

Simon Stevens
Chief Executive
NHS England
Skipton House
80 London Road
London
SE1 6LH

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Dear Simon Stevens

Individual Funding Request Process

I am writing to you after having my second Individual Funding Request (IFR) refused by the IFR Screening Group. As a result of this refusal I am highly likely to die this year despite the fact that, with the treatment requested for me, it is certain my life would be prolonged significantly with a reasonable chance of a full cure.

It would seem to me that the Individual Funding Request process has been designed to ensure that the majority of requests are declined, most of them are rejected by the IFR Screening Group.

I should give you some brief background of my case. I was diagnosed with Cutaneous Squamous Cell Carcinoma (CSCC) in January 2014, In April 2014 metastasis was confirmed down the right side of my head and neck. Between August and November 2014 I underwent surgery, 7 weeks of daily radiotherapy and had 2 doses of platinum based chemotherapy (Cisplatin). In March 2015 a scan indicated distant metastasis, confirmed by a bronchoscopy in April 2015. In May 2015 I was informed that my condition was incurable, terminal and no further treatment options were available, my prognosis was between 3 to 18 months.

CSCC itself is not particularly rare in the UK; estimated numbers of patients are 23,000 per year. However, metastasis is very rare; only 2-5% of cases. The NIHR Innovation Observatory Evidence Briefing: October 2017 – Cemiplimab for advanced cutaneous squamous cell carcinoma (http://www.io.nihr.ac.uk/wp-content/uploads/migrated_new/12662-Cemiplimab-for-advanced-cSCC.pdf) states " For advanced cSCC there is no standard of care and no licenced treatment available. Available guidelines suggest chemotherapy and EGFR inhibitors may be used in this population.". My oncologist stated on my IFR that ""Combination platinum-based chemotherapy eg. cisplatin or carboplatin combined with 5-flurouracil (or capecitabine) would be a standard

approach to first line systemic therapy with limited expectation of response and no proven survival benefit." Indicating the poor expectations of conventional treatment.

I was surprised to hear there were no other treatment options, so began researching what I could do to try and save my own life. For more details of what I tried you can consult my blog at <http://tryingtobeatcancer.org.uk/> .

In 2016 I read about immunotherapy, I found a number of examples where this treatment had been used, with considerable success, on patients with metastatic CSCC. I spoke to my oncologist about it and he told me I could not have the treatment in England even if I paid for it myself.

In early 2017, as my health was deteriorating, I read about a clinic in Germany where I could access this treatment so I contacted them. They insisted on testing my tissue samples before producing a treatment plan so they determine what my cancer was doing and what drugs I was likely to respond to.

I attended The Hallwang clinic in early March 2017 and continued treatment until June 2017. The cost of treatment including travel etc was in the region of £175,000 which I funded from my Army pension lump sum and my personal pension savings.

I was in extremely poor health at the time, I believe I had only weeks to live. The treatment began to work within 3 weeks, tumours on my body began to disappear overnight. As I continued through the treatment my recovery felt like a miracle. In March 2017 I struggled to climb my stairs at home, by July 2017 I was fit and healthy again. The before and after scans are available to view on my blog <http://tryingtobeatcancer.org.uk/scan-results-before-and-after-treatment/> .

When I returned from I naively thought that there would be some interest from the medical profession in the UK. Yet despite sending emails to around 20 individuals and organisations who specialise in skin cancer and have an interest in Immunotherapy, I received only 1 positive reply; from an Immunologist at Southampton University Hospital. I duly attended that hospital and arranged to be treated again (4 times) with the prime constituents of my treatment in Germany; the immunotherapy drugs Pembrolizumab and Ipilimumab. My oncologist's description of the effects of my treatment throughout 2017 were "Tolerated with no significant side effects. Excellent clinical/radiological response at all sites of disease."

Because the duration and dosage of treatment at Southampton could be costed, my oncologist submitted the first IFR which was refused by the IFR Screening Group for reasons that made no sense to me or my oncologist. My oncologist wrote to them requesting a more detailed explanation; they never replied.

When I complained officially via the NHS Complaints Team, my complaint was not investigated but simply forwarded to the IFR team for response. They claimed they "had no record of receiving the letter", I don't believe they didn't receive it though I do believe that they now have no record of receiving it, the other addressees all received it without issue. They have still not replied to my oncologist despite promising to do so.

I then asked my oncologist to resubmit the IFR with the additional evidence from my treatment in Southampton and subsequent scans. He did so despite the considerable time and number of people involved in supporting and approving the request at the local Trust level. This second IFR was duly refused again by the IFR Screening Group just before Christmas 2018.

