling process needs to consider not only the prospective impact of the new label, but also the impact on individuals already diagnosed with the condition, and provide education, support and guidance where necessary in how to proceed.

While it is clear there is a need to re-label some low risk conditions currently labelled as ‘cancer’, it is vital to be cognisant of the potential to also cause harm. A label may provide beneficial effects including an explanation and symptom validation for those presenting with symptoms, as indicated in other non-cancer conditions.\textsuperscript{52,53} There may also be implications for receiving benefits within the healthcare system, making some individuals ineligible for certain forms of support from government or health insurers. Furthermore, once labelled with cancer, individuals become part of a wider community of cancer survivors. Removing the cancer label could mean many patients may perceive
that they have been falsely classified, are no longer cancer survivors and may have potentially received unnecessary treatments. This may cause psychological distress and confusion for some patients. As a patient advocate recently suggested, doctors discussing why a change in diagnostic terminology has occurred may help individuals accept such a change.51

Moving forward

‘Indolent lesions of low malignant potential’ (IDLE) and variations of other similar labels including ‘abnormal cells’, ‘neoplasia’ and ‘micro-tumour’ have been proposed to help convey the favourable prognosis of these lesions,3 5 while others have suggested complete “elimination of the use of the anxiety-producing term carcinoma” for example in the case of DCIS.4 Although the label needs to be biologically accurate it also needs to be something patients can understand and that will not induce disproportionate concern. Civil society and consumer involvement in the re-labelling process will be imperative to help ensure that a potential reclassification of these conditions will be understood and supported by the broader community.

Careful consideration, deliberation and endorsement from cancer classification and staging groups, health agencies and cancer societies, as well as major civil society and consumer organisations is needed to begin and move this process forward. We believe that as a starting point, Round Table discussions involving key stakeholder representatives free from conflicts of interests should be considered to establish agreement and ensure that any future change is consistently and uniformly applied. In the meantime, there is much to be done now across clinical, education and research settings.

Ultimately removing the cancer label will create controversy and take time. The end result however will help ensure appropriate evidenced-based care moving forward for both future and current patients. Learning from past examples and planning a formal future evaluation of practice
implications and patient outcomes is vital to ensuring safe and effective reform. While it remains unclear exactly how to best move forward, it is clear we cannot continue to tell many people they have cancer, when that label may be doing them more harm than good.

**KEY MESSAGES:**
- A growing body of research demonstrates that the labels used to describe medical conditions can influence treatment decisions and psychological responses
- Removing the cancer label from low risk conditions that are unlikely to cause harm if left untreated has been proposed by several international experts as one potential strategy to address overdiagnosis and overtreatment, however to date no change has been made
- To start the major reform process, we endorse Round Table discussions involving key cancer classification and staging groups, health agencies, cancer societies and citizens and consumer groups, with participants free from any conflicts of interest
- Learning from past examples and planning a formal evaluation of practice implications and patient outcomes is vital as a way of both evaluating the changes and ensuring safety moving forward

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51. Syrett S. Why a change of diagnosis shouldn't matter . . . but it does. *Bmj* 2018;361:k1472. doi: 10.1136/bmj.k1472 [published Online First: 2018/04/14]


Table 1. Examples of candidate tumour types that could be considered for re-labelling

