much of it based at universities rather than hospitals. There are examples for acute care, primary care, emergency care, home care, medical device design, health IT, health systems design, architecture, simulation, education, and reliability. Studies have analysed systems of work, teamwork, decision making, displays, device interactions, risks, threats, performance shaping factors, environmental and organizational approaches, and regulatory influences.

One consequence of the lack of a professional approach to patient safety is that few opportunities exist in clinical settings for embedding qualified Human Factors professionals. Given that return-on-investment can be difficult to calculate, and effect on outcomes is difficult to measure in a non-linear system, a direct business case is still hard to make although the fact that Human Factors Specialists are integrated in the safety operations of all high-risk industries except healthcare should arguably be reason enough.

This has created a chicken-and-egg problem, where Human Factors professionals have not been employed in healthcare organizations, because there has been a limited understanding of what they can do, no clear and immediate application, no business case, and no clear evidence base. However, without embedded experience within healthcare organisations the application, evidence and business case will not be developed. Healthcare organizations need to know how they can employ Human Factors specialists and upskill key parts of the workforce who lack safety science knowledge and skills (e.g. patient safety advisors and quality improvement specialists) through accredited safety routes at comparative low cost.

The CIEHF have been working with Health Education England (HEE), Healthcare Safety Investigation Branch (HSIB), NHS England/Improvement, NHS Education for Scotland (NES), Academic Health Science Network (AHSN), Academy of Royal Medical Colleges, Royal College of Nursing (RCN) and others to create this innovative Learning Pathway. As we enter our first COVID winter, taking a professional approach to patient safety should be one of the highest priorities in the NHS to send strong reassurance to patients, families, staff and the public of the continuing importance of this issue. □

# MYELOMA, PRECISION MEDICINE AND GENOMIC MAPPING

Sarah McDonald - Director of Research, Myeloma UK

Myeloma UK is a patient focused charity, the only UK charity that deals exclusively with, the blood cancer, myeloma. We were established in 1997 and we have four central aims:

- Patients get a timely diagnosis
- They have the right treatment the right time
- They are supported, informed and empowered
- We fund research towards a cure.

On average 16 people in the UK are diagnosed with myeloma every day and we estimate that 24 thousand people are currently living with myeloma.

In the cancer world, myeloma is 18% of blood cancers and 2% of all cancers. This means myeloma is considered a less common cancer.

## THE CHALLENGES OF MYELOMA

Myeloma is a blood cancer arising from plasma cells, a type of cell found in the bone marrow. It's a remitting and relapsing cancer and at the moment, it's incurable.

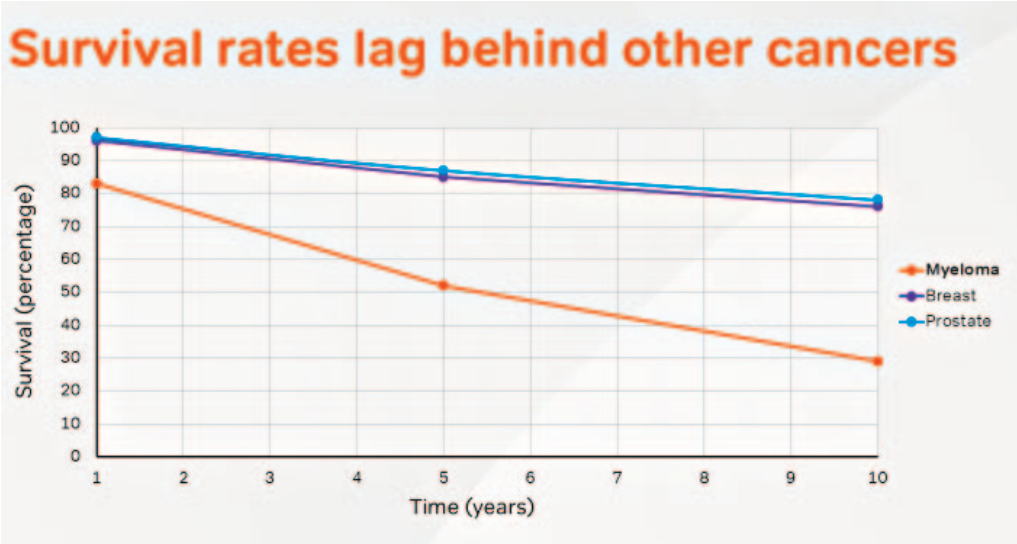
From a patient point of view, the biggest challenge about myeloma and usually the first thing patients experience is around diagnosis, and specifically late diagnosis. As a blood cancer myeloma isn't easy to detect, there isn't "a lump" and patients experience non-specific and vague symptoms like fatigue, a stiff back, or bone pain. At diagnosis, half of myeloma patients will have visited their GP three or more times. Around a third of patients are diagnosed via an emergency route presenting with serious complications caused by their myeloma such as kidney failure, bone fractures, spinal cord compression or severe infection. There is currently no screening programme for blood cancer and as a healthcare culture, the UK doesn't habitually take the blood tests which would pick up blood cancers earlier.