I received a copy of their response from my oncologist and was appalled by the comments. The IFR Screening Group have simply ignored the evidence presented to them, been disingenuous in their replies, have misrepresented statistics and made comments that are clearly untrue. Their consideration of the IFR has been done in the most negative manner possible and clearly with the intent to refuse treatment regardless of whether it would benefit me and possibly save my life. I have made the original IFR and the IFR Screening Group's response available on my blog and have commented on the majority of their responses, this can be viewed at <http://tryingtobeatcancer.org.uk/nhs-individual-funding-request-farce-number-2/> .

It is interesting to note that nowhere in the IFR Screening Group's response is there anything that asks them to consider the benefit of treatment (or lack of it) on the patient or whether the patient's life could be saved with treatment or the effect of refusing treatment.

For many people with rare conditions the IFR process is their only method of accessing useful treatment, as rare conditions are not a high priority for either the medical profession or pharmaceutical companies, resulting in a lack of licensed treatments. Yet the process seems to have been subtly engineered to ensure the failure of almost all requests.

The IFR Screening Group was introduced into the process in around 2012, probably not coincidentally, after some high profile successful challenges to IFR refusals from Clinical Commissioning Groups (CCGs). Prior to that the process consisted of local approval followed by consideration by a National Panel. Decisions made by the National Panel have a clear route to appeal by anyone including the patient. It is my feeling that this is why the Screening Group was introduced; to block requests reaching a National Panel and remove any opportunity to appeal decisions.

The issues with the current IFR process were highlighted in an opinion piece for the Kidney Cancer Support Network in 2016. This can be viewed here: <http://www.kcsn.org.uk/opinion-pieces/confusion-individual-funding-request-ifr-system/> . The issues are clear to anyone and predict what I have experienced, as they say the IFR Screening Group "is a duplication of work with an extra layer of administration – WHY?".

The Rt Hon John Healey MP submitted a question in the House of Commons in March 2017 regarding the numbers of IFRs where the decision is made by the IFR Screening Group. This can be viewed here; <https://www.parliament.uk/business/publications/written-questions-answers-statements/written-question/Commons/2017-03-01/66178/> . It's interesting to note that over the period for which there are figures; the number of IFRs submitted reduced considerably whilst the proportion of IFRs refused by the IFR Screening Group rose.

Every NHS clinician that I have spoken to, both in the course of my treatment or informally, has told me that submitting an IFR is simply a waste of their valuable time as "none of them ever get approved". From the figures above it is clear that clinicians have no faith in the IFR Process, a number went as far as to say "It is designed to fail patients". Clinicians' time is precious, it is understandable that they do not wish to use it engaging with a system that is designed to fail.

It's also clear that letters sent out by the IFR Screening group are simply cobbled together from a standard list of excuses not to treat people. The letter I received after my first IFR was often incoherent, it repeated and even contradicted itself. After I wrote about it on my blog I was contacted by another patient with an entirely different condition who said "*Here I am thinking I am the only person in this position! The quotes couldn't have been [more] similar to the response they gave me!*".

The criteria required for a Patient's IFR to be passed by the IFR Screening Group are almost impossible to meet. Having gone through the responses to my second IFR they seem to conflict in a way that is impossible to meet them all.

1. The IFR Screening Group seem to require overwhelming evidence that a requested treatment will be successful on a large patient group on the condition it has been requested for.

Surely if this were the case; the treatment would already be licensed for use and available to the patient?

As my oncologist stated in the request "*Squamous cell carcinoma of the skin with distant metastases is rare and the evidence base for palliative systemic treatment is inevitably weak mainly based upon case reports, small case series and extrapolation from other squamous cell carcinomas*". One of the drugs requested for me is already licensed for use on Head & Neck SCC and so is available for use on patients within the NHS. That form of cancer differs very little from mine in anything other than the location it is categorised under, however the condition is nowhere near as rare.

My prior successful treatment with the requested treatment (twice) was not enough to satisfy the IFR Screening Group that the treatment would be successful on me.

2. You must show that you are significantly different from other people with the same condition and you will benefit more than them, this is known as "exceptionality". This conflicts with the first requirement and anyway why this should be the case?

The actual wording in the criteria to define exceptionality is "the patient's clinical presentation is so unusual that they could not be considered to be part of a defined group of patients in the same or similar clinical circumstances".

As I point out in my blog post, there is nobody in England in the same or similar clinical circumstances as me; I am much younger than the average age of patients

with this condition, have no comorbidities, I am still alive nearly 5 years from diagnosis whereas the median prognosis is "less than 2 years" and, crucially, I have already had the treatment being requested twice and it was successful. This treatment is not available to people with my condition in England so nobody else has had it.

Yet this was all dismissed and the IFR Screening Group who simply stated that my clinical presentation was not unusual. I challenge NHS England to produce even one other patient with my clinical presentation.

