Breast cancer: NICE on familial breast cancer

“Ignorant GPs deny patients drugs that ward off cancer.”
“Majority also don’t know that they should prescribe aspirin to patients with high risk of colorectal cancer.”

Daily Mail 14th February 2017.

Oh, joy – big sigh (correction, overwhelming fury!) from this Red Whale author.

This article was written in response to a qualitative study published in the BJGP relating to using tamoxifen and raloxifene to prevent breast cancer.

It represented a wholly inaccurate reflection of the current situation in England – post-truth news!

NICE produced clear guidance on this in 2013 that states that the role of primary care is to identify women at moderate or high risk of breast cancer, and refer them to clinical genetics. Tamoxifen and raloxifene are also unlicensed for chemoprevention of breast cancer, and they are not risk-free interventions.

So, what is the truth behind the headlines? And how do we approach consultations about this?

Familial breast cancer statistics

- 49,000 women and 400 men are diagnosed with breast cancer each year.
- 1 in 5 of them will have a family history – the majority will not.
- 5% of all breast cancers are attributable to specific mutations in BRCA1, BRCA2 and TP53 genes.
- The cause of most breast cancers is not known, and is likely to be a combination of environmental, lifestyle and lower level genetic susceptibilities.

GPs attitudes to prescribing preventative treatment for breast cancer

First, the paper behind the headline. This was a national survey of 900 GPs in England, Wales and Ireland regarding their attitudes to prescribing tamoxifen or raloxifene for the prevention of breast cancer in moderate to high-risk women (BJGP 2017; DOI: bjgp17X689377).

Participants were presented with case vignettes of healthy women at different levels of risk seeking tamoxifen prescriptions. They were asked a series of questions. The study showed that:

- 52% of GPs were aware that tamoxifen could reduce the risk of breast cancer.
- Only 25% in this sample were aware of the NICE guideline.
- GPs were more comfortable to continue prescribing if the initial discussion and initiation took place in secondary care.

The authors concluded that secondary care initiation may overcome prescribing barriers for GPs, and increase uptake among eligible women.

The role of primary care

NICE does not ask us to proactively establish every woman’s family history of breast cancer, but rather to respond to those women who present with concerns.

It is also very explicit that preventative treatment should be initiated in secondary care – word for word:

“Healthcare professionals within a specialist genetic clinic should discuss and give written information on the absolute risks and benefits of all options for chemoprevention to women at high or moderate risk of breast cancer. Discussion and information should include the side effects of drugs, the extent of risk reduction, and the risks and benefits of alternative approaches, such as risk-reducing surgery and surveillance” (NICE 2013 CG164).

The National Cancer Strategy 2015-2020, published by CRUK and cited in the Daily Mail article, actually says:

“NHS England should work through CCGs to ensure that GPs are appropriately prescribing chemo-preventive agents to reduce the risk of invasive breast cancer where their use is established through NICE guidelines.”

We think our role is to:

- Identify women at greater than population risk, and refer them to secondary care for assessment.
- Use consultations where no increased risk is identified as an opportunity for high-impact lifestyle advice – ‘teachable moments’.
- After appropriate counselling in secondary care, initiate and continue prescribing if desired by the individual woman.
Definitions

Before we look at the NICE guidelines, it is important to clarify some definitions which we will need to take an accurate family history.

**Family history definitions:**
- **First-degree relatives:** mother, father, brother, sister, son, daughter.
- **Second-degree relatives:** grandmother, grandfather, aunt, uncle, niece, nephew, grandchild, half-sibling.
- **Third-degree relatives:** great-grandparent, great aunt/uncle, first cousin, great grandchild, great niece or great nephew.

Definitions of breast cancer risk categories as used by NICE (geneticists use a computer program to calculate the percentage risk):

<table>
<thead>
<tr>
<th>Risk Category</th>
<th>Near population risk</th>
<th>Moderate risk</th>
<th>High risk (e.g. BRCA1/2 and TP53 carriers)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lifetime risk from age 20y</strong></td>
<td>Less than 17%</td>
<td>&gt;17% but &lt;30%</td>
<td>30% or greater</td>
</tr>
<tr>
<td><strong>Risk between ages 40–50y</strong></td>
<td>Less than 3%</td>
<td>3–8%</td>
<td>&gt;8%</td>
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</tbody>
</table>