<table>
<thead>
<tr>
<th>Type of cancer</th>
<th>Risk of tumour progression</th>
<th>Disease-specific mortality</th>
<th>Conventional treatment options</th>
<th>Harms associated with invasive treatments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intrathyroidal papillary thyroid cancer (&lt;1cm in size)</td>
<td>3.8% over a period of 10 or more years</td>
<td>&lt;1% at 20 years</td>
<td>Thyroidectomy; hemi-thyroidectomy</td>
<td>Surgical complications including problems with voice and calcium levels; need for life-long thyroid hormone replacement medication and its associated side-effects; out-of-pocket costs; psychological harms</td>
</tr>
<tr>
<td>Low and intermediate grade DCIS (stage 0 breast cancer)</td>
<td>~14-53% over a period of 10 or more years</td>
<td>Breast cancer-specific mortality rate is 3.3% at 20 years</td>
<td>Lumpectomy +/- radiotherapy; mastectomy +/- reconstruction</td>
<td>Surgical complications including persistent pain; lymphedema; skin burns; long-term cardiovascular and pulmonary toxicity; out-of-pocket costs; psychological harms</td>
</tr>
<tr>
<td>Localised Prostate cancer (Gleason ≤6)</td>
<td>~18% over a period of 20-30 or more years</td>
<td>1.2% at 10 years</td>
<td>Radical prostatectomy; radiation therapy; active surveillance</td>
<td>Surgical complications including impotence and incontinence; skin burns, long-term cardiovascular and pulmonary toxicity; out-of-pocket costs; psychological harms</td>
</tr>
</tbody>
</table>
Table 2.

<table>
<thead>
<tr>
<th>Study</th>
<th>More medical label† (%)</th>
<th>Less medical label (%)</th>
<th>Difference in preferences between labels (%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Copp, 2017</td>
<td>Polycystic ovary syndrome 70</td>
<td>Hormonal imbalance 53</td>
<td>17</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>McCaffery, 2015</td>
<td>Polycystic ovary syndrome 70</td>
<td>Abnormal cells 40</td>
<td>30</td>
<td>0.23</td>
</tr>
<tr>
<td>Omer, 2013</td>
<td>Non-invasive cancer 47</td>
<td>Lesion, abnormal cells 32.5</td>
<td>14.5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Scherer, 2013**</td>
<td>Gastro-oesophageal reflux disease (GERD) 74</td>
<td>No label 67</td>
<td>7</td>
<td>&gt;0.1</td>
</tr>
<tr>
<td>Scherer, 2015**</td>
<td>Pink-eye 60</td>
<td>Eye infection 58</td>
<td>8</td>
<td>&gt;0.1</td>
</tr>
<tr>
<td>Azam, 2010**</td>
<td>Broken bone, fracture, greenstick fracture, hairline fracture 39</td>
<td>Crack in the bone 20</td>
<td>20</td>
<td>&lt;0.025</td>
</tr>
</tbody>
</table>

*adapted from Nickel et al, 2017; † data combined where applicable and mean percentages reported
**significant two-way interaction between the more medical label and interest in ineffective medications found in the study

Table 3. Examples of where the cancer label has been previously removed or changed

<table>
<thead>
<tr>
<th>Original nomenclature</th>
<th>New nomenclature</th>
<th>Year of change</th>
<th>Group/s initiating change</th>
<th>Reason for change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Papilloma and grade 1 carcinoma of the bladder</td>
<td>Papillary urothelial neoplasia of low malignant potential</td>
<td>1998</td>
<td>The World Health Organisation &amp; International Society of Urological Pathology</td>
<td>To provide better correlation of these lesions with their biologic behaviour using uniform technology</td>
</tr>
<tr>
<td>Cervical Intraepithelial Neoplasia (CIN)*</td>
<td>Squamous Intraepithelial Lesion (SIL)</td>
<td>2001</td>
<td>The Bethesda System Workshop Group (initiated by the Division of Cancer Prevention and Control, National Cancer Institute)</td>
<td>To reflect important advances in biological understanding of cervical neoplasia and cervical screening technology</td>
</tr>
<tr>
<td>Non-invasive encapsulated follicular variant of papillary thyroid carcinoma (EFVPTC)</td>
<td>Non-invasive follicular thyroid neoplasm with papillary-like nuclear features (NIFTP)</td>
<td>2016</td>
<td>The Endocrine Pathology Society working group</td>
<td>To highlight the low risk of adverse outcome of this tumour and reduce psychological and clinical consequences associated with the diagnosis</td>
</tr>
</tbody>
</table>

*original nomenclature still being used in the UK