Patient organisation submission

Cefiderocol for treating severe aerobic Gram-negative bacterial infections

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| Thank you for agreeing to give us your organisation’s views on this evaluation.  You can provide a unique perspective on the impact of life-threatening drug-resistant infections that is not typically available from other sources.  If you would like help with your submission or somebody to read a draft for you, please contact [PIP@nice.org.uk](mailto:PIP@nice.org.uk) or [Mandy.Tonkinson@nice.org.uk](mailto:Mandy.Tonkinson@nice.org.uk)  You do not have to answer every question – they are prompts to guide you. The text boxes will expand as you type. Please note that declarations of interests relevant to this topic are compulsory.  **Information on completing this submission**   * Please do not embed documents (such as a PDF) in a submission because this may lead to the information being mislaid or make the submission unreadable * We are committed to meeting the requirements of copyright legislation. If you intend to include **journal articles** in your submission you must have copyright clearance for these articles. We can accept journal articles in NICE Docs. * Your response should not be longer than 10 pages. |

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| **About you** |  |
| 1.Your name | **xxxxxxxxxxxxxx** |
| 2. Name of organisation | Antibiotic Research UK https://www.antibioticresearch.org.uk/ |
| 3. Job title or position | xxxxxxxxxxxxxxxxxxxx |
| 4a. Brief description of the organisation (including who funds it). How many members does it have? | Antibiotic Research UK is a small charity which was set up in 2014. We are a member of The Association of Medical Research Charities (AMRC) and the only charity dedicated to undertaking research into antibiotic resistant infections. Our funding is primarily raised through fundraising, donations, and grants. With no need to make profits, we can concentrate our efforts on those areas which will yield greatest benefit to humankind and deliver results fast.  Our mission is to tackle the global threat of drug-resistant infections by:   * Driving and enabling innovative and collaborative research to ensure future generations have access to effective treatments. * Supporting patients and families that are affected by drug-resistant infections. * Working in partnership with key stakeholders to raise awareness and reduce the spread of drug-resistant infections.   Antibiotic Research UK’s Science Committee which oversees our medical research activities, are eminent scientists, and clinicians – leaders in the field of antibiotic resistance from across the UK. The Education Committee also includes experienced pharmacists, health education professionals and lay people with a personal interest in antibiotic resistance. Antibiotic Research (UK) established the country’s first dedicated Patient Support (PS) Team in February 2019 realising the need for better patient information, support, advocacy for those suffering with resistant bacterial infections. It also recognised the lack of patient voice in decision making within AMR strategies. The charity uniquely fills that gap. |
| 4b. Has the organisation received any funding from the manufacturer(s) of the treatment and/or comparator products in the last 12 months? [Relevant manufacturers are listed in the stakeholder list.]  If so, please state the name of manufacturer, amount, and purpose of funding. | No |
| 4c. Do you have any direct or indirect links with, or funding from, the tobacco industry? | No |
| 5. How did you gather information about the experiences of patients and carers to include in your submission? | Led by a small team of pharmacists, our Patient Support Service provides a web-based portfolio of resources on resistant bacterial infections, a confidential email function, and a dedicated telephone number for people to speak to our team and request information and support. <https://www.antibioticresearch.org.uk/find-support/support-for-individuals/>  Patient enquiries are steadily growing, as are visits to the webpages, particularly on resistant UTIs. All the information provided below has been shared by patients who have contacted the Patient Support Service in need of help, information, and support. Those patients named have given their full written permission (recorded on a form approved by the Charity’s lawyer) to share their experiences. They agree to this for the purposes of improving public and professional understanding of the suffering and difficulties which face those who suffer with resistant DRIs. They wish to see funding and development of new antibiotic therapies prioritised. |
| Experience of infection |  |
