Age Gap Decision Tool™

Description

The Age Gap Decision Tool is an online reference tool developed and validated on UK registry data for women over age 70. It is designed to provide supportive information about potential cancer outcomes for older women with operable breast cancer when faced with a choice of surgery or primary endocrine therapy (PET), or, following surgery, whether to have adjuvant chemotherapy or not.

The tool is based on two models which were developed using UK registry data between 2002 and 2012 which calculate outcomes (overall and breast cancer specific survival) based on the patients' health status (age, comorbidity and frailty) and the tumour characteristics (stage and biology). The models have been published[1,2] and validated and have acceptable levels of accuracy on validation[1,2]. The tools were designed with input from older women whose information needs and preferences shaped its design and who have given feedback on the tool when used as part of a randomised trial. Feedback has been excellent.

The tool is designed to be used by health care professionals with expertise in the management of breast cancer. It may be used by the health professionals to inform their treatment recommendations to an individual woman and may also be printed out to be used to support shared decision making. Two booklets may also be downloaded and printed out about the surgery versus PET decision or the adjuvant chemotherapy decision. Again, these booklets have been developed with older women and an expert reference group, to ensure their contents are accurate, written in a style and format that suits women of this age group, and contains the appropriate information that is important to them[3-5].

Intended Purposes and Users

The purpose of the Age Gap Decision Tool is: Software that provides reference information to help a Healthcare Professional to use their knowledge to make a clinical decision

The tools are designed to be used by health care professionals to support two clinical decisions relating to UK women over the age of 70 with operable breast cancer. The two decisions are:

In older women with ER positive breast cancer, should they have surgery (plus adjuvant treatments) or primary endocrine therapy only.

In older women with high recurrence risk breast cancer, who have already undergone surgery, should they have adjuvant chemotherapy or not.

Contraindications

Non UK populations. As the data use to develop the tool is based on women in the UK, the tools have not been validated in other global populations and they may not be accurate.

Women with locally advanced or metastatic breast cancer breast cancer. Women with ductal carcinoma (DCIS).

Women <70 years of age.

How to Use

Starting from the home page, click on the Tools tab as shown in Figure 1.

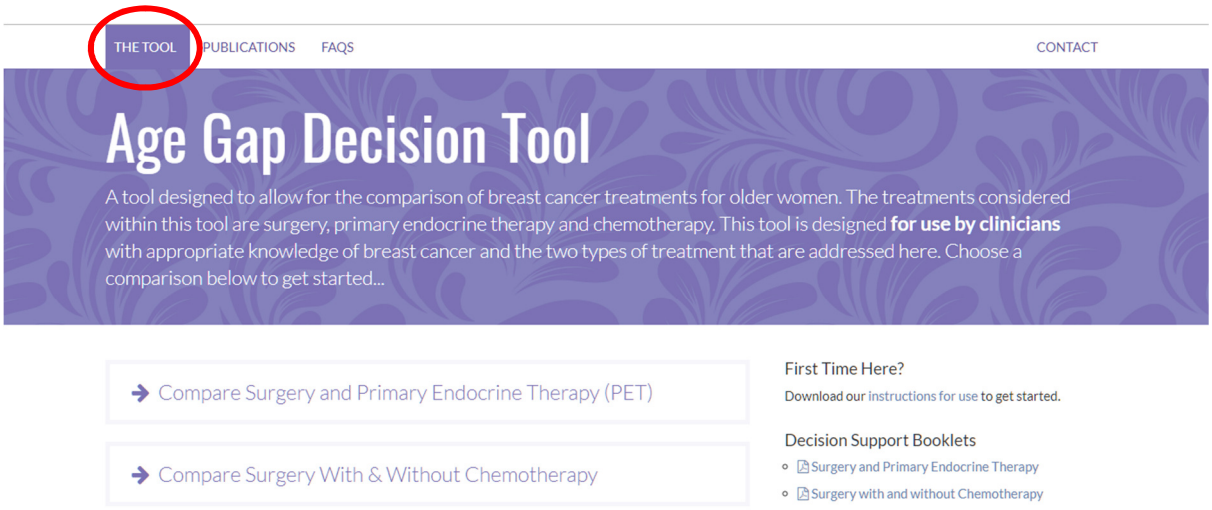

Figure 1. Home page of the age gap tool

You will see 2 hyperlink boxes (Figure 2) depending on which decision you need to explore. Choose either the **"Compare Surgery and Primary Endocrine Therapy (PET)"** or **"Compare Surgery With & Without Chemotherapy".** These links take you to a separate page where you can enter personalised data relating to a particular woman.

