Causation

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TORT : a wrongful act that injures another and for which the law imposes civil liability **:** a violation of a duty (as to exercise due care) imposed by law.

CAUSATION: The "but for " test.
It must be established that the defendant's tortious conduct caused or materially contributed to the damage to the claimant before the defendant can be found liable for that damage.

It is for the claimant to prove causation on balance of probability (more likely than not)

In breast cases, most of the time it is the failure to do something that leads to harm:-

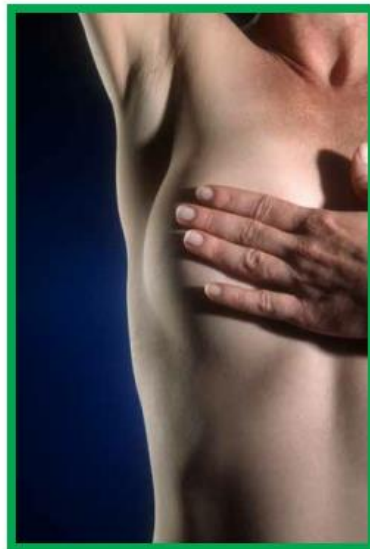*No core biopsy, No follow up, Inadequate information-Consent*

Standard of Care:--What is it for Breast?

Best practice
diagnostic guidelines
for patients presenting
with breast symptoms

ASSOCIATION OF
BREAST SURGERY

BAPRAS
British Association of Plastic
Reconstructive and Aesthetic Surgeons

NICE National Institute for
Health and Care Excellence

NICE
guideline

ABS
ASSOCIATION OF
BREAST SURGERY

ONCOPLASTIC BREAST RECONSTRUCTION
Guidelines for Best Practice

Early and locally advanced breast cancer:
diagnosis and management

NICE guideline
Published: 18 July 2018
nice.org.uk/guidance/ng101

Editors
Alexis M Willett, Michael J Michell, Martin J R Lee

November 2010

Editors: Dick Rainsbury and Alexis Willett

November 2012
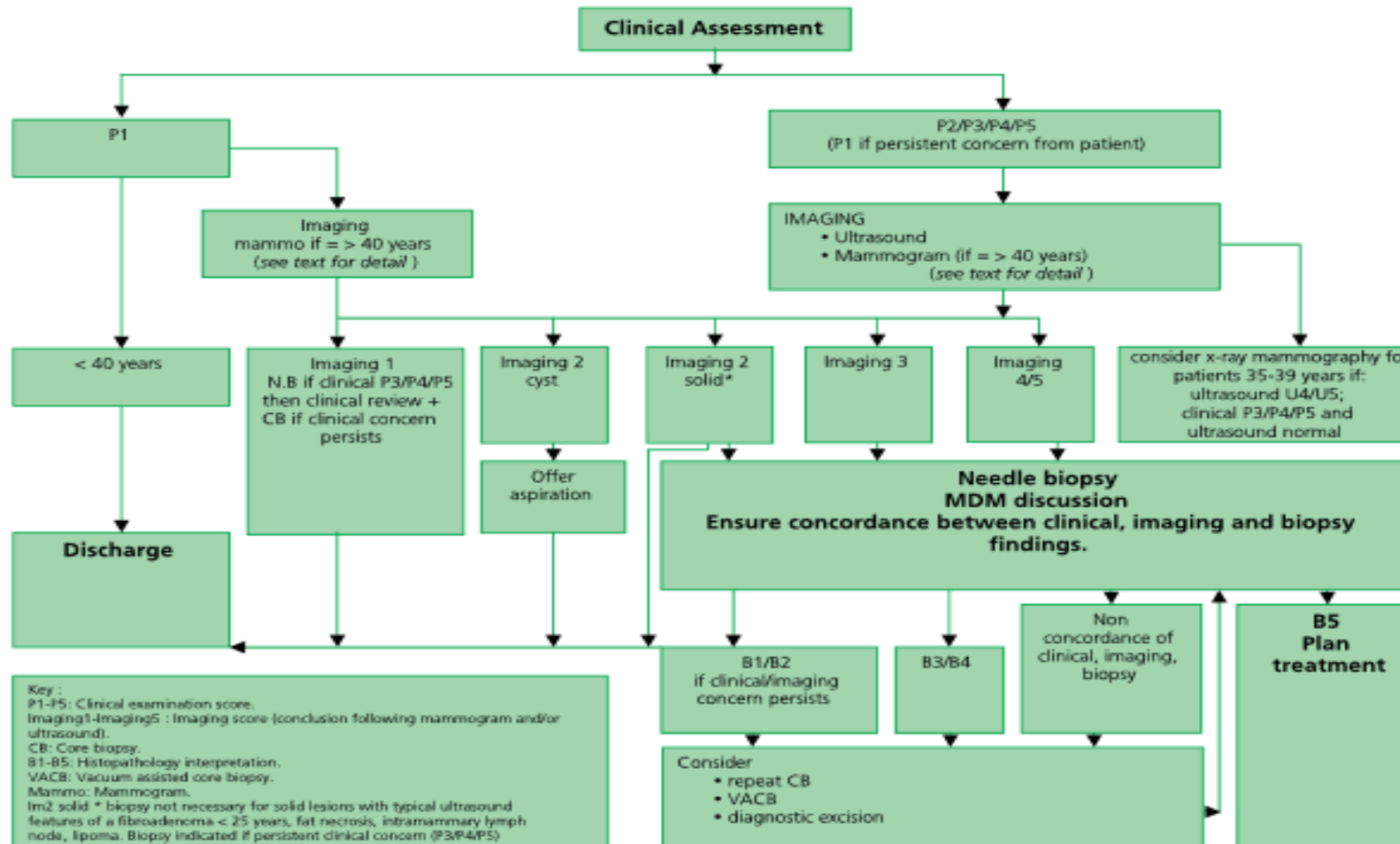
ABC breast disease 94-2012,   Oncoplastic guidelines updated 2021   Nice 2009/2018   www.ricklinforth.com

5. Algorithm A. Assessment: Lump/Lumpiness

Clinical Assessment

P1

P2/P3/P4/P5
(P1 if persistent concern from patient)

Imaging
mammo if = > 40 years
(see text for detail)

IMAGING
• Ultrasound
• Mammogram (if = > 40 years)
(see text for detail)

< 40 years

Imaging 1
N.B if clinical P3/P4/P5
then clinical review +
CB if clinical concern
persists

Imaging 2
cyst

Imaging 2
solid*

Imaging 3

