

Senate Community Affairs References Committee Inquiry
The availability of new, innovative and specialist cancer drugs in Australia

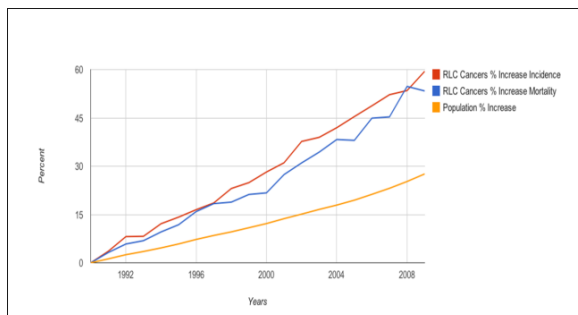
The Unicorn Foundation welcomes the Senate Inquiry into - ***The Availability of new, innovative and specialist cancer drugs in Australia.***

The current Rare / Less Common Cancer landscape in Australia

Rare or less common cancers (RCL) such as Neuroendocrine Cancers (NETs) are often overlooked by the health system; resulting in mortality of RCL's double that of the common cancers such as breast or prostate. If one develops an uncommon cancer such as NETs one has only 40% chance of surviving 5 years compared with 90% chance of surviving 5 years with breast cancer. These odds have not changed for decades.

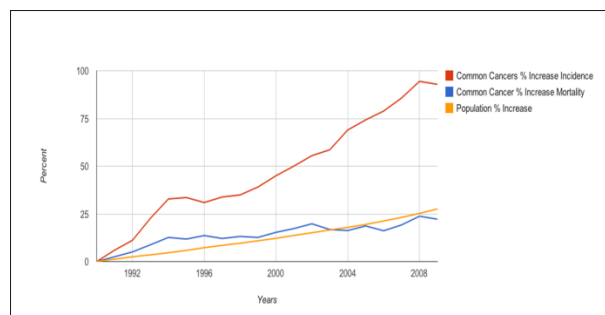
As distinct from common cancers, every year there are over 42,000 diagnoses of rare and less common (RLC) and around 22,000 deaths. For these Australians with an RLC there is very little available, from patient support through to new treatment options¹.

Mortality Graph RCL



Vs

Common Cancer



Source – *Just a Little More Time* – Rare Cancers Australia

During the twenty years under examination in the Rare Cancers Australia “*Just a Little More Time*” Report, Australia has seen the introduction of screening programs for common cancers (breast, prostate and bowel), awareness programs (lung cancer and melanoma) and significant monies allocated to both research via the National Health and Medical Research Committee (NHMRC) and treatments through the Pharmaceutical Benefits Scheme (PBS). The impact of these programs and funding has been significant for common cancers, but in contrast RLC cancers have not been given attention and resources and there has been little or no improvement.

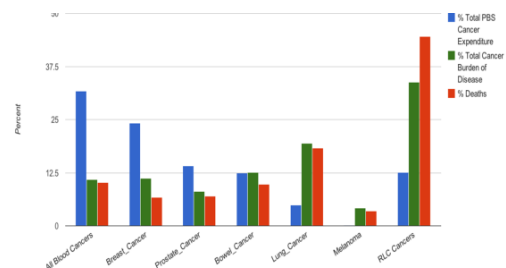
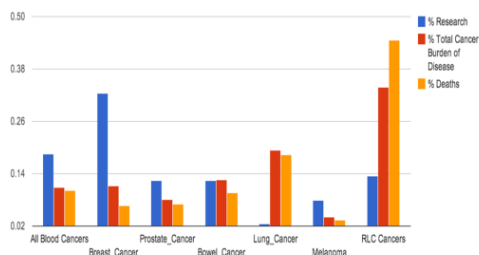
¹ *Just a Little More Time* - Rare Cancers Australia

Without similar mechanisms specifically designed to address the prevention, diagnosis, and treatment of RLC we cannot hope to have an impact on mortality or on improving patient outcomes in the future.

Research Spend

v

PBS Treatment Graph



Source – *Just a Little More Time* – Rare Cancers Australia

These statistics speak for themselves and gaps in care are clearly evident. How does this affect the actual patient? In a survey of over 220 Neuroendocrine Cancer (NET) patients conducted by The Unicorn Foundation, 41% of their patients reside in rural areas compounding the feeling of isolation and increasing the financial burden of cancer, with travel to city centres a necessity as rural centres are not equipped for less common cancers².