Myeloma is treatable but, sadly incurable. For patients finishing a course of chemotherapy, they don't worry if it will come back, they worry when it's coming back. Over the course of the disease, the time between remissions reduces and treatment side effects increase until the myeloma eventually becomes resistant to treatment.

Myeloma is heterogenous, every patient will have their own cell biology meaning patients may have different symptoms, respond differently to treatments and their myeloma grows at a different rate.

These challenges to diagnosis and treatment result in poor long-term survival rates.

The one-year survival for myeloma is 80% which is broadly in line with other cancers. However, the longer-term picture is bleak. with half of patients surviving for five years or more and only 30% surviving for at least ten years. This is where we get to the crux of the issue about rare disease, blood cancer in general and specifically myeloma, when compared to other cancers, we lag behind. We haven't had the long-term research investment leading to breakthroughs across the disease, we don't have effective awareness raising or a screening programme.




## GENOMIC MAPPING AND MYELOMA

Genomic mapping is incredibly important in understanding disease and treatment. It compares DNA in the cancer cell to DNA in the patient's normal cell; giving specific information about the genomic changes for that patient. By linking this genomic data to a patient's medical records, we can begin to tease apart the complex relationship between disease and genes. We have seen step changes in recent years in the field of genomic medicine, and we have the potential to identify the drug that would be most effective for a particular person or identify potential druggable targets for new treatments. This includes the launch of programmes like the 100,000 genome project which provided a huge amount of data, and the genomic medicine hub and spoke model, which aims to identify new treatments and consider appropriate trials for patients. In 2019, NHS England launched the National Genomic Test Directory commissioning several genomic tests as standard of care. Sadly, myeloma doesn't feature on the directory list, of the 978 approved tests for cancer, only 41 are for Blood Cancer and only one test linked to a precursor condition to myeloma. We know this is something patents want, they ask us how they can help, how can their sample be used for research?

There are some challenges with genomic medicine; firstly, there's critical mass, you need to collect lots of data so you have a statistically large enough sample. With 5,800 myeloma patients diagnosed annually, there would need to be a concerted effort or a global initiative to get the numbers.

Patients will also need to be reassured about what happens with their data and how their samples are stored. Whilst every cancer patient wants their sample to go into a study, it would need to be clear what that might mean. Media stories about data harvesting, what the information could be used for, will it affect their access to treatment and ultimately who will benefit, financially as well as scientifically need to be transparent.

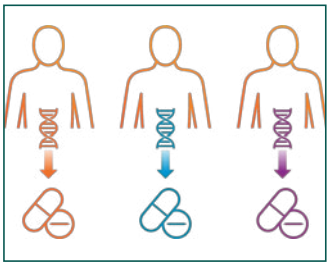
There are many organisations, such as Genomics England who have this infrastructure in place and there is a huge benefit to be part of the bigger picture. Patients, in fact anybody, could get a genetic screen themselves, we've all heard about 23 and me or similar programmes, where you send off saliva, or a cheek swab and get a report on your own genetic make-up have been available for some time. The challenge here is that testing done outside the healthcare system where an unprepared patient gets some information that they may not know what to do with it, or how it will affect them. There is a wider conversation about consent for tests, the associated counselling and how the results will be actioned and how patients are supported through any results from a standalone test, outside the healthcare system.