Imaging 4/5

consider x-ray mammography for
patients 35-39 years if:
ultrasound U4/U5;
clinical P3/P4/P5 and
ultrasound normal

Offer aspiration

Needle biopsy
MDM discussion
Ensure concordance between clinical, imaging and biopsy findings.

Discharge

Non
concordance of
clinical, imaging,
biopsy

B5
Plan treatment

B1/B2
if clinical/imaging
concern persists

B3/B4

Key :
P1-P5: Clinical examination score.
Imaging1-Imaging5 : Imaging score (conclusion following mammogram and/or ultrasound).
CB: Core biopsy.
B1-B5: Histopathology interpretation.
VACB: Vacuum assisted core biopsy.
Mammo: Mammogram.
Im2 solid * biopsy not necessary for solid lesions with typical ultrasound features of a fibroadenoma < 25 years, fat necrosis, intramammary lymph node, lipoma. Biopsy indicated if persistent clinical concern (P3/P4/P5)

Consider
• repeat CB
• VACB
• diagnostic excision

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Willet et al Best practice 2010

2.2	One-stop assessment
QI9	• At one-stop assessment all the required elements of triple assessment are performed during a single visit. This provides: – a basis for definitive diagnosis in the majority of patients – reassurance with no need for further attendance in most patients with non-malignant conditions – information for multidisciplinary meeting (MDM) treatment planning prior to review of those diagnosed to have cancer • Some patients do not require all the elements of triple assessment, as outlined below and defined in the Algorithms. This includes those with: – resolved symptoms and no clinical abnormality – clearly identified benign conditions with no other suspicious features found on clinical and imaging assessment such as: ▪ areas of benign breast change and diffuse nodularity without a dominant mass ▪ simple cysts whether aspirated or not ▪ breast pain ▪ non-bloody nipple discharge ▪ gynaecomastia

Beware the focal nodularity-P3

Needs a core biopsy!