| 6. What is it like for patients who experience severe, drug-resistant infection? This refers to an infection which requires urgent treatment in hospital, for which there are limited antibiotics that work. These infections can be life threatening. For example, sepsis (blood stream infection), hospital-acquired pneumonia, or complicated urinary tract infection. Please include details of the type of infections including location in the body, the type of bacteria that caused the infection, and how many courses of antibiotics might be used. | Patients who experience a drug resistant infection (DRI) endure sleepless nights worrying about whether their quality of life will continue to be diminished day by day and year by year. Some live in fear of death – especially those who have experienced sepsis or septic shock as a result of resistant infections like bacterial pneumonia or resistant UTIs. The most immediate impacts of the resistant infections are pain, fatigue, listlessness, inability to cope with daily tasks and life. For UTIs, this also includes urinary frequency, burning, and being forced to stay at home near a toilet – and in turn, impacts all other areas of life, work, responsibilities inside and outside the home, and social life. Most aspects of life completely stop until the infection is under control or patient discharged from hospital to recover. Patients talk of the difficulties they face convincing friends and family that there genuinely is something wrong with them and they feel very unwell, even though they look perfectly fine.  Many experience that sense of being viewed as ‘exaggerating the truth’ and often stop trying to explain, give up mentioning their health issues with DRI, and keep quiet. They suffer silently, as few of their family and friends can comprehend that antibiotics don’t always work, and that infection isn’t easy to live with. Some patients talk of losing their jobs through extended sick leave or inability to complete the work; others have lost homes, independence, even partners as a result of the suffering from resistant infections which keep recurring and disrupting lives in every shape and form. This includes financial impact, ability to care for their families and homes, intimacy reduced or stopped (usually due to UTIs). Some even talk of healthcare professionals having poor understanding of the scale of suffering and incapacity patients experience because of chronic resistant infection.  For most people I speak to, the impact on mental health is severe. Many are suffering or have suffered/been treated for depression and/or anxiety and this worsens with each episode of DRI. The physical suffering is already terrible, but the fear of not recovering or being able to resume aspects of ‘normal living’ causes severe depression. This is only exacerbated by the unspoken fear that one day there will be no antibiotic left to treat their DRI – and the outcome is too terrible for them to put into words. But they are all thinking about it. Living with a chronic drug resistant Infection feels like a life sentence to each of them, but one which they believe the general public have no understanding or concept of, until it happens to them or one their family.  Many of the patients I support will speak about trying every possible natural means of dealing with the ongoing infections; from special diets, to natural or herbal treatments, to infection avoidance strategies too eg avoiding sex to prevent a DR UTI flaring up. Many will undertake their own research in a desperate effort to find something that may help them.  There are many examples of patient experiences that could be recounted - here are a few, and many others can be found on the website at https://www.antibioticresearch.org.uk/find-support/patient-stories/  Ronda told me “ In 2018, I had laparoscopic surgery to diagnose and treat endometriosis, and I contracted an infection from the catheter, that developed into urosepsis. It wasn't treated correctly and that is why I'm suffering from a multidrug resistant urinary tract infection (*Citrobacter koseri*). When I was released from hospital and trying to access the right care to get better, it quickly dawned on me that I was one step away from sepsis, two steps away from death. That was a frightening reality for me. My GP did everything she could in her power and gave me lots of short rescue courses of various antibiotics, which didn't work at all. Unfortunately, two years and four months on, I've made little headway, and I don't see myself coming off antibiotics for a very long time because I keep on having horrible symptom flares, which are incapacitating and stop my life. I have pain when urinating, urethral burning, loin pain, dizziness, general feeling unwell. I get these horrific shooting pains in my lower region that are just tremendously painful and reduce me to tears. No one can see it, friends and family can't see it, I can present like I'm fine and look okay, but that is not the truth of what's going on in my mind. I suffer silently, just like the infection is invisible, my suffering is mostly silent and invisible. As we know, antibiotic resistance is a global serial KILLER, therefore, I hope the NHS and the government will thoroughly review all the statistics regarding patient’s cause of death and ongoing infections, and in light of these facts prioritise and develop new solutions to combat drug resistant infections. “  Lisa’s experience involves a constantly infected PEG fed site and a resistant recurring pneumonia related to scoliosis of spine. Lisa has said “My last bout of pneumonia caused by resistant bacteria was in Nov 2019 when I ended up in hospital. I was given intravenous antibiotics for 2 days then two oral antibiotics for another 5 days. Once my blood test levels had returned to normal, I was discharged home with advice to return if I got any worse.  I think I now have problems with resistant bacterial infections in both my PEG tube and also from these recurring lung infections.  Experiencing recurring infections where I end up in hospital or unwell have proved to be another ‘knock’ to me in my life – as it affects me being able to do my volunteer job. I may be disabled and not able to do paid employment, but losing that opportunity to give back, and to undertake the volunteering role which gives my life so much purpose and meaning can be extremely difficult to deal with. When illness and infection remove that, it has a major impact on all aspects of my life. I become more anxious and more depressed when this happens – as it’s another reminder that I’m not well and am disabled. But I remain determined not to let either bacterial infection resistant to antibiotics, or other conditions define me or prevent me from making a useful contribution to society and to life”. |