In regards to what NET patients identified as their priorities (multiple answers were allowed); 85% stated improved awareness in the medical community (GPs in particular); 72% wanted their case to be reviewed within a specialist Multi-Disciplinary Team; 64.2% wanted greater access to Peptide Receptor Radionuclide Therapy (PRRT); 57% wanted greater access to nuclear medical facilities (e.g. PET) and 48% wanted access to specialist NET nurses.

In February 2014 The Unicorn Foundation employed the services (through fundraising and without any government support) of a specialist Neuroendocrine Cancer nurse to provide online, in person and telephone support to the more than 10,000 NET patients around Australia. Demand for this service has grown exponentially, with more than 1400 contact points since inception. This support role has expanded to include an educator role to other cancer care nurses employed by Hospital Cancer Services and community based cancer organisations –e.g. Cancer Council helpline departments. This role is solely funded through fundraising and receives no government support.

For RCL patients the reliance on the internet for information and support is increasing as they search for services that are not provided or communicated to them. Access to accurate and correct diagnostics can be costly due to bureaucratic restrictions (such as those found by NET patients in accessing the superior Gallium 68 PET scans over the approved Octreotide scans)

² *NET Patient and Carer Survey 2013* – The Unicorn Foundation

and accessing cancer drugs through the PBS is difficult as patient numbers for each separate cancer do not provide economies of scale.

There is a common lack of education and awareness by General Practitioners of RCL's leading to misdiagnosis for, in some cases with NETs, 5-7 years. By the time correct diagnosis is made of a NET, **in over 50% of cases**, the cancer has spread to other organs. In a poster comprised of the survey results of 652 GPs from around Australia, presented by The Unicorn Foundation at the European Society of Medical Oncology (ESMO) in 2012; 62 % of doctors who responded do not know the prevalence of NET patients in Australia; 45 % were unaware that the incidence of NETs has increased over the past decade; and 91% recognised that NETs were often misdiagnosed but almost two thirds (63 %) did not realise that the most common misdiagnosis is Irritable Bowel Syndrome³.

Across the board more education needs to be undertaken about RCL's and their symptoms (which often mirror more common complaints) and a national approach is needed. In the last ten years heightened awareness of some rare cancers such as Ovarian, clearly show what can be achieved with a unified response from government, patients and advocacy groups. Support for a specific Rare and Less Common Cancer stream from organisations such as the Medical Oncology Group of Australia (MOGA), the Clinical Oncology Society of Australia (COSA) and Cancer Australia is imperative if there is to be any improvement to the high mortality rates of the last 20 years.

Comment on the Inquiry's Terms of Reference

a. The timing and affordability of access for patients

For NET Cancer patients the most pressing issues faced throughout their cancer journey is access to innovative and new treatments and diagnostics. In some cases patients live with NET cancer for over 10 years making it a chronic disease. This places huge pressure on the family finances, as well as community health resources due to the need for constant care, treatment and diagnostic tests. For this smaller cancer group, access to clinical trials is imperative as well as compassionate access to drugs through pharmaceutical companies. Clinical trials are not always available and pressure on the compassionate access program means it cannot be used as a sustainable model.

One of the more successful treatments for NET Cancer patients is Peptide Receptor Radionuclide Therapy (PRRT). PRRT or Lutate Therapy is a specific therapy suitable for some but not all NETs patients, delivered by Nuclear Medicine departments. In the majority of cases, Lutate stabilises or improves disease that has previously been progressive, and some patients achieve remission. For NET cancer patients this is often the "golden drug", however, as it is not owned by a Pharmaceutical company and therefore not sponsored, it relies on government support for funding. Last year the NSW government approved funding for patients in NSW and this is hopefully what we will see rolled out in each state. If not patients will have to pay over \$30,000 for the typical four cycle treatment.

³ *Awareness of the Clinical Presentation and Diagnosis of Neuroendocrine Tumors (NETs) in an Australian General Physician Population* – John Leyden MB BS FANZCA

NET Cancer patients are now paying up to \$800 for what is considered the “gold standard” in early detection and monitoring of NET Cancers, PET Scans. PET is subsidised via Medicare for some cancers but not all including NET Cancers. A number of NET Cancer patients have faced the situation where the subsidised CT scan or Octreotide scan has not shown tumors that upon further investigation with a Gallium 68 PET Scan show more accurate tumor numbers and spread, or as our patients say “they lit up like a Christmas Tree”. These tumors were not visible in the subsidised scans impacting on the ultimate success of the NET Cancer patients prescribed treatment. Clinicians need access to the most accurate information to deliver the best outcomes for patients.

b. The operation of the Pharmaceutical Benefits Advisory Committee and the Pharmaceutical Benefits Scheme in relation to such drugs, including the impact of delays in the approvals process for Australian patients;