Willet et al Best practice 2010

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INVESTIGATION AND MANAGEMENT OF GYNAECOMASTIA IN PRIMARY & SECONDARY CARE

Don't forget the blokes!   300 male breast cancers a year

GYNAECOMASTIA IN THE BREAST UNIT

Gynaecomastia does not require all aspects of triple assessment

1. History:
   - Drug history
   - Alcohol history
   - Recreational drug use
   - Steroid use
   - Family history

2. Clinical examination:
   - Chest, bilateral
   - Nodal areas: axillae and supraclavicular fossae
   - Gynaecomastia can be described according to the Simon Classification (Appendix 1)

3. Imaging
   - Bilateral pseudogynaecomastia: No imaging
   - Bilateral gynaecomastia P2: No imaging
   - Unilateral lump in age <25years: No imaging
   - Unilateral lump in age >25 years *and* P2: No imaging
   - Unilateral lump in age >25years *and* P3+: USS +/- mammogram according to local practice

4. Pathology
   - Biopsy only if one or more of the following: P3+, M3+, U3+

Any P3 gets a biopsy !

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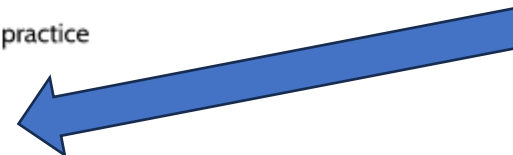
There is no clear consensus on the ideal biologic or synthetic mesh.

Specific points for discussion are.

- The origin of the specific mesh should be discussed.
- Whether the mesh remains permanently or is expected to be absorbed.
- Patients should be informed of local and global experience with the mesh used including uncertainty regarding long term outcome.
- Knowledge and acceptance that the reconstruction involves a breast implant.
- Patients should be aware that revisional surgery is frequent in the early stages following reconstruction.
- That a drain may be left in-situ for up to two weeks.

Patients need to be aware of the risks of complications, local and personal complication rates. Complications are common in implant only mesh assisted or dermal sling procedures. By 3 months national rates are [68].

- Readmission - 18%.
- Infection - 25%.
- Reoperation - 18%.
- Implant loss - 9%.

Oncoplastic breast surgery: A guide to good practice

A. Gilmour [a], R. Cutress [b], A. Gandhi [c], D. Harcourt [d], K. Little [e], J. Mansell [f], J. Murphy [g], E. Pennery [h], R. Tillett [i], R. Vidya [j], L. Martin [e, *]

[a] Canniesburn Plastic Surgery Unit, Glasgow Royal Infirmary, United Kingdom
[b] University of Southampton and University Hospital Southampton, United Kingdom
[c] Manchester Academic Health Sciences Centre & Manchester University Hospitals NHS Trust, Manchester, United Kingdom
[d] Centre for Appearance Research, University of the West of England, Bristol, United Kingdom
[e] Liverpool Breast Unit, Liverpool University Foundation Trust, United Kingdom
[f] Gartnavel General Hospital, Glasgow, United Kingdom
[g] Manchester University Hospitals NHS Trust, United Kingdom
[h] Breast Cancer Now, United Kingdom
[i] Royal Devon and Exeter NHS Trust, Exeter, United Kingdom
[j] The Royal Wolverhampton NHS Trust, Wolverhampton, United Kingdom