**NICE on familial breast cancer**

*Note, this guideline is currently being updated and will be re-issued in March 2017. Looking at the project documents, it appears the main change will be to include aromatase inhibitors as an option for chemoprevention. We cannot find any mention of recommending primary care initiation of treatment – we are awaiting a response from NICE regarding this.*

**NICE on familial breast cancer (CG164 2013)**

**Identifying patients who need referral:**
- Take a personal history of cancer, and a first- and second-degree family history, to assess risk.
- Refer immediately anyone with a known cancer predisposing gene in the family (BRCA1, BRCA2 or TP53).
- Refer any patient who meets any of the following criteria:

**Female breast cancers**
- One first-degree relative diagnosed with breast cancer <40y.
- Two first-degree, or one first- and one second-degree, relative diagnosed with breast cancer at any age.
- Three second-degree relatives diagnosed with breast cancer at any age (NICE says three first- or second-degree relatives, but if any of these were a first-degree relative they would fall into the category above, so we assume they mean three second-degree relatives!).
<table>
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<tr>
<th><strong>Male breast cancers</strong></th>
<th>One first-degree male relative diagnosed with breast cancer at any age.</th>
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<tbody>
<tr>
<td><strong>Bilateral breast cancers</strong></td>
<td>One first-degree relative with bilateral breast cancer, where the first cancer was diagnosed aged &lt;50y.</td>
</tr>
<tr>
<td><strong>Breast and ovarian cancers</strong></td>
<td>One first- or second-degree relative diagnosed with breast cancer AND one first- or second-degree relative diagnosed with ovarian cancer at any age.</td>
</tr>
</tbody>
</table>

**Are there special risk factors?**

If none of the above criteria are present, ask if there are any additional special risk factors:
- Presence of bilateral or male breast cancers anywhere in family history.
- **Jewish ancestry with a family history of breast/ovarian cancer**: increased risk of *BRCA* genes in Ashkenazi Jewish population.
- **Unusual cancers**: sarcoma in a relative aged <45y, gliomas or childhood adrenocortical carcinomas.
- Complicated patterns of multiple cancers at a young age.
- **Paternal history of breast cancer** (two or more relatives on father’s side of the family).

If any of these risk factors are present, seek written advice from secondary care.

**What about patients who don’t meet any of these criteria?**

All other patients can be managed in primary care, e.g. those with one first- or second-degree relative diagnosed with breast cancer aged >40y.
- Offer standard written information about lifestyle advice and breast awareness.
- Explain that risk changes if a new family member is diagnosed.

*The simplest way to offer this information is the NICE information leaflet – link in Useful websites below.*

**Risk reduction strategies for all women**
These consultations are an opportunity for high-impact lifestyle advice. Getting the basics right and handing over responsibility does matter. Key messages:

- Aim for a BMI between 20-25 (post-menopausal obesity is a significant risk for breast cancer).
- Physical activity is protective.
- There is no safe level of alcohol consumption.
- Stop smoking.
- Breastfeeding may be protective and should be encouraged.

Combined hormonal contraception

- Women at population risk require no additional precautions.
- Women at greater than population risk (so those you are referring):
  - Can take the CHC up to the age of 35y in line with standard guidance.
  - Once aged >35y with a family history, there may be a slight increased risk associated with CHC use, given that absolute risk increases with age – consider alternative?
  - For women with BRCA1 mutations, the slight increased risk of breast cancer with CHC use must be balanced against the lifetime protection of CHC use for ovarian cancer.
  - Women should not be prescribed the CHC purely to prevent ovarian cancer.

Hormone replacement therapy

- HRT use in women at greater than population risk should be restricted to the shortest duration and lowest dose possible.
- Where possible, use oestrogen-only HRT.
- Risks should be discussed with women.
- Women who experience premature menopause, either naturally or artificially (due to prophylactic oophorectomy), can be offered HRT until age 50y – though I suspect many women may be reluctant to take it in this situation!

The rest of this guidance now talks about the role of secondary care.

Clinical genetics assessment

A more detailed family history assessment will take place to determine whether an individual is moderate to high risk. This will take place alongside counselling about the advantages and disadvantages of discovering this risk. If appropriate:

- Genetic testing will be offered (ideally an affected relative will be tested first).
- Computer software can be used to determine an individual’s risk of being a carrier, and testing will be offered if that risk is ≥10%.

