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Scotland and Precision Medicines – Why not lead?

"Why do we always have to follow? Why not lead? We should be learning by doing things. Let's lead by doing things – by making decisions to lead." – *An NHS head of service*

Clinicians, scientists, NHS leaders (managing laboratory, research and clinical teams) and patient advocates have highlighted increasing concern that Scotland is not delivering the care it could for patients:

- every time a companion diagnostic test for precision treatment is not available on the NHS, and
- every time patients cannot be identified for a clinical trial because tests have not been done.

The Scottish Precision Medicines Industry Group (SPMIG) has been formed by four pharmaceutical companies at the forefront of innovation in the area. The group is calling for Scotland to lead the way by making **a step change in strategy in genomic testing** to ensure Scotland can meet the growing opportunity for patients from a deepening understanding of molecular diagnostics and a growing number of precision medicine treatments.

It is a call echoed by patient advocates:

"There should be testing right at the start and then repeatedly thereafter, every time that you fail on a drug and your cancer progresses.

"If I had had that information at the beginning, I could have avoided the treatments I received that were never going to work. It would have saved me and the NHS a lot of money. It would have avoided false hope.

"If there is one request I would have of policymakers seeking to create a molecular diagnostic service for Scotland, and a strategy to go with it, it would be: please hurry up. We have the tools and knowledge to do much better for cancer patients, and to start to base their treatment more on the science and less on a 'fingers crossed', guesswork approach.

"Scotland as a small country could and should lead the way on this."

- *Lesley Stephen, a Scotland-based patient advocate, volunteer adviser to the National Cancer Research Institute, and trustee of Make 2nds Count*

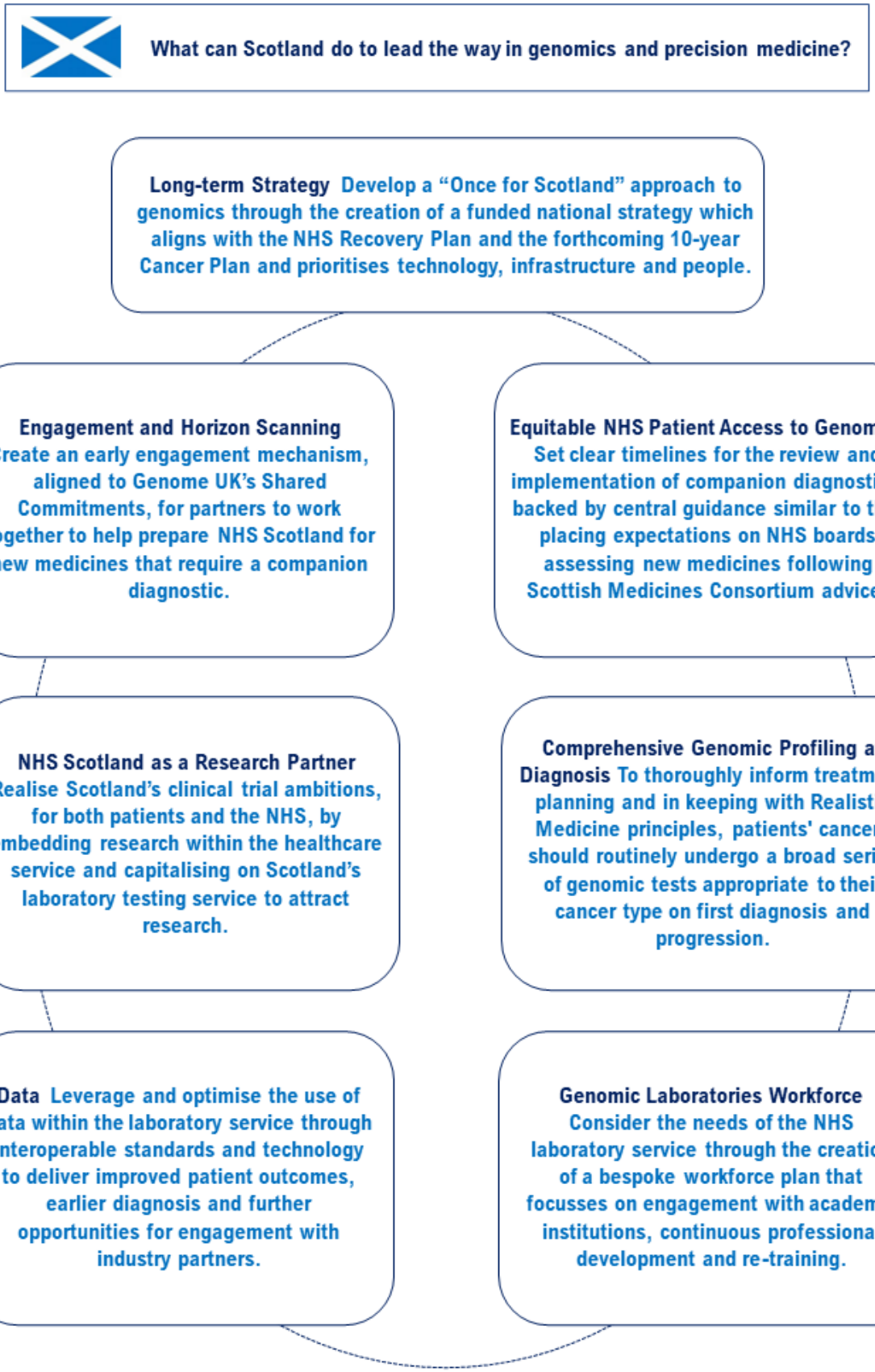
To realise the potential of precision medicines for patients, SPMIG says a new Once for Scotland strategy and delivery framework must:

- embed early comprehensive genomic testing as a routine standard of care in NHS treatment pathways;
- assume a right to, and accelerate equitable access to, precision treatments; and
- prioritise and fund both the data infrastructure and NHS genomic laboratory services Scotland needs.

The Scottish Government says it is committed to investing in a 'transformation' of Scotland's network of four specialist genomic laboratories.

These labs are currently under unprecedented pressure, while the processes to identify and commission companion diagnostic tests to coincide with new treatments being accepted into NHS Scotland are being described by one oncologist as 'broken'.

Based on in-depth interviews with 15 experts working in, or with lived experience of genomic medicine, this paper makes a series of recommendations, summarised here, to ensure Scotland can meet the opportunities from the rapid expansion of new precision treatments being developed for patients.


What can Scotland do to lead the way in genomics and precision medicine?
Long-term Strategy Develop a "Once for Scotland" approach to genomics through the creation of a funded national strategy which aligns with the NHS Recovery Plan and the forthcoming 10-year Cancer Plan and prioritises technology, infrastructure and people.
Engagement and Horizon Scanning Create an early engagement mechanism, aligned to Genome UK's Shared Commitments, for partners to work together to help prepare NHS Scotland for new medicines that require a companion diagnostic.
Equitable NHS Patient Access to Genomics Set clear timelines for the review and implementation of companion diagnostics, backed by central guidance similar to that placing expectations on NHS boards assessing new medicines following Scottish Medicines Consortium advice.
NHS Scotland as a Research Partner Realise Scotland's clinical trial ambitions, for both patients and the NHS, by embedding research within the healthcare service and capitalising on Scotland's laboratory testing service to attract research.
Comprehensive Genomic Profiling at Diagnosis To thoroughly inform treatment planning and in keeping with Realistic Medicine principles, patients' cancers should routinely undergo a broad series of genomic tests appropriate to their cancer type on first diagnosis and progression.
Data Leverage and optimise the use of data within the laboratory service through interoperable standards and technology to deliver improved patient outcomes, earlier diagnosis and further opportunities for engagement with industry partners.
Genomic Laboratories Workforce Consider the needs of the NHS laboratory service through the creation of a bespoke workforce plan that focusses on engagement with academic institutions, continuous professional development and re-training.

What we were told in our interviews

There needs to be **a Once for Scotland Precision Medicine strategy** to transform services and delivery

"The thing that is missing at the moment is a long-term strategy for the delivery of genomics for cancer and rare disease. With that we could start to make decisions about delivery, about which patients with which diseases will get whole exome sequences, and when."

A head of service

"None of us sees the full picture. We have to bring everyone together – industry, NHS, academia, government, the genomics laboratories, the cancer policy teams, the Chief Scientist Office – around the table to gather information so that we can look ahead three, five and 10 years to join the dots."

A head of service

"We don't have a national forum where we discuss things properly and coordinate a national approach, rather than the current university by university or NHS board by board approach."

An oncologist

Service pressures are preventing Scotland's genomic laboratory network realising its potential

"This service can be transformative in terms of healthcare." *A patient advocate*

However, the laboratories are under pressure, with **workforce** a particular area of concern:

"We owe it to these incredibly highly skilled people to make sure they don't work in silos. They need to know they are really part of the team. After all, you can't have next-generation cancer services without oncology and pathology, any more than you can have it without clinical science."

A head of service

Scotland is falling behind in access to precision treatments because too few tests are commissioned too late

One clinician and academic said there is a 'profound impact' where the tests they know they will require are not funded by the National Services Division (NSD) of NHS National Services Scotland. Currently **the pre-requisite companion diagnostic test may not be available in a Scottish lab when SMC publishes advice accepting a new treatment for use in NHS Scotland. This makes it impossible for an SMC-accepted medicine to be used.**

"We're behind other comparable nations. That's evident… both in patients who do not get routine testing and also with new drugs that have been licensed that have a molecular test that goes along with them, where, without the test, the patient misses the opportunity."