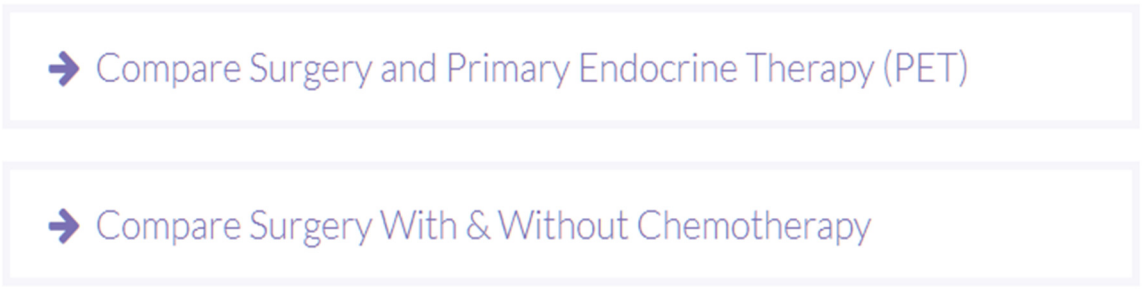

Figure 2 Treatment comparison option hyperlinks on Age Gap Decision Tool homepage

For the PET versus surgery comparison:

You should enter details about her age, the grade of her tumour (1 to 3), the size in mm and whether the disease is node positive or node negative. The section on comorbidities relates to a number of key illnesses and their severity. Check all that apply. Lastly, you need to ask the woman a few questions about her level of frailty and independence, such as whether she has trouble eating, dressing or walking and the degree of impairment. Again, check the relevant boxes (Figure 3). It may be easier to print out this form and complete it in the consultation with the woman if you do not have access to a computer in the consulting room. Once you have completed this, click on **'generate outcomes'.**