2021

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Tools to demonstrate causation

http://radclass.mudr.org/content/doubling-time-calculation-growth-rate-lesion-or-mass

https://nomograms.mskcc.org/breast/

https://breast.predict.nhs.uk/predict_v2.0.html

http://www.lifemath.net/cancer/breastcancer/therapy/index.php
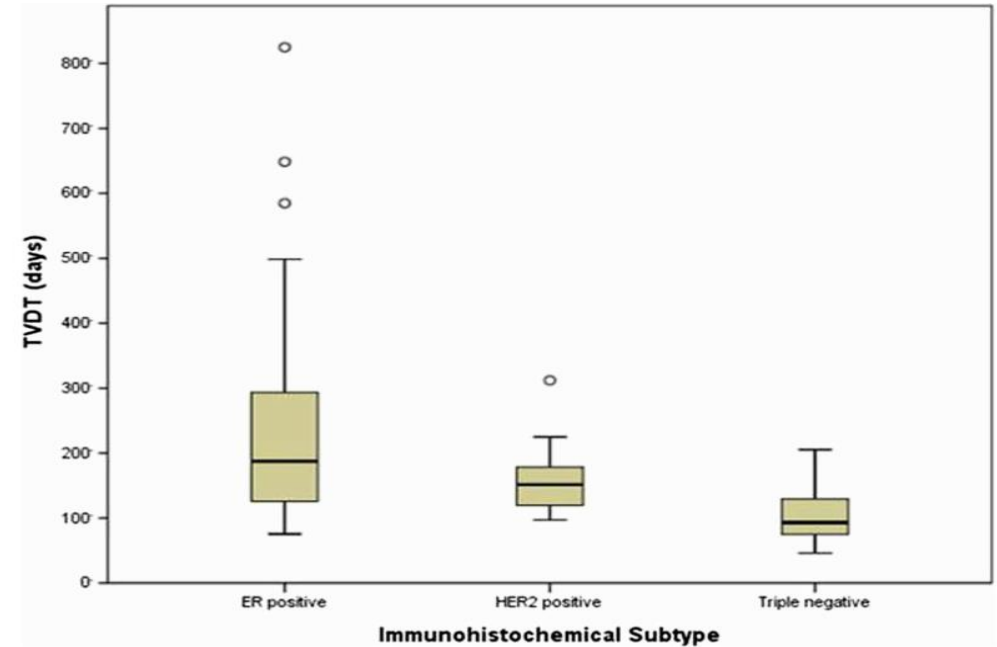
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Tumour Volume Doubling Times: TVDT: How fast does it grow !
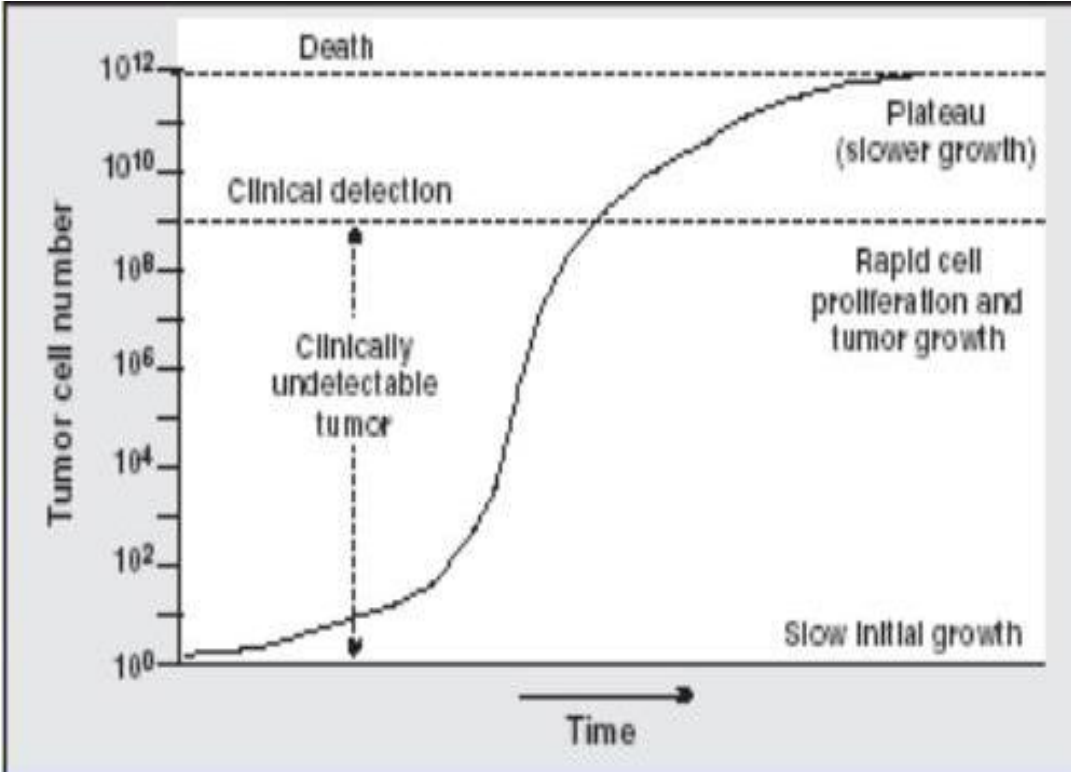
Benjamin Gompertz 1779-1865

