Systemic Anti-Cancer Therapy (SACT) V3 dataset review

11 August 2023

Introduction

The National Disease Registration Service (NDRS), which now sits within NHS England, sought the help of use MY data Members to **Shape the future of the Systemic Anti-Cancer Therapy (SACT) data set.**

As part of this work, an online workshop took place on Monday, 31 July, at which use MY data Members gave their time to contribute views and ideas direct to the SACT team. The value and importance of those Members questions, ideas and contributions was immense.

Following the workshop, the NDRS team drafted a summary of the discussions and key points. The Secretariat of use MY data circulated these to delegates, asking them to check for accuracy and completeness.

The Secretariat also sought the views of all Members of use MY data and their direct views, together with the summary notes from the workshop, have been collated into this summary response to submit these formally to the NDRS, on behalf of use MY data. We have also worked closely with METUPUK to produce this joint submission. (Some of our Members are also connected with METUPUK.)

Timescales were short, so we asked Members for responses by the end of Tuesday, 08 August, noting the deadline for the submission was Friday, 11 August.

This response has been submitted directly using the online web form. The contents of our response are also shown in this document below, to make it more readily accessible to our Members and other readers, via our website.

How we have structured our response

The questionnaire on the NDRS website comprises three specific questions, plus a general question. For the purposes of our submission, we have included all of our points in our response to the final, general question.

For reference, the questions on the NDRS's website focussed on:

- Existing data set items – suggestions for improvements/updates
- New data set item suggestions
- Existing data set items that should be considered for exclusion
- Any additional feedback.

Members words were used to make particular themed comments, and some direct quotations from our Members have been included. These are in blue text, to provide emphasis.

Our Members' feedback on the review, including points from our Members workshop

1. **Comments and questions on the dataset itself**

   Does SACT collect details of patient outcomes and side effects? Patients would be keen to know how well a specific treatment works. We note that the SACT dataset currently collects 'outcome' of a treatment regimen, in terms of whether the cycle was successfully completed and, if not, whether this was due to e.g., treatment toxicity. But we are unsure how.

   Should a standard method of patient well-being be taken at each change of regimen e.g., EQ5D5L as well as side effects?

   On the list of SACT data items, what is the difference between Required and Mandatory in column headed CSV Schema?

   The dataset list has 44 lines, one for each data item. The data item numbers have a maximum value of 61. Are there any items not on this list?

   Does the medicine code indicate the preparation of the drug i.e., whether the drug is oral or IV preparation?

   Of major importance and progression/line of treatment should be included.

   All drugs given to aid cure/survival should be recorded in SACT.

   Are pre or post menopause recorded?

   Are the following items available (see also our later points about data linkage):

   - Year of diagnosis
   - Age at recurrence
   - Type original BC and ER/PR status
   - Year of re diagnosis of MBC
   - Age at re-diagnosis
   - Local or distant metastasis and if local if this has happened once, twice, three times
   - Denovo Breast Cancer - is this indicated as a separate category
   - Type on recurrence such as Triple Negative Breast Cancer (TNBC) and Inflammatory Breast Cancer (IBC). We believe there are around 11 different types and within TNBC that around 20 different subtypes have been identified.
   - BRCA status
   - What drug regime they are on in each treatment line
   - Next line of treatment and date.
   - Whether a clinical trial was started, when it was stopped (subtypes and all the info as above the same for clinical trials).
   - The name of the trial for linkage.

   "Cancer Drugs Fund data" - Definitely should be coded, we don't understand why it's not coded already. It cannot just be assumed from the type of treatment if this is CDF or routine NHS - because the same treatment might be CDF for one indication, routine for another.

"Route of administration" should specify how IV treatment is given cannula, port etc. Not just IV, also treatment given as an injection etc., subcut or intramuscular, where is it given etc.

2. **The need for patient involvement in governance and decision making about SACT**

   There appeared to be a significant lack of patient involvement in the governance and decision making (e.g.. SACT Review Board).

   We encourage the adoption of our Position Statement, Expectations of organisations which use our patient data, in particular the need to have an embedded patient voice throughout programmes like SACT. This is to ensure patients remain part of the decision-making process, but also that patients and the patient community are kept much better informed about the work of the programme, in this case the recording and analysis of SACT Data.