People who have terminal cancer already have quite a battle on their hands without being failed by their country's Health system. Since being declared terminally ill I have struggled to get any medical treatment such as monitoring scans. It would seem that once the NHS has written you off there is only a very limited budget for treatment. Cancer is physically debilitating but the chaos that is the NHS also debilitates your mental health.

The IFR Screening Group has over-ruled my oncologist and everybody at the local Trust level, including the Clinical director, who supported and approved the IFR before it was submitted to NHS England. Are these people not best qualified to decide whether a patient will benefit from a certain treatment?

The IFR Screening Group seems to have been inserted into the IFR process to second guess the National Panel. It seems to be simply a cost saving measure; refusing treatment and negating the need to convene the National Panel. Whether it does save money is a moot point as the cost of processing the paperwork together with palliative and end of life care in my case is probably more than the amount the treatment would have cost (£31,000).

The IFR Screening Group is unaccountable, doesn't have to explain its decisions and those decisions cannot be appealed or challenged other than by a Judicial Review. I am taking legal advice, but the likely cost of seeing a case through to trial is prohibitive without legal aid. Also I have been warned that NHS England are happy to spend unlimited amounts of taxpayers money defending their decisions even if they are likely to lose. Perhaps this would be better spent on treatment.

The final insult from the IFR Screening Group is the fact that on the bottom of the letters telling me they have again refused treatment which I have proved works on me and will save my life, is the strap line "Health and high quality care for all, now and for future generations". I don't know how much this cost to dream up but I can assure you it is a lie.

The IFR Process seems to be just a bureaucratic scheme to allow NHS England to claim there is a route to treatment not normally available whilst ensuring that hardly anybody is successful. This seems very similar to the process recently put together to facilitate the prescription of medicinal cannabis products. The same abstract test of exceptionality must be met and the number of people who can prescribe is severely limited. As I understand it; to date not a single person has been prescribed a medicinal cannabis product by the NHS.

In January 2018, Tessa Jowell made an impassioned plea in the House of Lords for experimental treatment to be made available to terminally ill patients. I was at home, in tears and cheering, someone with a voice, with media and parliamentary access, had finally raised this issue publicly. Your comment after her death was “.. she leaves a deep legacy with the potential to benefit many thousands of other cancer patients long into the future.”. All that actually happened after her death was that a token sum was thrown at Brain cancer research while everything else she talked about was ignored. In the end, her faith in the NHS evidently gone, she went to a German clinic for treatment, as I did, unfortunately she didn't have the same success I had.

Experimental treatment is still not available to terminal cancer patients, even in cases like mine where there is no licensed treatment yet I have shown there is treatment that works on me. The incredibly restrictive system through which new drugs and treatments must go before they are approved for use means it takes years, sometimes decades, before they are available to patients. When your prognosis is 3 to 18 months you simply cannot wait, you will be long dead.

I've written this letter to highlight the faults in the IFR system. It isn't just a complaint about the way I've personally been treated. The IFR system is failing almost all patients who manage to convince their reluctant clinicians to go through the process. People are dying because of the actions of the IFR Screening group, and the majority of these are people with rare conditions for which there is no licensed treatment.

I have absolutely no complaints about the people within the NHS who have treated me over the last few years. With very few exceptions they have been kind, committed and have helped me as much as they can, many sympathise with my plight. However they seem to be working with their hands tied by the bureaucratic nature of NHS England and its constituent, mainly autonomous, organisations. They seem under a barrage of conflicting instructions, policies and procedures which only serve to make their working lives more difficult than they should be. It is no surprise that they are leaving in droves.

I have made this an open letter and distributed it to as many media outlets that I can think of in an effort to get this problem publicly discussed. I hope that somebody other than me and my oncologist thinks that this is something that should be addressed and brings some pressure to bear on NHS England to do so. I feel I have to do this as my MP Rachel Maskell wrote to you about my case in early 2018 and you chose not to reply to her letter, which was disappointing.

I implore you to review the IFR Process and put it in a state where it actually works for both clinicians and patients. People at the local trust level are far more qualified to decide on whether a patient will benefit from a particular treatment than the IFR Screening Group, at least they have been involved in the patient's treatment to date. At the moment the IFR Process looks very much like it is simply a means of saving on treatment costs whilst giving the impression there is a route to otherwise unavailable treatment. It should be aimed at achieving one of the objectives of the previous system, the Cancer Drugs Fund, which was to “put clinicians and cancer specialists at the heart of decision-making, consistent with the Government's wider policy of empowering health professionals and enabling them to use their professional judgement about what is right for patients”.

I have very few options available to me now. I cannot afford to fund another course of private treatment and I cannot get treatment from the NHS. So I must prepare for my imminent death. It would be easier to accept if I didn't know that there is treatment that will save me but I can't have it unless I can afford it.

Yours sincerely

Paul Thomas-Peter