| 7. How long on average do patients spend in hospital receiving treatment for drug-resistant infections? | The patients I have spoken to generally spend 1-4 weeks in hospital, but some have needed extended times due to difficulty in finding the right antibiotic, and complications of treatment. Others, like Lisa, find themselves admitted 9 times over a twelve-month period. Frequency of admissions due to recurring DRIs often causes more upset than length of admission. Another patient, in her thirties, has been admitted for sepsis five times now, considered to be the result of a DR UTI which has not yet been eradicated. |
| 8. Are patients required to isolate in hospital (that is be in a room on their own) to reduce the risk of passing on infection to other patients?  If yes, can you provide examples of the duration and impact on patients. | Some with known DRIs such as ESBLs are put in isolation, treated for 2-6 weeks, bringing its own issues. Many patients say they understand the reason for isolation – provided it is explained with clarity, compassion and without blame attached.  Sharon’s story illustrates this: Sharon had quite a few health concerns and illnesses including 3 heart attacks at age 38, bladder and bowel problems which required a sacral nerve stimulator to be fitted in March 2019 to allow bladder emptying to occur. She developed sinusitis at first, then 3 weeks later developed yet another UTI. Her husband took her to A&E as he realised Sharon could hardly speak and couldn’t breathe properly. Sharon thought she was dying. She had to convince the nurse in A&E that she had sepsis, recognising symptoms she’d had before. Sharon was treated for sepsis, given oxygen and Meropenem. After a few weeks, a member of staff came into the ward and simply told her “ you’ve got ESBL *E Coli*” and moved her into isolation. No one explained what ESBL *E Coli* was, how she got it, or why it made her so ill. Each day, specific staff came in to take bloods, to check how long she had to be on the IV antibiotic, but nobody explained why she was in isolation or what was happening to her. (This raises a different issue of communicating well with patients about DRIs, what they mean and providing adequate information to them). Compounding this fear of being in isolation without explanation, was the questioning about her history and lifestyle, as staff were also investigating and testing for HIV and Sexually Transmitted Infections. Sharon was absolutely mortified and embarrassed by all these questions – especially as a happily married mother of three teenagers! The issue for patients in isolation is not just the loneliness, but the sense of feeling ‘dirty’ as Sharon said to me, and fear of being a danger to other patients, vulnerable in oneself, and unsure whether family visiting were then at risk from acquiring the infection. These experiences add huge unnecessary stress to the patient who is already fighting hard to recover from DRIs and sometimes sepsis. |
| 9. Do resistant infections impact other treatments? For example, does infection delay acceptance for organ transplant, other surgery or other types of treatment? | For some with co-morbidities this is true eg Sharon has been awaiting spinal treatments/operation, but these have been delayed by her DRI and post sepsis syndrome. Others like Lisa cannot undergo replacement PEG tube surgery because the combination of her reduced lung capacity and DRIs will no longer allow surgery under general anaesthetic; so she lives with resistant infections in both areas of her body with no real promise of eradication. |
| 10. What do carers experience when caring for someone who has had a severe, drug-resistant infection? | Many partners, parents, and even adult children find themselves caring for the patient physically, emotionally, and financially. They often carry responsibility for running households, while supporting the patient to seek yet more treatment. The restrictions on freedom, choices, and quality of life experienced by the patient equally apply to the carer/family but this is rarely acknowledged or voiced.  Lisa’s parents have to care for her as well as being employed fulltime. Her whole family are affected by her resistant infections. Lisa told me “My mum has to take time off work to care for me when unwell, so there’s practical considerations for them as well as me.  My niece and nephews see me struggle at times and worry whenever I’m admitted to hospital due to bacterial infection. They feel guilty if they think they have passed any kind of infection onto me. So, all generations of my family are impacted by the resistant bacterial infections I experience”  Sharon’s husband has to look after Sharon, take her to appointments, undertake household duties and care for three teenagers since Sharon isn’t well enough. He also works to provide financially for the family. Relatives of patients often speak of the fear that they hide from the patient; fear of infection flaring up again unexpectedly; of antibiotics not working the next time, of sepsis occurring ( sometimes again) and fear of what the future holds for their loved ones, and for them.  