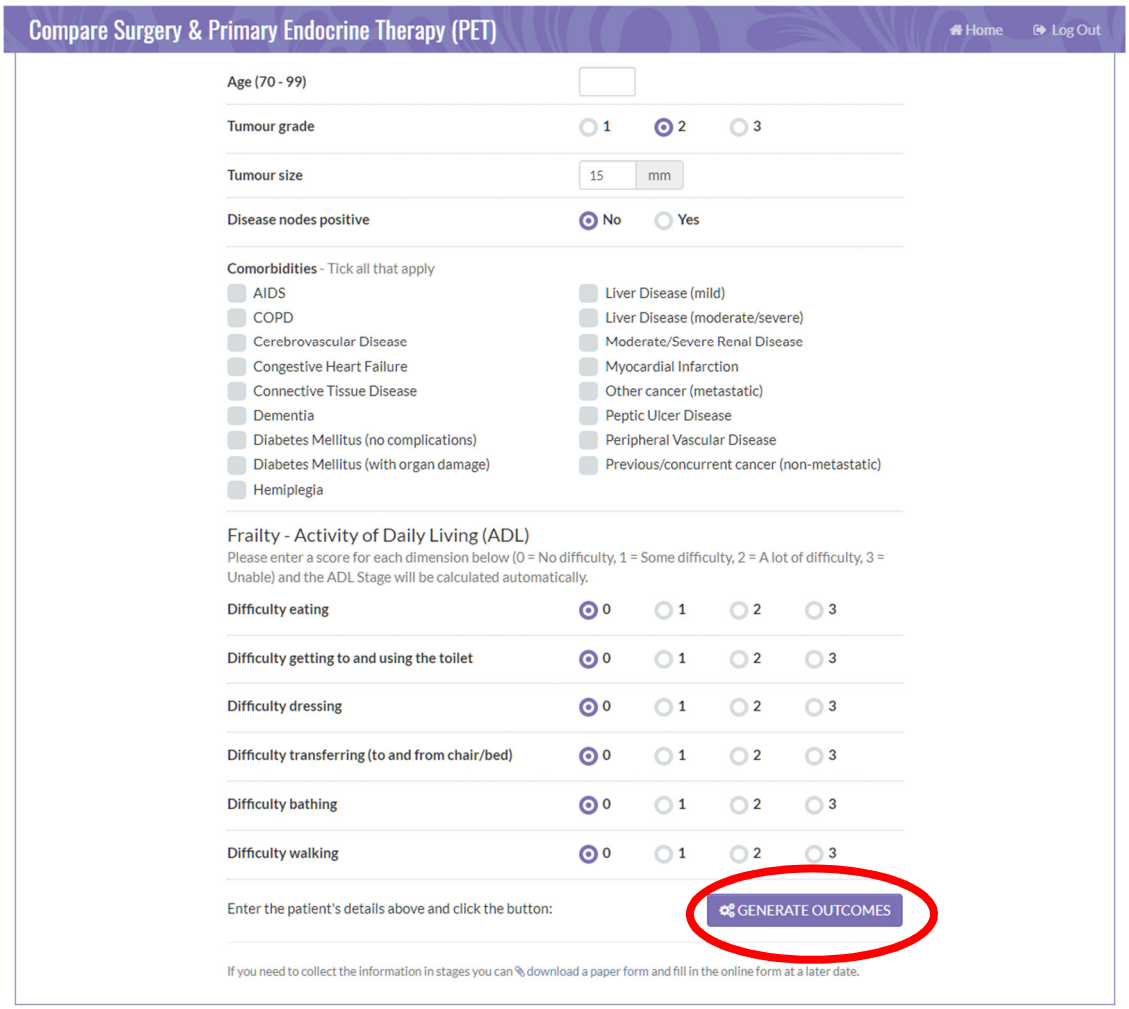

Figure 3 Data entry page for Compare Surgery & Primary Endocrine Therapy (PET)

This prompts the web site to present data in a selection of formats and timelines. These are

Chart 2 years OR 5 years

Graphic 2 years OR 5 years

Table 2 years OR 5 years

These are available by clicking on the tabs on the screen.

