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Llywodraeth Cymru
Welsh Government

Welsh Government
Consultation – summary of responses

Genomics for Precision Medicine Strategy

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Mae'r ddogfen yma hefyd ar gael yn Gymraeg.
This document is also available in Welsh.

Contents

1. Introduction

New genetic and genomic technologies are allowing us to develop a much more detailed understanding of the link between our genes and health. In recent years there has been international recognition that these technologies have the potential to revolutionise medicine and public health. The pace of change in this area is rapid and a clear strategy is needed to ensure that opportunities are not missed. The Genomics for Precision Medicine Strategy sets out the Welsh Government's plan to create a sustainable, internationally-competitive environment for genetics and genomics to improve health and healthcare provision for the people of Wales.

In its 2016-2021 strategic plan, 'Taking Wales Forward', the Welsh Government highlighted that it will place a focus on health at the heart of everything it does. It announced plans to increase investment in facilities and digital technologies to reduce waiting times and speed up the diagnosis of illness. It also announced plans to invest in training NHS staff and support good relations with industry in the interests of staff and patients. The Strategy will show how these plans will be fulfilled in the fields of genetics and genomics, supporting the delivery of precision medicine in NHS Wales. However, it is clear that patient benefits in this field will not be delivered by the NHS in isolation. Links to research and industry activities are more important than ever, and the wider ecosystem for genomics must be aligned to maximise health and economic benefits for Wales

In March 2016, the Welsh Government published a Statement of Intent (SoI) outlining the key principles that would underpin the development of a Genomics for Precision Medicine Strategy. The Taskforce consulted widely with stakeholders through a series of workshops, focus groups and 1:1 meetings, and feedback and comments from these meetings informed the development of the Strategy. The Strategy outlines the key initial actions, as part of a 5-10 year plan that will:

- Develop internationally-recognised medical and public health genomics services in Wales – that are innovative, responsive and well-connected to the major genetics and genomics initiatives that are evolving worldwide.
- Develop internationally-recognised research in genomics and excellent platforms for precision medicine, with All-Wales leadership and coordination and strong links to clinical genetics.
- Be outward-looking, and actively seek out partnerships that can strengthen genomics and precision medicine services and research in Wales, with a focus on those partnerships that will bring the biggest benefits for patients.

- Develop the NHS and research workforce in Wales, in recognition that this investment will have the biggest impact on our ability to realise the potential of genomics and precision medicine for patient benefit.

This 6 weeks consultation sought views on the draft Strategy which set out the Welsh Government’s plan to create a sustainable, internationally-competitive environment for genetics and genomics to improve health and healthcare provision for the people of Wales.

The consultation commenced on 12 April 2017 and closed on 24 May 2017. In total 47 responses were received. A list of respondents is at Annex A. A summary of the consultation responses, together with the Welsh Government’s response can be found in Section 2.

2. Summary of responses / Responses to questions

Overall the responses received supported the strategic approach and the stated priorities for action. There was considerable enthusiasm

Question 1 - The Strategy outlines five key areas for action:

- **Co-production - working with patients and the public in genomics**
- **Clinical and laboratory genetic services**
- **Research and Innovation**
- **Workforce**
- **Strategic Partnerships**

Do you feel that additional areas for action should be included?

Yes	No	Partly	No answer
8	21	14	4
17%	45%	30%	8%

Comments: Information Technology

Many respondents commented that IT is an enabler for the Genomics for Precision Medicine Strategy, and the success of the Strategy will depend on the development of IT capabilities to support the safe and secure integration and sharing of genomic data.

Welsh Government Response

The Welsh Government has a Digital Health and Social Care Strategy and is working with NHS Wales Informatics Service to deliver interoperable IT systems on a ‘once for Wales’ basis and engage with the public regarding patient data usage in line with Caldicott 3 recommendations¹. There will be cross talk between the Digital Strategy

¹ <http://gov.wales/docs/dhss/publications/151215reporten.pdf>

and the Genomics for Precision Medicine Strategy implementation groups. The Genomics for Precision Medicine Strategy recognises the need for an increase in bioinformatics and high capacity data storage/processing. The Genomics Taskforce will work with NHS Wales Informatics Service and external partners (e.g. Super Computing Wales) to ensure that all relevant IT and data science aspects are included.