   Some pertinent comments from Members were:

   "We really don't know what is being collected so we are starting at the beginning"

3. **The use of SACT data must be for patient benefit**

   There is a serious lack of publicly available analysis of SACT data.

   Most of the analyses which are done routinely using SACT data are only being available to NHS users (in tools such as CancerStats). Given the progress made in recent years on releasing previously unpublished data (such as the Get Data Out programme), there must be an urgent emphasis on getting SACT analyses published.

   The lack of published reporting of comparative analyses of chemotherapy treatment and outcomes should be addressed, by providing a basic set of outputs, including but not limited to:

   - Some basic counts
   - Which Trusts are/aren't submitting data, and how good is it
   - Do people survive longer with or without chemotherapy
   - What drugs are given to what sorts of people, where and for what
   - Information on toxicity.

   We need an increased emphasis on using SACT to measure the real-world benefit from treatments between the sexes, and different ethnicities.

   For instance, there may be benefits from smaller doses of drugs or those taken for a shorter period of time due to patients needing to stop their chemo, perhaps due to toxicity. Covid, which affected both men and women differently, and people of different ethnicities, taught a valuable lesson on this point, although the issue has been raised for several years and importance not realised.

   How can we measure effects (i.e., longevity, lack of spread etc.) on treatments for outliers, those who live long sometimes with minimal treatment, and those who do not despite doing everything and more. Combined with DNA analysis, there may be valuable insights to be gained.

An important requirement of the dataset is to distinguish primary versus secondary treatments.

One of our Members highlighted this, saying:

“Another hard to explain area as this is about when you are primary you may be offered a drug that may be "preventative" (and I have an issue with that word as I don't believe we can really prevent cancer).”

“So a drug may be offered to a primary patient like phesgo or abemaciclib or suchlike which apparently can work in primary setting and patients are on a year, 2 or 3 years of the drug. To "prevent" metastatic breast cancer. Now this patient MAY metastasise so firstly that patient thinks that this drug will work 100% and if it doesn't 1. where is the data for progression and 2. they then lose out on their 1st line treatment and will HAVE to go onto a 2nd line of treatment (I believe?). This is NOT being made clear to patients that they will very probably lose a line of treatment.”

An additional example raised was:

“For HER2-positive breast cancer the first line treatment is 6 cycles of a taxane (usually docetaxel) plus Phesgo, and then Phesgo carrying on until progression. So the taxane isn’t stopped because patients aren’t benefiting, it’s stopped because evidence shows it’s not needed. The covid protocol was to substitute the taxane for capecitabine for around 6 cycles or 18 weeks, and then stop and carry on with Phesgo. So the important point is that capecitabine is stopped because it’s no longer needed, not that patients are not benefiting. In fact they will generally not have progressed.”

Patients will tend to assume that newer drugs are ‘better’ and don’t have access to data to understand more. There needs to be longer term follow up on patients (several years) after treatment so that we build understanding/ evidence of which drug worked for patients.

SACT data and analyses are not visible to patients and patient groups

Two related comments were also made about the dataset seeming to be about benefits to the NHS and not patients:

“20 years ago, a paper was published in Australia to the effect that chemotherapy used as adjuvant treatment after surgery for early breast cancer only gave a 1 to 2 percent survival benefit. Looking at the NICE standards for current treatment, it seems that in the same circumstances, radiotherapy does not give any survival benefit either. Just think of the pain and distress we could save patients if they were given this information and a better choice of options. Not to mention the cost savings! Real world evidence would be very valuable here.”

“My overall impression was that the service is more focussed on the effect on the hospital (how many sessions, how long etc.) rather than the effect on the patient and that’s wrong.”

“Massively important and there are many gaps they are quite obviously not thinking of which patients experience and only patient experts know this. Many patients don't even know at the moment that they don't have access to a drug because they’ve been on Capecitabin.”

"And a drug specific for brain metastases - around 50% of people with HER2+ disease like me will experience metastases to the brain so for them to be told and excluded from access to a treatment will be devastating.... I can't make this point enough."

use MY data **proposes** that we work with the NDRS to set up a closed session/forum where the NDRS team can show a set of patients what is already available to the NHS (Trusts, Alliances, etc.), but not available to the public. We feel that some of these readily available outputs could be really helpful, are unlikely to be disclosive or "risky", and could be a quick win for a joint piece of work between use MY data and the NDRS.