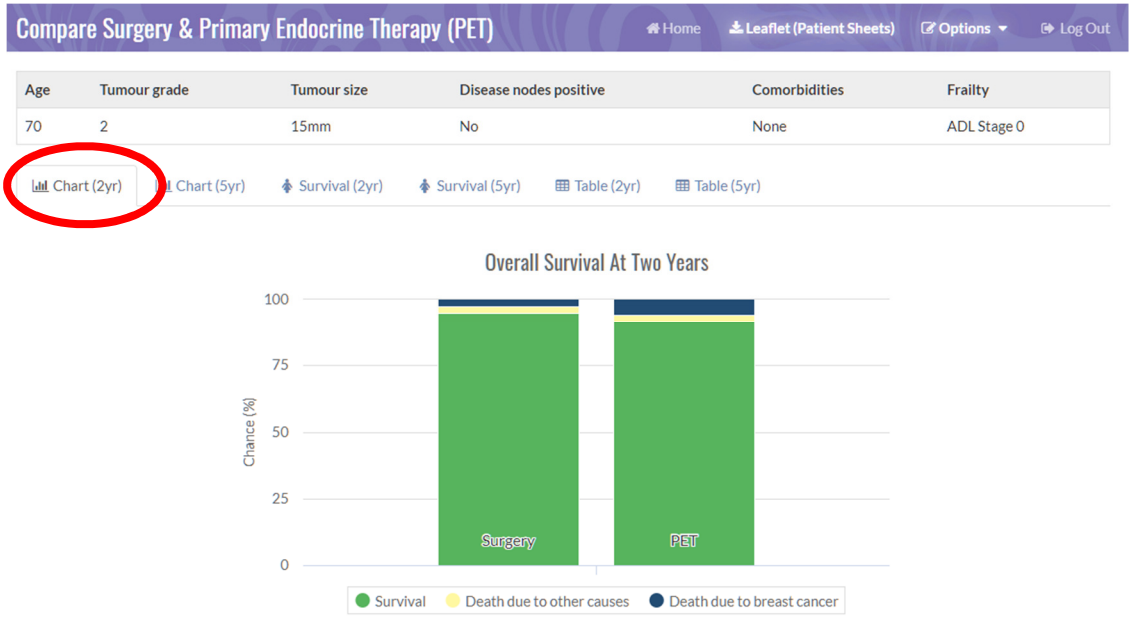

Figure 4 Compare Surgery & Primary Endocrine Therapy (PET) - 2 year chart

The survival estimates at 2 and 5 years can be displayed in a chart, pictogram and a table by using the tabs above. **Choose which display and the length of follow up** you wish to use. For a very frail women with a very short predicted life expectancy, the 2-year tab may be most appropriate as the 5 year tab may show a very nihilistic outcome if you are using the tool with the women present. For the 'chart' option, survival is shown as a bar chart (Figure 4). The green bar is the percentage survival, yellow is deaths due to non-breast cancer causes and dark blue is deaths due to breast cancer.

If you click the 'survival' options tab at 2 or 5 years, the data are displayed as a pictogram depending on whether the woman has surgery or PET (Figure 5). Women in dark purple are alive at 2 years, those in grey are deceased and the differential or excess survival between the 2 treatments are highlighted as purple with a dark grey background (Figure 5).