Comments: Workforce

Respondents commented that the Workforce section should be replaced by 'Education and Training', and questioned if there could be more emphasis on the multi-organisational nature of healthcare science roles. It was also commented that the Directors of Therapies and Healthcare Science will support the delivery of the strategy by ensuring the right numbers of appropriately trained healthcare scientists are available. Additionally, Brexit effects on the workforce should be considered.

Welsh Government Response

The workforce section of the Strategy includes education and training. The Taskforce will work with Workforce, Health Education Wales and Workforce Education and Development, Directors of Therapies and Health Sciences to ensure there is a coordinated response to needs of genomics. Furthermore, a Healthcare Science Workforce Strategy is in development and this will also take into account the needs of genomics in NHS Wales. The taskforce will work with partners and relevant work programmes within Welsh Government to consider the impact of Brexit on the workforce.

Comments: Strategic Partnerships

Respondents commented that the strategy should be expanded to include consumer and partners (genome technology, biotechnology, pharmaceutical and other industrial collaborators). The voluntary sector should also be considered.

Welsh Government Response

The list of organisations listed in the action for strategic partnerships is non-exhaustive; consideration for partnerships extending beyond the list will be included in the strategy.

Comments: High through put molecular diagnostics ('omics) and advanced therapies

Several respondents commented that the Strategy does not adequately capture epigenetics, cellular, immune or other therapeutic areas which have cross-over with genomics. It was noted that emerging cellular therapies require Next Generation Sequencing.

Welsh Government Response

The major focus of this Strategy is the development of genomics capabilities to underpin precision medicine. This is because genomic technologies are becoming increasingly affordable and already having an impact on precision medicine and the management of infectious diseases. In order to act quickly and ensure that Wales

keeps pace with developments, it has been necessary to maintain a focus on genomics.

Broader high throughput technologies and subject areas e.g. metabolomics, epigenetics, micro-arrays and proteomics are not covered in the Genomics Strategy, however, there is scope for a future strategy in this area. WG are working with the Welsh Blood Service to deliver a parallel strategy called 'Advanced Therapeutics for Precision Medicine' and this will cover regenerative medicine, gene editing and immunotherapy.

Comments: Communication:

It was also commented that clarity and clear definitions were needed for genetics, cancer genomics and regenerative medicine, with need for further communication and education strategies.

Welsh Government Response

The development of a communications strategy is outlined as part of the the Strategic Partnerships section of the Strategy. The text has been modified to more explicitly outline that this work will be developed in co-production with the public.

Comments: Research and Innovation

Respondents commented that thought needs to be given to possibilities to integrate genomics with other innovative tools (remote sensors, precision imaging, biosensors). There is a need to improve clinical trials research infrastructure.

Welsh Government Response

There are wider programmes that WG use in order to explore, support and fund these types of innovations (e.g. Efficiency through Technology Fund). Where relevant, the Genomics Taskforce will work to build links between funded programmes and the genomics strategy.

Comments: Clinical and Laboratory Services:

One respondent commented that there is a need for the Strategy to encompass the public health aspects of genomics and microbiology and epigenetics. Another commented that it was important to consider the integration of laboratory genetics with other pathology disciplines. Respondents also noted that there is a need for a greater focus on the clinical service in the Strategy, with a commitment to commission the clinical service on an All Wales basis.

Welsh Government Response

The Genomics Taskforce are working closely with Public Health Wales to integrate public health and health protection into the Strategy (e.g. by including infection control and outbreak mapping through sequencing of pathogens). Members of the Taskforce are also working with National Pathology Groups to ensure cross talk and collaboration between disciplines, particularly where there are convergent diagnostic pathways (e.g. histopathology/genomics). Considerable attention has been paid to clinical services for patients in the Strategy, and the commitment to support and develop the component has been highlighted in the strategy. The Strategy also

recognises that there are short, medium and long term requirements which may shift and change overtime, a dynamic approach will therefore be adopted, and this has been made more explicit in the text.

Comments: Finance

Respondents commented that it will be important to explore flexible pricing models with industry.

Welsh Government Response:

The Taskforce will explore pricing models and industrial links in the next stage of the work. We will also try to develop better metrics in order for us to measure the benefit of the service for patients and financial impact on the NHS.