4. **It is unclear why the SACT data is not routinely linked to registry, clinical activity and outcomes data**

Members raised several questions which could be resolved if the SACT dataset was linked to wider datasets, covering demographics, diagnosis and treatments. As the SACT dataset only collects treatment administration information, the eventual outcome for patients would not be captured by SACT and would need to be linked from another dataset.

Cancer specific data - the SACT database is for all cancer types and stages. For data specific to a cancer type (e.g., breast cancer) is this stored elsewhere? And is it linked?

Demographics – a suggestion that sex at birth should be recorded, as well as current self-identified gender. If sex at birth and self-identified gender are different it would ideally record if cross sex hormones are being taken. Other demographic data that is needed is:

- Date of birth (enables ability to measure treatment success in different age groups, then drilled down between sex and ethnicity etc.)
- Age.
- Female / male.
- Ethnicity (t looks like it was removed in V3 -don't know why that was?)

Treatment sequencing - Is it possible to link sequences of treatment with progression of disease for an individual patient?

Other treatment modalities - Chemotherapy is only one of the modes of treatment offered to patients. There are surgery and radiotherapy treatments, sometimes followed by drugs e.g., bisphosphonates etc. No one treatment can be taken in isolation. More patient benefit would be obtained if the radiotherapy dataset (RTDS) was combined with SACT and any surgery dataset. From a patient perspective it is largely meaningless on its own.

- Why is there (apparently) no date of diagnosis?
- What surgery they had and to where (for me I'm wanting to build a picture).
- What radiotherapy they had and to where.
- Any other specialist treatment or intervention.

Death details – we also need to link to cause of death in outcomes. It is not just about the 30 days or even about if chemo/cancer are killing people. There is mental health too. We need this information collection/linkage to continue to death, including:

- Date of death.
- Cause of death.

Some specific comments that we received form Members concerned about SACT data not being linked to other data included:

"The systems not linking up and CDF not owning the data is bad...."

"I could not believe when they said it was not linked."

"If I understood correctly, it's also not fully linked to the Cancer Registry data and so they seem to be missing an opportunity for wider research."

It is important for patient groups to be able to understand the patient treatment experience: where other patients who are on the same drug are, in terms of their journey and treatment pathway.

"But I'm sitting here with a NICE scoping document in front of me, for our charity to respond to. One of the things they ask is what the new drug should be compared to. I can write to the haematologists I know to get their input about what they use, but I know the haematologists who see a good number of patients, not those who just see a few, so I don't get any idea of what is being actually used (correctly or incorrectly) for patients who are treated outside the main nodes of knowledgeable care. Our patients are rare (mastocytosis is rare, and advanced mastocytosis in which cytoreductive therapies are used are rare within the mastocytosis community). We would love to have access to data that tells us what's actually being used without having to poll every haematologist in the country."

The only independent UK movement of patients, relatives and carers focussed on the use of patient data to save lives and improve outcomes

Our vision:

Every patient in the UK willingly giving their data to support medical research and their own care

Our mission:

To be a Trusted Voice for patients and the public in all discussions and decisions about the use of our data for research and improving healthcare

Our aims:

- To promote the responsible and accountable use of data to improve health and health research, and to help to remove barriers preventing this
- To highlight the benefits of using patient data for our individual health and for our communities
- To help to ensure patient data is used to create and support an NHS that is better for all
- To advocate for robust and transparent safeguarding of data, which is clearly communicated to patients and the public
- To provide balance as a trusted voice in patient data, highlighting aspirations and concerns around the use of patient data
- To act as a critical friend and sounding board to organisations who want to collect, store and use patient data to benefit society
- To build knowledge and expertise for patients, families and carers to help them play a more active and informed role in discussions and decisions about patient data

"use MY data to help others and help me"

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About METUPUK

We are a patient advocacy group aiming to turn metastatic breast cancer (MBC) into a chronic illness and support MBC patients to gain access to the best medicines to prolong and improve their quality of life.

We work towards a day when MBC can be cured.