Surveillance

Clinical genetics will determine a surveillance plan. Currently:

- No surveillance is recommended in women aged <30y.
- From 30y, MRI and/or mammography may be recommended, depending on risk (MRI is usually only used in women with confirmed or high probability BRCA1/2 or TP53 mutations).

Annual mammography is usually offered to women:

- Aged 40-49y with moderate risk.
- Aged 40-59y with high risk.

After this, women return to the national screening programme.

Chemoprevention and surgery
NICE recommends that moderate and high-risk women be offered the option of taking tamoxifen or raloxifene to reduce their risk of developing breast cancer. This is an unlicensed indication at present, and should be discussed and initiated by secondary care because:
- Other preventative treatments may be more effective and appropriate, e.g. prophylactic mastectomy/ oophorectomy.
- There are risks as well as benefits (see below).
All women in the high-risk group should be offered the opportunity to consider bilateral mastectomy +/- oophorectomy, and this should be within the context of a specialist MDT.

If prophylactic surgery is unsuitable or unacceptable, the following women may be offered chemoprophylaxis:
- All high-risk women who are not at increased risk of endometrial cancer or thromboembolism:
  - Pre-menopausal women – tamoxifen for 5y.
  - Post-menopausal women – tamoxifen or raloxifene for 5y if uterus intact; tamoxifen for 5y if no uterus.
  - Do NOT continue treatment with raloxifene or tamoxifen past 5y for chemoprevention in women with no personal history of breast cancer.
  - Consider 5y of chemoprophylaxis for moderate-risk women.
- Women should be advised to stop tamoxifen:
  - 2m before trying to conceive.
  - 6w before elective surgery.

The evidence for tamoxifen and raloxifene as chemoprophylaxis

Tamoxifen and raloxifene are selective oestrogen receptor modulators (SERMs). Their role in the prevention of breast cancer has been an evolving story. The state of current evidence was well summarised by two comprehensive meta-analyses of available RCTs (Ann Int Med 2009;151:703 and Lancet 2013;381:1827) which showed that:

- Tamoxifen and raloxifene reduced oestrogen receptor positive breast cancer by 7–10 cases per 1000 women per year, if taken for 5y.
- This equates to a NNT=42 – 42 women would have to be treated with a SERM for 5y to prevent 1 breast cancer over 10y.
- Tamoxifen is equally effective in pre- and post-menopausal women; raloxifene only in post-menopausal women.
- They do not reduce oestrogen receptor negative disease (as is typically seen in BRCA1).
- They do not reduce all-cause mortality over the duration of the studies currently available.
- Both drugs are associated with harms:
  - VTE risk was increased in tamoxifen users, with about 4 extra cases per 1000 women over 7y.
  - Endometrial cancer risk was increased in tamoxifen users, with an extra 11 cases per 1000 women over 7y.
  - VTE was increased in the raloxifene group, but to a lesser extent.

So, in summary, for every 1000 women who take tamoxifen for 5y, we will:
- Prevent 7–10 cases of breast cancer.
- Cause 11 cases of endometrial cancer.
- Cause 4 DVTs.
- Have no impact on whether you die.

A single well-designed RCT compared tamoxifen with raloxifene, and demonstrated that tamoxifen was significantly better at preventing breast cancer than raloxifene, but had more side-effects, particularly the risk of endometrial cancer (JAMA 2006;295:2727).

NICE therefore recommends tamoxifen first line for women without a uterus, and in pre-menopausal women at high risk who stand most to gain from breast cancer prevention. However, in high-risk post-menopausal women with a uterus, a choice of raloxifene or tamoxifen is offered.

What about aromatase inhibitors for prevention?

A US-based double blind RCT compared the incidence of breast cancer in 4500 post-menopausal women of moderate to high risk taking exemestane vs. placebo (NEJM 2011;364:2381). Women with the BRCA mutation or previous history of breast cancer were excluded. It found that:

- Exemestane significantly reduced invasive breast cancer over 3y (HR 0.35, CI 0.27–0.79).
- NNT=96 – 96 women need to take exemestane for 3y to prevent 1 breast cancer.
- There was no difference in other cancers, fractures, CV events or mortality between the two groups.
- Discontinuation rates were 15% in exemestane group vs. 10% in placebo – usually due to hot flushes and arthralgia.

NICE commented that the quality of this study was not sufficient to make specific recommendations, because of its relatively short follow-up and the fact that it excluded women with BRCA. Other studies which have considered aromatase inhibitors have ‘lumped them together’, making it difficult to make specific recommendations.