Some partners of women with severe and recurring DR UTIs also live with the dread of the next flare-up. These spouses develop a language where “Are you ok?” actually means “oh no… are you becoming ill again? What can I do to help?” Often, they have no choice but to be the ‘breadwinner’ and support the partner financially too, as resistant infection usually prevents the patient maintaining employment.  The other group I am often contacted by are sons/daughters of older people; where they wonder if four different consecutive antibiotics means their parent has a resistant chest infection; or why the same antibiotic is given over and over but no resolution of infection is achieved. These family members/carers are constantly worried, and see first-hand the effects of DR infection on their relative – witnessing their confusion, listlessness, fatigue, difficulty breathing etc and this leaves them feeling guilty and helpless to resolve it. |
| Current treatment of life-threatening drug-resistant infections in the NHS |  |
| 11. What do patients or carers think of current treatments and care available on the NHS? | Patients who suffer from ongoing resistant infection have often been told by doctors that there may not be many other options left to treat them; or that they didn’t know what else to try to treat the infection. This is a frightening prospect and implies rescue may not always be possible. These patients understand the issue of antibiotic resistance; they know why antibiotics have to be used sparingly, appropriately, in correct doses and for right length of time. However, their own experience is that the IV antibiotics may appear to work at the time, but on completion, the symptoms flare up almost immediately again. They wonder if the drug choice was right, or if the dose was powerful enough; and if the length of treatment was sufficient- as many of them have suffered with the resistant infection for months and often years. Patients sometimes question whether GPs understand and recognise resistant infection; and whether specialist treatment should be offered and initiated earlier than happens, often on emergency admission.  Many patients talk of wonderful, empathetic care from consultants and nursing staff; but there are also disturbing reports of patients being told by, for example, urologists, that they “don’t know what else to do” to treat a resistant UTI. This leaves patients without treatment – and without hope. I have known of two patients who have travelled hundreds of miles from their home (and local consultant who has not treated the infection) to another hospital where they know a ( previous) consultant will believe them, make a clinical decision based on their history (not negative tests) and extreme UTI symptoms, and initiate IV treatment. |
| 12. Is there an unmet need for patients who have a life-threatening, drug-resistant infection? | Yes definitely. Patients report to me the frustration, fear and dread of that next flare-up and episode of the DRI. Sometimes it is made worse by health professionals not always accepting or believing there is DRI present; often as a result of poor testing, out of date testing techniques (especially in UTIs) despite full blown infection symptoms being experienced and life on ‘stop’. Patients describe how they had to become their own ‘expert’, learn to discern when infection is flaring up, and seek treatment (sometimes in A&E). Some have even recognised signs of sepsis and had to convince hospital staff serious illness was developing, as described in Sharon’s experience above. |
| Advantages of the treatment |  |
| 13. What do patients or carers think are the advantages of the treatment? | Patients are constantly looking for the treatment which will eradicate their ongoing resistant infection once and for all; to allow them to return to a more ‘normal’ pattern of life and be able to live and plan and even work again. Many of them have experienced numerous flare-ups of drug resistant infection; some have almost given up hope of eradicating the infection and are now just hoping to keep it under control enough to allow a degree of daily living to be maintained – that is how low their expectations now are. So, a more powerful effective treatment against gram negative resistant infections would be a game changer and a life changer for most of the patients I speak to. This would also have a profound effect on their mental health, their ability to undertake physical activity in some form, to be less reliant on family and carers for daily help and financial support, and to finally enjoy a better quality of life than that described previously. Patients also recognise the benefits of eradicating or controlling DRI to society, including economic benefits (increased productivity, decreased reliance on state benefits etc), fewer hospital admissions, improved mental health resulting in reduced need for services/therapy. |
| Disadvantages of the treatment |  |