An oncologist

"When you get to the end of your pathway… access to clinical trials and research becomes of critical importance then because it could mean extra months to live and spend with your family. That is why it's so galling for a patient to be told, 'Sorry, you can't get access to this new drug because we can't do the appropriate genetic tests for you to receive it'."

A patient advocate

"A new patient lottery has opened up that depends on a patient's cancer."

A patient advocate

"The capability is considered in the process, but nobody considers building the capacity until the SMC say yes when, of course, it's too late. Building that capacity takes quite a long time. From a patient's perspective, it can be too long, too late." *An oncologist*

Patients in Scotland would benefit from a permissive policy on comprehensive genomic testing

Currently, when tests are not available in Scotland, patients here lose the opportunity to be enrolled in **clinical trials** for potential new precision medicines. There is the option of being sent to centres in England instead – but some cannot go.

A strong case was made for **comprehensive genomic profiling at diagnosis** – the tests being appropriate to the cancer type and delivered by any suitable technology – to inform optimal upfront treatment planning. This would be in line with the principles of Realistic Medicine and may actually save the NHS money.

"The ability to test upfront and find out what will actually work for an individual patient based on a profile of their cancer would enable us to have really powerful discussions – both between clinicians and with patients about what matters to them, what will work and what won't."

A head of service

"Currently, to my knowledge, there is nobody who is really focused on this from a pathway perspective, really setting out the costs and benefits to patients and the system as a whole. With this information we might make some very different strategic financing decisions."

A head of service

"It is clear that some patients have got inherent resistance to some of these expensive drugs that we give. If we were to do more comprehensive molecular testing, you might be able to pick that up early."

An oncologist

"A CT scan can cost up to £1000. Molecular tests cost less than that. You wouldn't consider giving a drug to a patient if you didn't know that their cancer was getting worse. You will also do a CT scan to see if a treatment is working. So, why would you not want to do a molecular test that would give you an idea whether the patient is likely to benefit from a really expensive drug?"

An oncologist

As we do more genomic testing, **we need the data systems and people** to harness the benefits of all the information collected to improve patient care.

"The catch is that research is not the primary driver in the NHS. We completely lack the infrastructure, for example, to recycle available data into studies." *A clinician*

Over time, **an integrated data platform** would offer unparalleled insights into genomic cause and effect:

"Just as we've learned many things in clinical practice over centuries, it's because we've recorded information and we followed people up. We can do the same with genomics. The risk is that we are going to get left behind again because we are slow to see the opportunities." *An oncologist*

Background and Context

The Scottish Government has recognised the important role of genomics in patient care, as set out in Cabinet Secretary for Health, Humza Yousaf's answer to a Parliamentary Question[1], and ministers have committed in their Programme for Government 2021-2022, in a chapter on *A Caring Society* (page 23[2]), to ensure availability of companion diagnostics by investing in genetic labs and frontline genetics services 'to embed genomics medicine into routine healthcare'. In this context, the Scottish Precision Medicines Industry Group commissioned specialist health policy and communications consultancy Ettrickburn Limited to gather the insights of a mix of stakeholders on the current state of play and the opportunities – and steps required – to build the best genomics service for Scotland.

Clinicians, scientists, NHS service leaders (managing laboratory, research and clinical teams) and patient advocates provided a snapshot of opinion on: policy; the relationships and understanding between different stakeholders; patient pathways; and sustainable workforce.

The Scottish Precision Medicines Industry Group is an informal interest group that brings together four pharmaceutical companies that are increasingly developing precision treatments for patients based on targeting particular genetic or molecular characteristics of their illness.

The companies are:

Under the ABPI Code, Novartis agreed to act as the lead company coordinating inspection and review of all materials, including this report, and certifying all questions and all outputs as being non promotional.

Several respondents chose to cite specific cancers, pathways and related diagnostics during this research, which had the potential to directly or indirectly identify particular prescription-only medicines.

SPMIG is governed by the ABPI Code and strictly adheres to the letter and spirit of all applicable laws and regulations on the appropriate and rational use of medicines. To ensure we do not inadvertently promote the use of any specific prescription-only medicine to the public, we have not included these examples.

[1] Parliamentary written answer 12 May 2022 https://www.parliament.scot/chamber-and-committees/debates-and-questions/questions/2022/04/22/s6w08163

[2] Programme for Government 2021 https://www.gov.scot/publications/fairer-greener-scotland-programme-government-2021-22/documents/ (page 23 third paragraph). Also presented as a pdf document at https://www.gov.scot/binaries/content/documents/govscot/publications/strategy-plan/2021/09/fairer-greener-scotland-programme-government-2021-22/documents/fairer-greener-scotland-programme-government-2021-22/fairer-greener-scotland-programme-government-2021-22/govscot%3Adocument/fairer-greener-scotland-programme-government-2021-22.pdf