Since the publication of NICE guidelines in 2013, IBIS-II, a double-blind placebo-controlled RCT comparing anastrazole with placebo in 4000 women at ‘high risk’ of breast cancer, has published; this was partially funded by the makers of anastrazole (Lancet...
2013;Online http://dx.doi.org/10.1016/S0140-6736(13)62292-8). It showed a reduced incidence in breast cancer in the women taking anastrazole compared with those who were taking placebo:

- For women taking anastrazole over 5y, the absolute risk reduction in breast cancer was 2%, equivalent to an NNT of 50 to prevent 1 case of breast cancer over 5y.
- However, there was no difference in breast cancer or all-cause mortality between the two groups, and longer follow-up is needed.
- Musculoskeletal and vasomotor side-effects were common in both placebo and anastrazole groups, but more so in those taking anastrazole.

NICE considered evidence from the IBIS-II RCT in its guideline surveillance report (Nov 2015). It says that the results could potentially impact on the guideline, but comments on the need for further follow up to determine the longer term impact of anastrazole. NICE does not make any specific new recommendations about the use of aromatase inhibitors for chemoprevention. The next guideline review is due in 2017.

Remember, aromatase inhibitors cannot be used in pre-menopausal women because their action is on preventing the conversion of androgens to oestrogens. They do not affect ovarian oestrogen production which is the main source in pre-menopausal women.

Surgical treatments for BRCA1/2 related cancer prophylaxis

Many women who discover they are carriers of the BRCA1/2 gene consider prophylactic surgery. This may take the form of contralateral mastectomy when they have had treatment for the primary cancer, or preventative oophorectomy. Two recent studies have looked at effectiveness.

Contra
lateral mastectomy

This small study compared women with known BRCA1 or BRCA2 mutations who underwent treatment for stage I or II breast cancer and chose to have unilateral or bilateral mastectomy (BMJ 2014;348:g226). It looked at survival rates. This was not a randomised study, so there was prognostic imbalance between the two groups from the outset. However:

- Women who underwent bilateral mastectomy were 48% less likely to die of breast cancer over the next 20y than women who had unilateral mastectomy.
- This was only statistically significant in the second decade after initial diagnosis.
- Women who elected to have bilateral mastectomy were also more likely to have had oophorectomy, and this may influence the results.

Oophorectomy

This prospective cohort study of women with BRCA1 or BRCA2 mutations looked at the incidence of ovarian, fallopian tube or peritoneal cancers in women who had and had not had prophylactic oophorectomy (J Clin Onc 2014 Online doi:10.1200/JCO.2013.53.2820).

- Preventative oophorectomy was associated with an 80% reduction in the risk of ovarian/fallopian or peritoneal cancer.
- It was associated with a 77% reduction in all-cause mortality.
- The study did not specifically look at breast cancer incidence, but previous studies have shown that oophorectomy reduces the risk by 48% in women with BRCA1 mutations.

PALB2 mutations and breast cancer risk

It is known that germline mutations in genes other than BRCA1 and BRCA2 are associated with breast cancer. The partner and localiser of BRCA2 (PALB2) protein interacts with BRAC1 and BRAC2 as a tumour suppressor. Loss of function germline mutations in PALB2 have been found in 0.6–3.9% of families with a history of breast cancer. However, the exact effect on breast cancer risk conferred by PALB2 mutations is not known.

This study looked at the lifetime risk of breast cancer in 154 families where one person had breast cancer and germline loss of function mutation in PALB2, with negative tests for BRCA1 and BRCA2 mutations (NEJM 2014;371:497, editorial NEJM 2014;371:566).

- Compared with the general UK population, the risk of breast cancer in carriers of PALB2 mutations was increased by a factor of 9.47 (CI 7.16–12.57).
- The cumulative risk of breast cancer for female PALB2 mutation carriers was estimated to be:
  - 14% (CI 9–20%) by 50y.
  - 35% (CI 26–46%) by 70y.
- Family history of breast cancer also increased the risk, suggesting other genes or environmental factors were also important. By 70y, the breast cancer risk was 33% (CI 25–44%) in women with no affected relatives, compared with 58% (CI 50–66%) in women with two affected first-degree relatives.
- The risks of ovarian and male breast cancer were not significantly increased in carriers of the PALB2 mutations.
- The country of residence did not significantly alter the risks in PALB2 mutation carriers.
- The authors suggest that the high level of risk may justify adding PALB2 to genetic testing for BRCA1 and BRCA2.
- Further research is required to see if enhanced surveillance or prophylactic surgery in women with loss of function mutations...
in PALB2 will improve outcomes.