Question 2. Within each key area, we have identified a number of proposed key actions. Do you feel these are the right ones? Please tick the appropriate box below:

Yes	No	Partly	No answer
21	2	17	7
45%	4%	36%	15%

Comments: Co-production

Respondents commented that the Strategy should recognise the importance of co-production for service delivery as well as service development, and noted that there needs to be greater clarity about how patients are involved in the Strategy. Additionally, it was proposed that the Strategy makes a clear commitment to dynamic consent when gathering data to identify the genetic and genomic cause of diseases, following on from the publication of the Genetic Alliance UK Patient charter.

Welsh Government Response

Co-production is a vital element of the Strategy; a patient and public representative sat on the Genomics Taskforce and the public, patients and patient interest groups were consulted at an early stage in the development of the Strategy. The Strategy recognises the importance of co-production to drive service developments and delivery and now references the Genetic Alliance UK Patient Charter.

Comments: Clinical and laboratory services

Several respondents again commented that clinical genetics and genetic counselling will be key to the genomics Strategy. One respondent noted that there is a need to describe and apply a flexible approach to incidental findings from genomic analysis, and another commented that the Strategy should acknowledge the need to determine the approach for clinically relevant incidental findings.

Some respondents highlighted the importance of developing a governance framework for genomics technologies, and this should be developed together with

the Directors of Health Therapies and Healthcare Science, and in parallel with the Strategy. There should also be a transparent framework developed for consent.

Several respondents noted the need to consider All Wales solutions that support strong IT and estates solutions and incorporate the needs of smaller teams working in the periphery and North / South Wales. There is a need to involve wider clinical specialties in developing the Strategy and ensure that the genetics service is appropriately linked to pathology and other diagnostics.

Welsh Government Response

The ambition of the strategy is to support the development of high quality integrated Genomic services for all of Wales which includes clinical services, such as genetic counselling, for all Welsh NHS patients and this has now been made more explicit in the Strategy text. A Quality Assurance/Governance framework will be developed in parallel and this will include the interrelationships between the Service hosts and those that use the Service. The short and long term future of Genomics Services will be considered by the Taskforce, this will include location of Services. Laboratory Information Management System specifications that enable sharing of information for clinical purposes (e.g. oncology) across Services (e.g. histopathology and genomics) will be considered by the Taskforce and also in National Pathology Programmes that lead on the re-procurement of the Welsh Laboratory Information Management System. The Strategy highlights that a flexible approach will be taken for incidental findings.

Comments: Research and Innovation

Respondents commented that it is essential that there is close working between Welsh Government and the medical research sector to deliver enhanced horizon-scanning practices. It was also noted that there may be a need to re-engineer or withdraw existing clinical pathways for disruptive genomic technologies. Health technology Wales and CEDAR, working with WHSSC, both have a role to play.

One respondent commented that research access to clinical samples should include clinical data for maximal value, and another noted that it will be important to support the emergence of new techniques, such as liquid biopsy. Another respondent proposed systematic collection and analysis of the quality, activity and performance of molecular testing in NHS Wales.

Welsh Government Response

Members of the Taskforce work closely with other related groups and organisations that are mandated to drive forward healthcare innovation or assess new healthcare technology. The interoperability between these stakeholders is an important element of the strategic partnership working. The Genomics Strategy also brings together clinical service providers and academic partners to create a critical mass where best practise and new innovations can be shared and new ideas, policies and research developed.

The All Wales Medical Genetics Service has a long history of working with research groups in and beyond Wales to support the translation of research through to new /

improved services in NHS Wales. This work will continue to be supported through the Strategy.

Comments: Workforce

Respondents commented that there is a need to build skills in genomic data handling and analysis and ensure that genomics is a core part of curricula. Partnership working, for example with health professional bodies and higher education institutions, will be key to underpinning this work. Respondents also noted that genomic literacy should be developed as a priority and it will be important to consult other specialties beyond medical genetics in developing the workforce programme.

It was also commented that training alone is not sufficient for non-genetic professionals; there is a need to engender an understanding of the benefits genomics can bring.

Welsh Government Response

A parallel 10 year Healthcare Science Workforce Strategy will also consider educational and training needs and there will be interoperability between both strategies to support the work of Health Education Wales in meeting the future needs of Genomics in Wales. Additionally, the Taskforce will work with health professionals and Higher Education Institutions in Wales to deliver the workforce element of the Strategy.

Comments: Strategic partnerships

Respondents commented on the need for the genomics taskforce to engage with Supercomputing Wales project and work cooperatively with industry, AWMSG, NICE to ensure there is joined-up thinking around the appraisal of new innovative treatments. It was also noted that there are opportunities afforded by the commercialisation of diagnostics across microbiology and genetics and there is a need for transparency in the formation of strategic partnerships.