The aim of the PBS is to ensure Australian patients have equitable access to cancer drugs. Although recognised and respected globally, improvements to the PBS provision need to be made so that it can keep abreast with technological advances in cancer treatment and clinical practice. For patients with rare cancers whose market size is small and does not deliver the required economies of scale dictated by the PBS, getting access to drugs is an even greater challenge. There is little incentive for Pharmaceutical companies to invest in the expensive submission process to then have to negotiate on price and justify patient numbers. This means that drugs that may be effective in other cancer groups are not researched for effectiveness in rare cancers in clinical trials and the likelihood of failure at subsidy due to patient numbers. More incentive needs to be given to rectify this or alternative access models considered, especially when dealing with rare cancers. This will take the burden off unsustainable compassionate access programs that rare cancer patients and their clinicians often rely on.

Some examples and recommendations of **Innovative Access Models** are;

- Review and further development of a Managed Access Program for cancer drugs
- An Interim Access Scheme (using a similar model to the UK Cancer Drugs Fund, but learning from mistakes made) - this would only be an interim fund designed to bridge a set period of time required to undertake reform to the current PBS system
- Private Health Insurance reform – in which individuals have the option to protect against the high cost of medicines by paying for additional coverage
- Social Impact Bonds – they have the potential to improve results, overcome barriers to social innovation, and encourage investments in cost saving preventive services. They also provide the government a viable option for funding high cost drugs.

The Unicorn Foundation was involved in the Cancer Drugs Alliance (CDA) work stream looking at “*Innovative Access Models*” and support their recommendations.

Limited opportunity for consumer/consumer group input into the PBAC and MSAC process

This is an issue that was researched extensively last year through a survey commissioned by CDA (November 2014). A total of 17 representatives from 15 consumer organisations representing over 200,000 cancer patients took part in the survey. The key findings from the

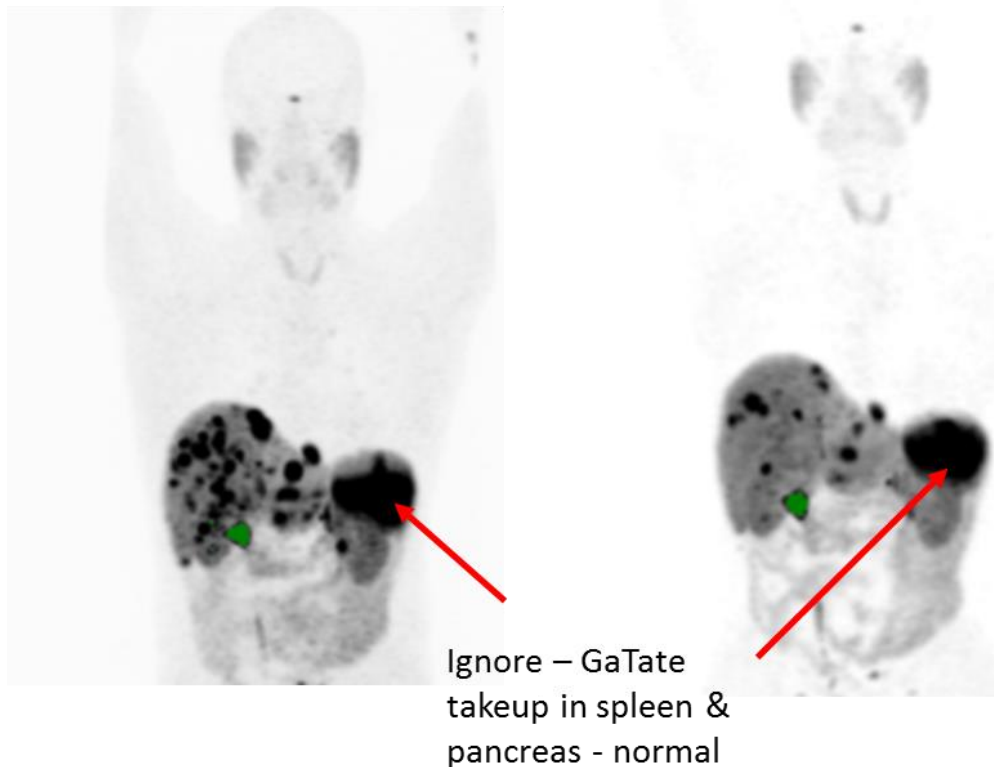
survey showed that individual patients and consumer organisations have an urgent need for significant changes to the way PBAC operates, makes decisions and involves consumers in the decision making process (from clinical trial development to listing of the drugs). The Unicorn Foundation participated in the survey and supports the recommendations which included:

- Greater communication with consumers and consumer groups (including through social media)
- Improved guidance on how to make submissions, how submissions are used and how decisions are made.
- Using different evaluation criteria for different cancers and diseases.
- Establishing a consumer sub-committee the PBAC can call on for information regarding specific conditions
- More frequent revisions to PBAC system and processes to accommodate medical advancements

c. The Impact on the quality of care available to cancer patients

This impact should be viewed as not only quality of care but also quality of life. In regards to the impact on quality of care for NET Cancer patients is the high cost of PET scans and the importance of regular PET Scans in ongoing treatment (unsubsidised), in addition to the PET scan at initial diagnosis (subsidised). Optimal treatment plans available are then provided to the patient as clinicians have the most accurate data available to them.