| 14. What do patients or carers think are the disadvantages of the treatment? | Disadvantages are weighed up by patients alongside benefits of treatment. Admission to hospital may be a disadvantage- although Outpatient Parenteral Antibiotic Therapy (OPAT) now offers alternative options that are attractive to patients requiring IV treatment. The risk of potentially serious side effects is the most obvious disadvantage.  They desperately want the new treatment to eradicate the infection, not just control it; and are prepared to take the risks of side effects and disadvantages if the likelihood of clearing the life-changing infection is good. However, some patients have found themselves left with post treatment anxiety and depression – sometimes because the treatment failed, or the infection returned. On other occasions, it was because other factors caused more fear – such as Helen’s experience of treatment during pregnancy for Group B streptococcus infection leaving her with post birth anxiety during breastfeeding. She developed real fear for her and the baby’s safety in a hospital environment, after mastitis didn’t respond to oral antibiotics and resulted in hospital admission and IV treatment for sepsis. Despite gratitude the IV antibiotics eventually worked – numerous encounters with resistant infections left her afraid for the side effects on her baby, her own health and for the future. <https://www.antibioticresearch.org.uk/stories/helens-story/>  Lisa is a 40 yr old woman who receives PEG feeding, and lives with her parents. https://www.antibioticresearch.org.uk/stories/lisas-story/ They act as her carers, to support her while working fulltime themselves. When her resistant respiratory infection flares up, she will often know herself when hospital admission and IV treatment is required. This drastically affects her own mental health, as it stops her volunteer work, which in turn gives necessary purpose to her daily life when she cannot work for a living. It also puts her parents under additional pressure as they seek to visit and support her in hospital, alongside their own daily commitments. Again, they understand that risks of serious side effects and ADRs, and more admissions to hospital must be weighed up against potential benefits of treatment. Minimum days in hospital alongside successful treatment would be a worthwhile goal for these patients. |
| **Patient population** |  |
| 15. Are there any groups of patients who might benefit more or less from the treatment than others? If so, please describe them and explain why. | From my experience in patient support, the groups which I think would benefit most include:  -Women age 30-70 yrs who appear to have more severe UTIs from DRI than males, or younger people. Additionally, this group often have additional family responsibilities and dependents (both older parents and younger children) and so they and their dependents would benefit hugely from this successful treatment, and consequently experience fewer hospital admissions and illness.  - Older patients with recurring resistant respiratory infections, who don’t realise they have resistant infection but are constantly receiving short rescue courses of antibiotics (which don’t work) and frequently end up being admitted to hospital for IV treatment. |
| Equality |  |
| 16. Are there any potential [equality issues](https://www.nice.org.uk/about/who-we-are/policies-and-procedures/nice-equality-scheme) that should be taken into account when considering drug-resistant infection and the treatment? | From my experience in patient support, the groups which I think present equality issues are as above:  -Women in age group 30-70 yrs who appear to have more severe UTIs from DRI than males, or younger people.  - Older patients with recurring resistant respiratory infections, who don’t realise they have resistant infection but frequently end up being admitted to hospital for IV treatment. |
| Other issues |  |
| 17. Are there any other issues that you would like the committee to consider? | Here are some links to supplementary info on/from patients about their experiences.  <https://www.youtube.com/watch?v=FfJePrXcSng>  -this is Mary who suffers with DRI in UTIs….*proteus mirabilis* just discovered after years of suffering UTIs, previously considered to be due to *E Coli* only.  <https://vimeo.com/user121198295/review/554182151/19ca35d63c> - this is about Helen’s fears of antibiotic resistance and when antibiotics don’t work any more.  More patient stories about DRIs can be found here:  <https://www.antibioticresearch.org.uk/find-support/patient-stories/> |
| Key messages |  |
| 18. In up to 5 bullet points, please summarise the key messages of your submission: | * A DRI is, for many patients, a chronic condition and a potential death sentence which is invisible and which they must live with. * Symptoms often include severe pain, fatigue, lethargy, brain fog, leading to severe depression & anxiety as quality of life decreases * Ongoing DRIs result in an economic burden on individuals, many of whom cannot work other than in a voluntary capacity, and on the NHS and social services due to the need for care, * DRI has a huge impact on carers /families; looking after the patient, homes and children, and providing financially; and the inability/loss of freedom to plan for leisure/trips/outings/holidays significantly affects them too. * Over reliance on poor testing methods means patients often feel they are “not believed” by healthcare professionals or by family and friends |
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Thank you for your time.

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