Welsh Government Response

The Taskforce will engage with Supercomputing Cardiff (a subsidiary of Supercomputing Wales) and also develop strategic partnerships with a wide range of organisations, such as those listed above in an open and transparent manner.

Question 3 - In the Strategy, we outline a number of actions under ‘Clinical and laboratory genetic services’ to underpin the provision of genomics technologies for improved clinical services and care. What do you think are the key challenges / barriers to the provision of high quality, innovative genetics services in Wales? How might these be overcome?

Clinical and Laboratory Genetic Services

Priority 1 – Hosting and commissioning of All Wales Medical Genetics Services

Comments

One respondent commented that insufficient evidence was presented in the strategy to support the clinical case for genomics technologies, and it is important to demonstrate that use of these technologies leads to improved patient outcomes. Another respondent commented that it will be important to establish what evidence of clinical benefit is required from a small patient sample who may live longer as a result of having a more effective treatment at the right time, and it is important to establish a mechanism for determining the overall cost to the NHS.

It was noted that the Genetics Service needs appropriate resourcing to deliver the Strategy. Two respondents commented that the Welsh Government should consider commissioning and funding an initial six molecular diagnostic tests and reimbursing the costs of new tests approved as part of a NICE Technical Appraisal or an approved commissioning policy, as recently approved in NHS England.

One respondent queried if WHSSC adequately represents service users. Another commented that commissioning of genetics services needs agreement from Local Health Boards in Wales. Respondents noted the need for flexibility and horizon scanning to be able to implement new technologies and treatments as soon as they are available. One respondent reiterated the need to focus on North in addition to South Wales to support the recruitment of highly qualified staff across Wales. Additionally, there is a need to develop an integrated service specification, incorporating Local Health Boards, Trusts and Higher Education Institutions.

Welsh Government Response

Every effort will be made to ensure that the best practise guidance and evidence based approaches are applied to clinical and laboratory service development. In the Strategy we have added references to sources of evidence for the use of genomics in microbiology and public health. We have also added lines to clarify that new genetic or genomic tests will undergo full appraisal for clinical utility prior to introduction into NHS Wales, working with the National Institute for Health and Care Excellence and the UK Genetic Testing Network. The initial six molecular diagnostic tests will be supported through the Strategy. The Taskforce will work with health economists, NICE and the All Wales Medicines Strategy Group to evaluate the costs to the NHS.

Health Technology Wales (HTW) is a new development in Wales that will be able to undertake health technology assessments and evidence base reviews when there is an agreed requirement. AWMGS will develop links with HTW to ensure a sound working arrangement is developed. The formation and further strengthening of strategic partnerships is an integral component of the strategy as is working with Genomics England and other national partners to ensure that the most up-to-date and evidence based genomics approaches are delivered for all of Wales.

WHSSC will retain the specialist commissioning model for AWMGS. Welsh Government will work with NHS Wales to support full engagement with LHBs and NHS Trusts to deliver the Strategy.

Priority 2 – IT Infrastructure requirements:

Comments:

Respondents reiterated the need for robust IT to underpin the Strategy and commented that databases would need to interface with the NHS Wales Laboratory Information Management System (LIMS).

Likewise, the integration of genomics with clinical records systems was felt to be critical and a clear alignment with NHS Wales digital strategy is key. Additionally, Respondents commented that IT / bioinformatics support would also be important for the Wales Genomics Medicine Centre, and cooperation between diagnostic and research fields will be crucial.

Welsh Government Response

The Taskforce will work with NHS Wales Informatics Service and external partners such as Supercomputing Cardiff and the Office for National Statistics Data Science Campus to develop robust IT services. Work will also be undertaken to ensure that NHS Wales has sufficient bioinformaticians and access to training and development opportunities in genomic computer science.

Priority 3 – Estates requirements:

Comments:

Several respondents commented that there was a need to develop and expand estates for the genetics service, with some noting that this also needs to incorporate wider service developments (such as Welsh Blood Service, Public Health Wales, pharmaceutical and pathology services). There needs to be investment in facilities, equipment, staff and transport networks and an early development of an integrated service specification (including Local Health Boards, Trusts and Higher Education Institutions).