Tilanus-Linthorst et al Clinical Cancer Res 2007;13(24) December 15, 2007

	≤40 y (n = 31)	41-50 y (n = 42)	>50 y (n = 27)
No. BRCA1/2	23	24	12
No. high risk	8	18	15
Mean DT days (95% reference)			
BRCA1/2	28 (4-222)	68 (9-553)	81 (10-653)
High risk	83 (12-593)	121 (17-850)	173 (25-1,202)

Peer et al :.Cancer, June 1,1993,Volume 71, No 11.

Table 3. Tumor Volume Doubling Time of Primary Breast Cancer According to Age

Age at diagnosis (yr)	Geometric mean in days (95% confidence limits)	68% range*
< 50	80 (44–147)	24–273
50–70	157 (121–204)	46–533
> 70	188 (120–295)	55–640

Likelihood ratio test: $P = 0.06$

* Sixty-eight percent of the tumor volume doubling times are between the presented limits: 16% is smaller than the lower limit, 16% is larger than the upper limit.

Ryu et al Eur Radiol 92014) 24:2227-2235.

Faster Doubling times seen in:
AGE <50
Grade
Biology: Triple negative>HER2>ER pos
Pregnancy
BRCA status (often Triple negative)

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Example of back calculation:

35 female, No FH, referred with lump UOQ left breast .

Patient seen in clinic: 1/1/20 P3 lump uoq: imaging normal u1: discharged.

Patient seen in clinic 1/1/21   P5 lump with lymph node : final pathology
                                 T2 35mm ILC G3, Er positive Her 2 neg. 1 node

pos.

Back calculation:

Doubling time - calculation of growth rate of a lesion or a mass

🏷 calculator   🏷 CT   🏷 MRI   🏷 ultrasound   🏷 x-ray

Calculating doubling time of focal lesions or massess can give a hint, whether it has a malignant or rather benign growth dynamics. Doubling time of malignant lesions is between 30 and 500 days with a median of 100 days.

Calculate		⦿ Diameter [mm]	○ Volume [mm³]
First examination	Date (d/m/yy)	01/01/2020	
	Diameter [mm]	8.5	
Second examination	Date (d/m/yy) [Today]	01/01/2021	
	Diameter [mm]	35	
[Calculate doubling time]			

Days between: 367
Doubling time: 60 days
[Clear]

Breast Cancer Nomogram: Sentinel Lymph Node Metastasis

TEXT SIZE ↓A ↑A

This nomogram can be used to help newly diagnosed breast cancer patients assess the likelihood that their breast cancer has spread to the sentinel lymph nodes.

