

# Contextualizing qualitative analysis with quantitative data on the symptoms and side effects associated with melanoma treatment in the real world – the value of patient registries

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## Objectives

The Melanoma UK digital registry, founded in collaboration with the charity Melanoma UK, explores real-world patient-reported impacts of melanoma using a mobile application (app). Alongside measures of quality of life (QoL), the app includes 11 questions about symptoms and side effects from the Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE™) measurement system.

This study’s objective was to explore registry participants’ experience of symptoms and side effects during melanoma treatment, using both quantitative registry data and qualitative focus group data.

## Methods

Four registry participants took part in a focus group, primarily held to better understand fever as a treatment side effect, as fever is not included in the PRO-CTCAE symptoms and side effects instrument. A thematic analysis was conducted to identify prominent themes from the discussion.

Focus group participants’ experiences were contextualized using PRO-CTCAE data from registry participants that received the same treatment. One registry participant receiving dabrafenib+trametinib and another receiving ipilimumab+nivolumab were used as reference cases. Five additional registry participants were matched to either reference case one or two by treatment, age, or disease stage. The demographics (age and disease stage), frequency of side effects (moderate to severe), and QoL data (EuroQol Five Dimensions Five Levels survey [EQ-5D-5L] and Quality of Life Questionnaire–Core 30 Items [QLQ-C30]) of reference cases and matched cases were compared.

## Results

### Qualitative analysis of data from the focus group

Focus group participants were aged 33–66 years; all had Stage 4 melanoma. Two participants reported receiving immunotherapy (Participants 2 and 3), with one specifying ipilimumab+nivolumab (Participant 3); two received dabrafenib+trametinib (Participants 1 and 4).

Participants most commonly reported experiencing shivering, shaking, dehydration, and poor appetite with fever (**Table 1**). Fatigue and sensitivity to cold were most commonly reported as long-term side effects of melanoma treatment (**Table 1**).

Three participants also reported treatment changes due to side effects (termination, interruption, or reduced dose) and one reported the dilemma of continuing with treatment to remain in remission while experiencing life-limiting side effects.

Table 1: An overview of key quotes about participants’ side effects, categorized into themes and sub-themes