- For us, it remains important to refer women with a strong family history of breast cancer for further assessment. Women who do not have \textit{BRCA1} or \textit{BRCA2} mutations may still be at considerably increased risk of breast cancer due to germline mutations in other genes, and shared environment or lifestyle factors.

\textbf{NICE on familial breast cancer}

- 1 in 5 cases of breast cancer occur in women with a significant family history.
- In concerned women, take a first- and second-degree family history, and consider other risk factors such as ovarian cancer, male breast cancer.
- Refer all women who meet the criteria for genetic assessment.
- Moderate and high-risk women will be offered additional screening, chemoprophylaxis with tamoxifen or raloxifene, and consideration of prophylactic surgery.
- If 1000 at-risk women take tamoxifen for 5y, we will prevent 7–10 cases of breast cancer, but cause 11 cases of endometrial cancers and 4 VTEs.
- Aromatase inhibitors may be recommended in the future.

\textbf{Reflect on your last 3 consultations about family history of cancer:}

- Did you feel confident in taking a family history and considering other risk factors?
- How could you have improved the opportunity to make it a teachable moment, i.e. to give high-impact lifestyle advice?

\textbf{NICE patient information leaflet:}


This is a useful online tool for patients (and GPs!) to assess genetic risk in women with a family history of breast and ovarian cancer:

www.macmillan.org.uk/Cancerinformation/Causesriskfactors/Genetics/OPERA.aspx

The BOADICEA tool was developed by CRUK and Cambridge to calculate and assess an individual’s risk of being a carrier of a cancer gene – it is free to download and access:

http://ccge.medschl.cam.ac.uk/boadicea/

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The Cancer Update Course

Within the next 15 years the need for cancer care will double and you will look after as many cancer survivors as diabetics. Shared care follow up will become the norm, and secondary care will pass responsibility to us.

A key 2015 Lancet Oncology commission paper warned that: “GPs are inadequately trained and resourced to manage the growing demand for cancer care in high income countries”.

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Glasgow
Wed 17 May
Fri 19 May
Wed 7 June
Fri 9 June
Fri 6 Oct
Fri 13 Oct
Sat 4 Nov

The Medically Unexplained Symptoms Course

Manchester
London
Thur 18 May
Thur 19 Oct

The Effective Consultation Course

Manchester
London
Leeds
London
Wed 10 May
Fri 12 May
Wed 4 Oct
Fri 24 Nov

Prices

GP Update Course:
GP £195 | GP Registrar £150 | Nurse £150

All other courses:
£225 or £210 for members of www.gpcpd.com

(GPCPD members, please log in and then click on the relevant button within the ‘Member information’ box on the right of the home screen to get your discount code)

Join the Red Whale pod

Plan ahead! Save £60 when you book three courses in 2017 - use discount code 3BUNDLE2017 when booking via www.gp-update.co.uk or by phone 0118 960 7077.
I would like to come on the following course(s) (please write legibly!):

- The GP Update Course (location) .............................................................   (date).........................
- The Women’s Health Update Course (location) .............................................................   (date).........................
- The Cancer Update Course (location) .............................................................   (date).........................
- Lead. Manage. Thrive! Course (location) .............................................................   (date).........................
- The Telephone Consultation Course (location) .............................................................   (date).........................
- The Effective Consultation Course (location) .............................................................   (date).........................
- The Medically Unexplained Symptoms Course (location) .............................................................   (date).........................

I can’t attend a course, but would like to order your Handbook or DVD:

- GP Update Handbook and 12 months’ access to GPCPD £150
- GP Update Handbook, DVD and 12 months’ access to GPCPD £225
- Women’s Health Update Handbook £70
- Cancer Update Handbook £70

Name...............................................................................   Address...................................................................................................

(Please write your email address clearly as we’ll use it to send your confirmation letter and receipt.)

Price as stated in the flyer for each course. If applicable, please provide your discount code here............................

Please send this form with your cheque payable to GP Update Limited to:

Red Whale, University of Reading, Reading Enterprise Centre, Earley Gate Entrance, Whiteknights Road, Reading, Berkshire RG6 6BU

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