## PRECISION MEDICINE AND MYELOMA

Precision medicine for myeloma would be truly groundbreaking. Currently, myeloma patients and their clinicians have a defined and restricted choice of approved treatments, some of which are only available at certain points after patients have relapsed. Treatment decisions are based on; clinical data, patient preference and the overall health of the patient. For some patients, they will receive treatment, experience the side effects and have no real benefit.

If we routinely tested patients as a standard of care, where clinicians can select the treatments which are most likely to help patients based on the genetic profile of their disease, with an increased likelihood the treatment would work; this would benefit so many patients. They would live longer, have a better quality of life and both patients and clinicians would be more informed about treatment choices.

This would take us a step closer to a functional cure; being able to give a patient the right treatment in the right order could add years to their life, and reduce anxiety about "what next".



However, there are risks involved; some patients tested

may not have a specific tailored treatment option, there would need to be thought into how these patients are cared for, what treatment can be offered. A treatment may be profiled to work and it just doesn't, or the side effects are more severe than anticipated and this may be more devastating to the patient.

We must also consider that not all patients want to engage with their treatment or discuss their prognosis. Some patients want to know everything to help them feel in control, others only want to know things if and when they really need to. When implementing precision medicine, we must not forget the patient voice and their wishes and preferences. For some patients, the right treatment and care is not the most effective but the one that lets them live the life they want.

Myeloma patients are losing out twice as science progresses. Lower patient numbers mean myeloma patients aren't a priority in developing precision medicine or for inclusion in larger research driven clinical initiatives. This double blow means that not only is myeloma patient data not being routinely collected to provide more knowledge to drive drug discovery or diagnostic screening tests; they are also not included on programmes which might offer them more options, like the genomic medicine hubs. Issues around data use needs to be transparent and we simply need more research into leveraging the potential of genomic medicine for myeloma.

Genomic testing and precision medicine would be life changing for myeloma patients. Having biologically matched treatments could add years of good quality life and from the patient perspective, then can stop thinking about what will happen when their myeloma comes back and they would have hopeful futures. □

# TRANSLATING COVID-19 CHALLENGES INTO PRACTICAL GUIDANCE FOR THE FOOD SECTOR

Dr Rachel Ward
Scientific Policy Director at the Institute of Food Science and Technology who also works as a freelance food system risk management consultant.

**Institute of Food Science and Technology (IFST) is the UK's leading professional body for those involved in all aspects of food science and technology.**

**Our core aim is to promote the advancement and application of food science and technology for the benefit, safety and health of the public.**

Access to safe, nutritious and affordable food is critical to UK national security. In the current COVID-19 pandemic, food has not been identified as a likely source or route of transmission of the SARS-CoV-2 virus. However, the food system is being impacted both economically and socially, across the entire food chain, in relation to: human resources, such as changes in key personnel; supply chains of ingredients, packaging, finished products and equipment; sourcing as manufacturers may need to rely on alternative suppliers at short notice; and transportation of people, materials and goods. These wide-ranging impacts were, and still are, occurring concurrently with consumers buying additional food and other consumer goods and supplies through retail channels to cope with the pandemic and consequences of lockdown.

The resilience of the food system, and food business operators within it, and its capability to supply food to meet the needs of the UK population relies upon complex interdependencies and upon competent food technical professionals involved in keeping food systems operations working safely, even when at full capacity. The work and expertise of food technical professionals are especially of value when it comes to adapting successfully to changing circumstances without compromising quality or safety.

The publication by the FSA of the quantitative risk assessment relating to SARS-CoV-2 and food was well-timed and helped Food Business Operators (FBOs) to ensure they were taking the right steps to manage any potential food safety risks relating to COVID-19. The activities and reports issued by the Parliamentary Office of Science and Technology (POST) on