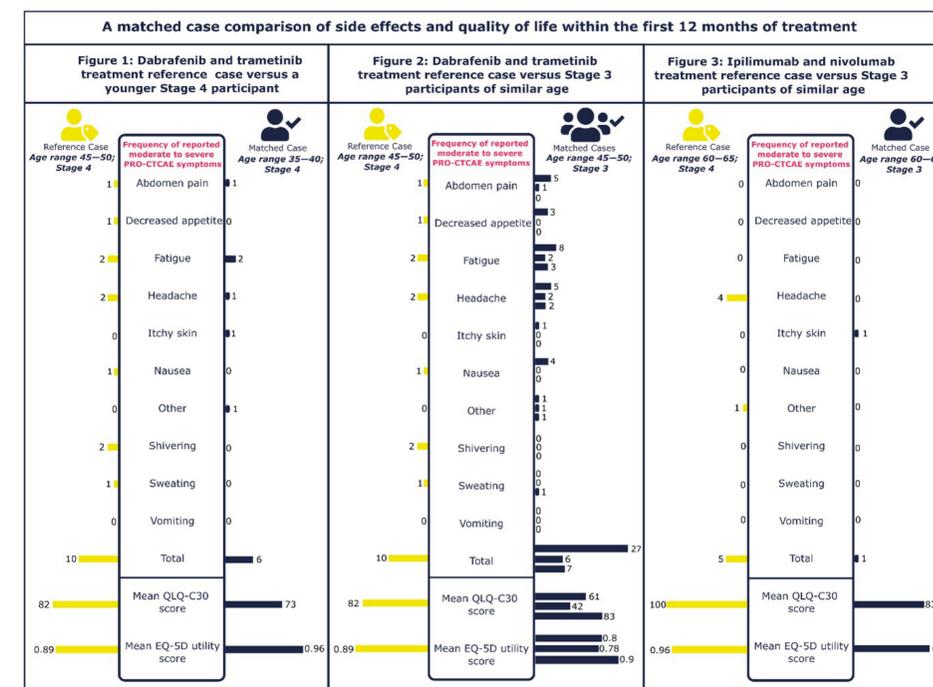
Theme	Sub-theme	Quote(s)
Side effect accompanying fever	Shivering	<b>Participant 1:</b> “but also when I first started taking it- was having these episodes of fever and shivering” <b>Participant 2:</b> “I put them all down to be honest down to the immunotherapy so just as a reaction so it was sickness, it was the temperature it was the- the shivering it was the- which you know I just put down to the fever, and the night sweats” <b>Participant 3:</b> “I was delirious I would say, shivering not really with it”
	Shaking	<b>Participant 1:</b> “just violently shaking, just could not get warm the bed used to- the bed used to shake as well and my partner could not get to sleep because of the shaking it usua- usually only happened at night for some strange- strange, peculiar reason” <b>Participant 3:</b> “-for the fever yep and as Participant 1 said you’re spaced out really you know shaking shivering et cetera” <b>Participant 4:</b> “the shaking, going from extreme cold with the shaking”
	Dehydration	<b>Participant 2:</b> “but I got pretty dehydrated, I was sick and shi- you know violently shivering and bad night sweats as well, was really sort of drenched and sort of you know having to change bedclothes and nightwear” <b>Participant 3:</b> “I was certainly dehydrated certainly off my food and came home and eventually g- got better afterwards” <b>Participant 4:</b> “and then boiling hot and sweating loads and then dehydrated with that”
	Loss of appetite	<b>Participant 1:</b> “the nausea was constant, I couldn’t really eat for about three months, I lost about probably two stone in weight” <b>Participant 2:</b> “I couldn’t eat. I mean a bit like- I think it was Participant 1 was saying I completely lost my appetite” <b>Participant 3:</b> “generally after the immunotherapy which one would have every month generally I’ve felt pretty ti- tired and jaded the day or so after and off my food survived on tomato soup and other additives”
Side effect of melanoma treatment	Fatigue	<b>Participant 1:</b> “y- yeah I still experience them if I’m honest with you I don’t work anymore I’ve been signed off from work the- the- the biggest side effect which I feel now is massive fatigue” <b>Participant 2:</b> “I’ve felt my bones ache I get fatigued I get tired and sometimes it’s my age I know but I’m- I’m pretty fit generally and it did affect me...”
	Sensitivity to cold	<b>Participant 1:</b> “I don’t know about the other guys, I feel the cold now a lot more than I ever used to a lot more” <b>Participant 3:</b> “I would be pretty hot blooded and not- and- find that [inaudible] the cold. I think there’s degrees of it but I would concur with Participant 1 that since having the treatment I’m more susceptible to colds and I feel it more...”

Note: The most important quote for each participant has been selected; this is not an exhaustive list.

### Contextualizing qualitative data with quantitative data from the registry

The dabrafenib+trametinib reference case showed a higher number of side effects and a slightly higher overall QoL than a matched patient who was 10 years younger (**Figure 1**). Compared to the reference case (Stage 4), three matched cases with Stage 3 melanoma experienced a mixed number of side effects (between 6 and 27), and lower QoL (**Figure 2**). Among this sample of registry participants that received dabrafenib+trametinib, the most commonly reported symptoms were abdomen pain (4 out of 5 cases), fatigue, and headache (both 5 out of 5 cases) (**Figures 1 and 2**).

The reference case for ipilimumab+nivolumab was compared to a matched Stage 3 patient. The QoL was higher in the reference patient despite greater frequency of side effects; no common side effects were reported between the two participants (**Figure 3**).



## Conclusions

In a focus group on side effects in patients participating in a digital registry, the most prevalent symptoms occurring with fever were dehydration, loss of appetite, shaking, and shivering. The most common longer-term effects of treatment were fatigue and sensitivity to cold.

These findings would have been more representative if more focus groups were conducted and a larger sample size achieved, which may be possible as the registry’s recruitment numbers continue to increase. Subject to data completeness, future studies could also supplement quantitative PRO data with qualitative data from the same participants.

Combining qualitative data with the quantitative data from the registry showed the value in using one data source to enrich the other; it also demonstrated the potential impact on a focus group if different participants had opted in and provided data, which can only be explored with available matchable, quantitative data.