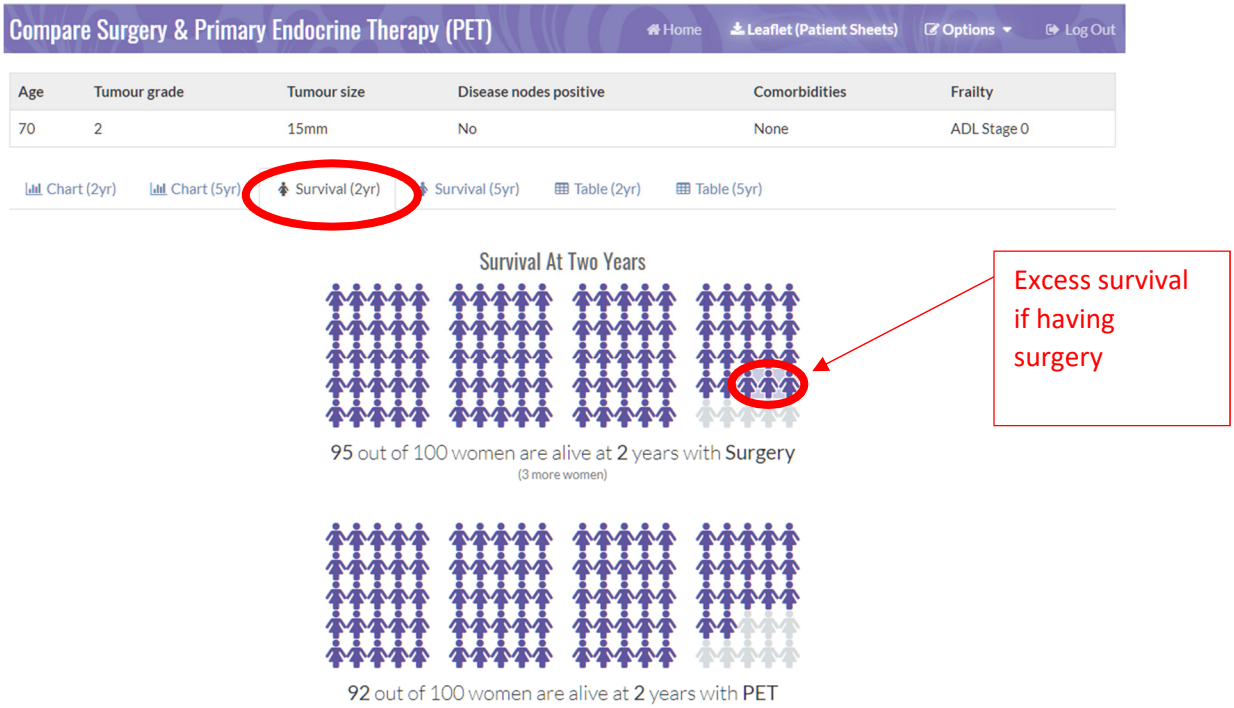

Figure 5. Figure showing the survival tab outputs

The table tab gives the same data but in numeric form (Figure 6). These options were created because some women and some health care professionals prefer data in different formats.

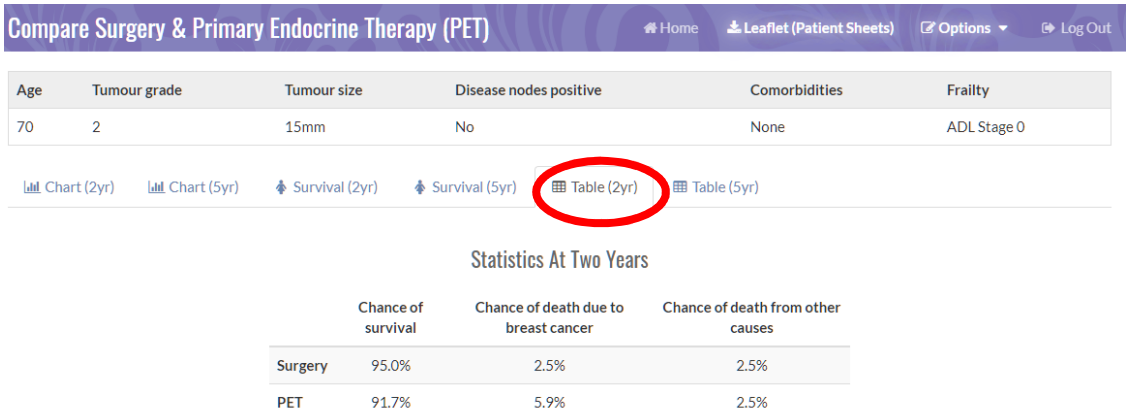

Figure 6. Figure showing the statistical outputs tab.

The personalised survival data for an individual woman may be downloaded and printed out to be used in consultation with the women or taken home to support her making her own decisions or to discuss with friends and relatives. To print out a personalised sheet, use the tab in the top right-hand corner of the page (Figure 7).

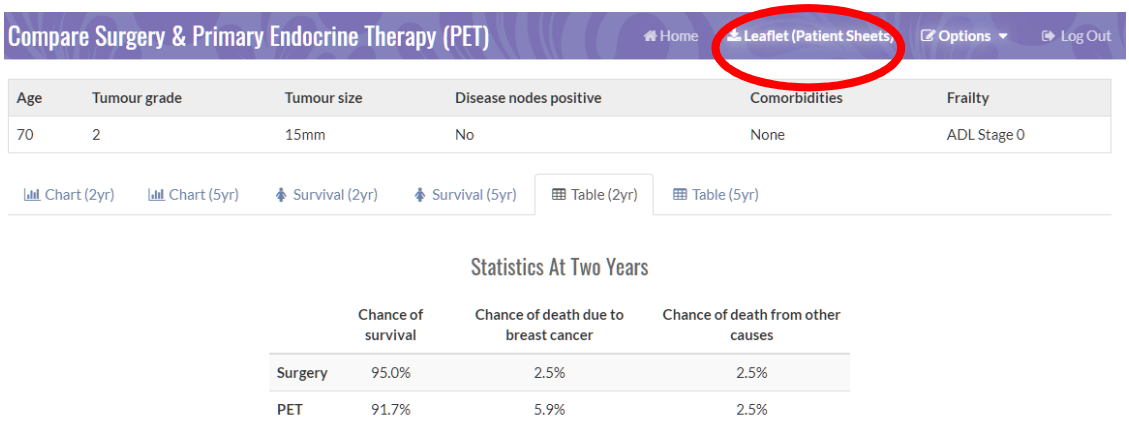

Figure 7. Figure showing how to access leaflets

The leaflet will be downloaded and available to print in the usual way.