The impact of care is affected negatively when minimal options are available to patients, with little access new and relevant clinical trials available. We have seen robust and globally respected clinical trials fail to gain NHMRC funding despite positive recommendations from the assessors. This has lead our small charity to fund the CONTROL NETs clinical trial through the Australasian Gastro Intestinal Trials Group (AGITG) to the amount of \$200,000. We receive no government funding support and rely purely on fundraising. This study will positively affect close to 100 patients in the initial trial with the hope that data collected with lead to NHMRC funding opening the trial to more patients. If we did not support this trial what hope to our patients have?



August 2013

November 2014

PET scan of NET Cancer Patient after Peptide Receptor Radionuclide Therapy with Lutate (PRRT) – clear disease regression. Patient has started up his own business, is a loving husband and father to his teenage son and volunteers at the Unicorn Foundation.

The impact on quality of life is just as important. With cancer becoming a chronic disease and patients living longer due to the advancement in certain patient groups, quality of life and contribution to society is a factor that we feel should have greater importance in the PBAC process. On paper, a person living for an extra year at a cost of \$70,000-\$100,000 might not seem economical, however, in that time that person may have been able to continue to work, help their child through VCE or even start school, or walk their daughter down the aisle on her wedding day.

Drugs allow patients a better quality of life, so too do support services and resources. Limited, consistent and relevant information available to NET Cancer patients leads to a feeling of isolation and negatively impacts the success of their care. The Unicorn Foundation identified this as a huge problem and has provided NET Cancer patients with a world class website and resources as well as the first specialist NET Cancer Nurse Telephone and Internet Support service. This role is 100% funded through fundraising and receives up to 10 contact points per day. Referrals come from clinicians, cancer council helplines (as rare cancers are not understood as well as common cancers), the internet and word of mouth. It is a respected

and necessary service that has directly improved the quality of life of our NET Cancer patients and lifted the burden off the health care system. We beg the government to help us keep this vital service running.

I have used the service that Dale the Net nurse provides on many occasions. Just recently I had my first treatment of Lutate and she was very helpful to me during this time explaining that my reaction to it was a good sign. Explaining that it was a sign that the tumours had been hit hard by the treatment. She calls me back after I have a concern and has been a great support to me as a country patient.

Dorothy Knight NET Cancer Patient – Sydney NSW

Having a rare cancer is frightening beyond belief. I almost envied those with breast or bowel cancer - That's where the support and answers seem to be. Finding a NETS nurse who could help understand NET issues has been one of the most powerful experiences of my NETS years. Please, please support this position. Is one single nurse in our whole country too much to ask for? I hope not. Deborah

Burdett NET Cancer Patient – Camperdown NSW

d. Related Matters

We believe there also needs to be a discussion around how to change the research and clinical trial process and that one size does not fit all. This is especially the case for targeted cancer therapies for smaller groups of patients.

- NMRC should be more flexible when looking at trial design for rare cancers
- Greater consumer input in trial development
- Examine the case for a public interest facility which could sponsor drugs and technologies which are not of interest to industry – Lutate and PRRT.
- Few available registries and tissue banks
- Success of targeted therapies and research in rare cancer and the knock on affect for common cancers

About The Unicorn Foundation Australia

The Unicorn Foundation was formed in 2009 by Dr John Leyden (Chair and co-founder) and Simone Leyden (CEO and co-founder) due to the experience they had with their sister Kate's diagnosis with Pancreatic Neuroendocrine Cancer. The Foundation receives no government funding and is an independent medical not for profit directed towards improving the outcomes of patients with NET Cancers.

The mission of the Unicorn Foundation is; to assist and support patients and carers, through support groups and access to networks of expertise; to lobby for access to new and appropriate investigations and treatments; to raise awareness and knowledge of neuroendocrine cancers within the medical community and general public; to encourage and support Australian based research in the area of neuroendocrine cancers.

We once again thank the Senate for this much needed inquiry and welcome their report.