Enter Your Information   Clear   Calculate ▸

Current Age
Enter current age. Must be between 20 and 91.
`35` (20 to 91 yrs)

Breast Tumor Size
Size of the primary tumor (as measured either in imaging study or pathological exam), in centimeters.
`0.85` (0.1 to 11.0 cm)

Special Type?
Check box if tumor has been pathologically defined as pure tubular, pure colloid (mucinous), or typical medullary carcinomas on the pathology report. Other histologies such as atypical medullary carcinoma or carcinoma with ductal and lobular features should be classified as ductal -- see Tumor Type and Grade section below for more details.
☐ YES

Tumor is confined to UIQ?
Check box if tumor is confined within the upper inner quadrant (UIQ) of the breast.
☐ YES

Lymphatic or Vascular Structure Involvement (LymphovascularInvasion)
Select YES if one or more tumor cells found in the blood or lymphatic vessels.
☐ YES

Multifocality?
Select YES if breast cancer has cancer cells seperated from the main tumor mass.
☐ YES

Tumor Type and Grade
Indicate if tumor type is ductal or lobular, as noted in the pathology report. If ductal, indicate the nuclear grade -- I: slight or no variation in the size and shape of the nucleus; II: moderate variation in the size and shape of the nucleus; III: marked variation in the size and shape of the nucleus.
`Lobular ▾`

Estrogen-Receptor Status
Select NEGATIVE if estrogen receptors stain positive in <10% of cells; select POSITIVE if estrogen receptors stain positive in ≥10% of cells.
`Positive ▾`

Progesterone-Receptor Status
Select NEGATIVE if progesterone receptors stain positive in <10% of cells; select POSITIVE if progesterone receptors stain positive in ≥10% of cells.
`Positive ▾`

Your Results

Learn more about your results below.

| Probability of Spread to Sentinel Lymph Nodes | 35% |

🖨 Print These Results

Enter Your Information   Clear   Calculate ▸

Current Age
Enter current age. Must be between 20 and 91.
`35` (20 to 91 yrs)

Breast Tumor Size
Size of the primary tumor (as measured either in imaging study or pathological exam), in centimeters.
`3.5` (0.1 to 11.0 cm)

Special Type?
Check box if tumor has been pathologically defined as pure tubular, pure colloid (mucinous), or typical
☐ YES

Your Results

Learn more about your results below.

| Probability of Spread to Sentinel Lymph Nodes | 71% |

🖨 Print These Results

Treated : T2 (35mm) N1 M0
Mastectomy, ANC, Chemotherapy , Radiotherapy.

Hypothetical : T1(8.5mm) N0 M0

WLE/SLNB,   RT, Endocrine therapy.

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T1 8.5mm N0 M0 Tamoxifen

Results

Table | Curves | Chart | Texts | Icons

Select number of years since surgery you wish to consider:

5 | 10 | 15

This table shows the percentage of women who survive at least 15 years after surgery.

Treatment	Additional Benefit	Overall Survival %
Surgery only	-	87%
+ Hormone therapy	3.5% (1.1% – 4.0%)	91%

If death from breast cancer were excluded, 97% would survive at least 15 years, and 3% would die of other causes. ℹ

Show ranges? ℹ Yes No

T2 35mm N1 M0

Results

Table | Curves | Chart | Texts | Icons

Select number of years since surgery you wish to consider:

5 | 10 | 15

This table shows the percentage of women who survive at least 15 years after surgery.

Treatment	Additional Benefit	Overall Survival %
Surgery only	-	61%
+ Hormone therapy	11.8% (3.5% – 14%)	72%
+ Chemotherapy	7.9% (5.9% – 9.8%)	80%

If death from breast cancer were excluded, 97% would survive at least 15 years, and 3% would die of other causes. ℹ

Show ranges? ℹ Yes No

Survival reduced by 11% over 15 years .