The **"Options"** tab allows movement between screens without losing the data inputted.

Clicking the **"Home"** tab will take you back to the home page

It is also possible to download a booklet providing additional, age specific information about both treatment choices. The booklet also contains a brief decision aid which is a question/answer format sheet to help women decide on their own personal priorities when making their choice. To download these booklets, go to the home page, (Tools tab) click on the link under the heading Decision Support Booklets in the bottom right hand corner (Figure 8). Chose the link you require: surgery and primary endocrine therapy or surgery with and without chemotherapy. The booklets may be downloaded as a PDF to print as normal.

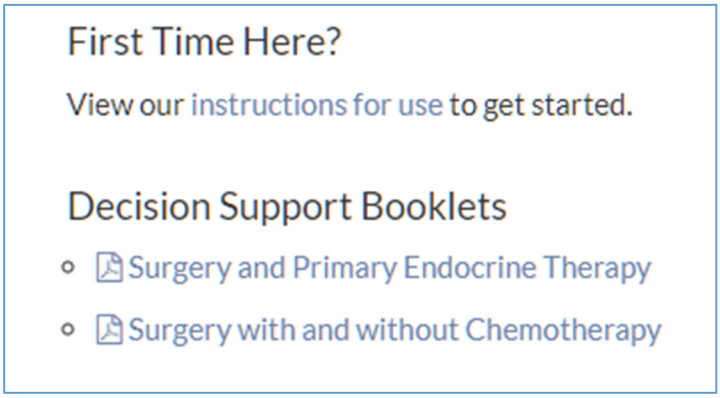

Figure 8. Tabs for downloading booklets

Other materials

The Home Page also has several other tabs which may be of interest.

The publications tab lists publications which show how the tool was developed and validated.

The FAQs tab (frequently asked questions) gives a list of questions commonly asked by users of the tool and their answers. Please let us know if important questions are missing and need to be added.

Contact Us

The Contact tab gives details of how we can be contacted to let us know if you have any problems or give feedback about the Age Gap Decision Tool.

Clinical enquiries including adverse events and feedback: **agegap@sheffield.ac.uk**

Technical enquiries: **support@healthresearchsuite.org.uk**

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The Age Gap Decision Tool website is a software medical device that provides reference information to help a Healthcare Professional to use their knowledge to make a clinical decision.

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Date of issue of this document: Last updated: 08.11.19
Version of Age Gap Decision Tool to which this IFU applies: published model v1.0

1. Ward SE, Richards PD, Morgan JL, et al. Omission of surgery in older women with early breast cancer has an adverse impact on breast cancer-specific survival. *Br J Surg* 2018; **105**(11): 1454-63.
2. Ward SE, Holmes GR, Ring A, et al. Adjuvant Chemotherapy for Breast Cancer in Older Women: An Analysis of Retrospective English Cancer Registration Data. *Clin Oncol (R Coll Radiol)* 2019.
3. Burton M, Collins KA, Lifford KJ, et al. The information and decision support needs of older women (>75 yrs) facing treatment choices for breast cancer: a qualitative study. *Psycho-oncology* 2015; **24**(8): 878-84.
4. Burton M, Kilner K, Wyld L, et al. Information needs and decision-making preferences of older women offered a choice between surgery and primary endocrine therapy for early breast cancer. *Psycho-oncology* 2017; **26**(12): 2094-100.
5. Lifford KJ, Edwards A, Burton M, et al. Efficient development and usability testing of decision support interventions for older women with breast cancer. *Patient Prefer Adherence* 2019; **13**: 131-43.