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15.9 yrs-11 yrs= 4.9 years lost

3.8 yrs -1.2 yrs=2.6 years lost

Amount loss due to breach=4.9-2.6 = 2.3 years of life lost

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Quantum

Additional treatment: Mastectomy/ANC/Lymphoedema/pain

Chemotherapy would have been avoided (18 weeks)
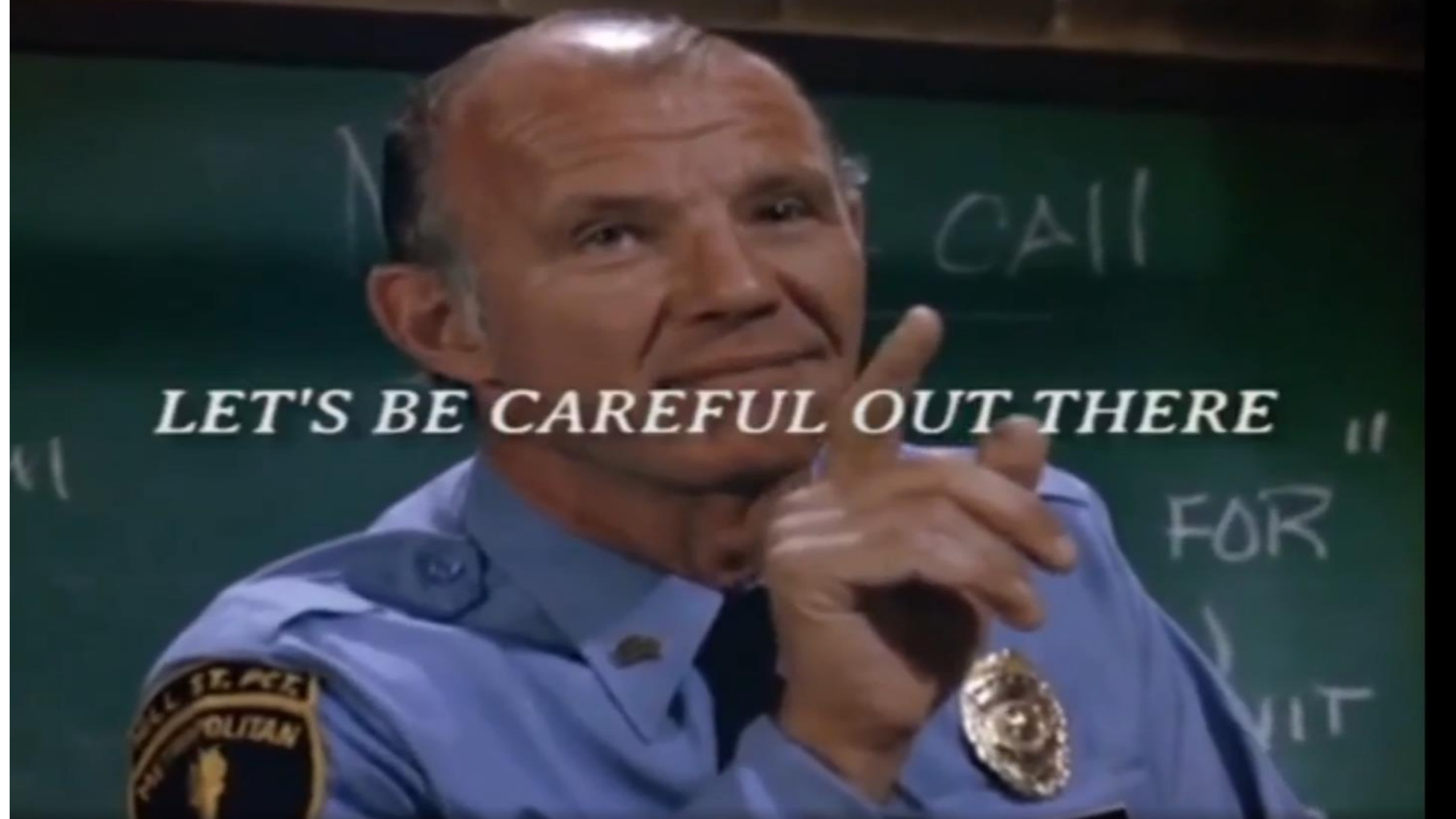
Radiotherapy to chest wall

Reconstruction avoided

Loss of amenity /income

Psychological impact

......Quite a lot of taxpayer's money!