Barrier were perceived to be the tendencies of heads of services to empire build, and the “why always Cardiff” attitude. One respondent commented that the Strategy should consider if multiple or central laboratory estates would be optimal, whereas others commented that a single, centralised clinical and lab service would be an advantage.

Welsh Government Response

The short and long term needs of Genomics services in Wales will be explored in the next phase of the work, with recommendations made for Welsh Ministers. Work is also ongoing to modernise pathology services in Wales, synergies and areas where convergence or cross linking may be beneficial will be explored (e.g. pathology/genomics laboratory results information). Genomic service requirements beyond NHS Wales (e.g. veterinary, agricultural, academic) will also be considered.

The Taskforce will continue to work with and engage with Health Boards and Trusts across Wales to support the development of genomics solutions for the whole of Wales.

Priority 4 – Provision of clinical services

One respondent commented that the Wales Genomic Medicine Centre should be hub-and-spoke, with a clinical team supported by bioinformatics, lab and IT. The potential for creative disruption of services through the Genomic Medicine Centre was also noted. One respondent agreed that genomic MDTs will be required, and another requested more detail about proposals for MDTs.

It was commented that the boundary between clinical practice and research can blur, and overlap, at the point where new conditions are being identified as part of the diagnostic pathway. It is important to consider that patients and families are sometimes only interested in diagnosis, and research activities are more covert.

It was commented that liaison between the laboratory services and clinical service is essential in the interpretation of genomic results and the Strategy will need to take into account the core business of laboratory and clinical genetic services.

Again respondents noted the potential for interfacing genetics services with the Welsh Blood Service, pathology programmes and public health Wales, and noted the importance of embracing all stakeholders early on in development. Collaborations with Public Health Wales could link human genetics and microbiology genetics to enable the study of host-pathogen interactions.

Respondents commented that sufficient resources and investment would be required to deliver the strategy, and the All Wales Medical Genetics Service needs to be able to reinvest its income into the provision of new services and developments. Several respondents noted the need to develop flexible and novel pricing streams to pay for technologies.

Respondents commented on the need for the genetics service to adapt quickly, provide training and staff time for innovation in order to attract high quality staff. It was commented that healthcare scientists have significant role to play in innovation, and also the roles of clinical geneticists and genetic counsellors will need to evolve to encompass new ways of working. It was also noted there there is a need for democratisation in genomics, to enable other specialties to deliver genomic services. One respondent noted that clinical Geneticists will continue to play a key role in the diagnosis and management of multisystem genetic disorders, but it will be the focus of other disciplines to manage an individual's day-to-day care.

Welsh Government Response

The strategy recognises the needs to work within multidisciplinary teams across Wales in order mainstream the benefits of genomic technology into the service and ensure that robust clinical pathways for patients are strengthened and developed. The strategy recognises the need to strengthen and develop clinical services in parallel with the laboratory services so that the patient pathway for genomics is seamlessly integrated into NHS Wales.

The strategy describes the need to work with other NHS Service providers such as Welsh Transplant and Immunogenetics Laboratory and bone marrow registry. A parallel strategy on Advanced Therapeutics for Precision Medicine is underway in

Wales and there will be linkage between the two to ensure that they both support the precision medicine agenda in Wales in a collaborative and coordinated manner. We recognise the opportunities which can arise from aligning human and pathogen genomics, and the Taskforce will look to identify and act on opportunities to share resources and opportunities for learning via close working between the All Wales Medical Genetics Service and Public Health Wales.

The strategy provides an opportunity to bring together different services into a single nationally coordinated centre for genomics. A coordinated approach to planning future services in order to support the development of Local Health Board Integrated Medium Term Plans (IMTP) in a timely manner will be undertaken.

Workforce is a mainstay of the strategy and there are clearly expressed ambitions to further strengthen and develop the workforce so that genomics can grow and mainstream into NHS Wales. Similarly Research and Innovation and developing strategic relationships with academia and industry is clearly described and supported elsewhere in the strategy.

Question 4 - The document outlines our approach for working with partners to deliver the Strategy. What do you think are the key barriers to progress in this area? Which strategic partnerships do you think should be prioritised, and why?

Priority 1 - A business strategy

Respondents commented that there is a need for better visibility for genomics in Wales and high-level leadership to bring together key stakeholders. It was commented that financial modelling must recognise that continued and predictable investment in both capital and revenue will be needed to develop internationally-recognised and competitive clinical and laboratory genomics services.

It was also suggested that a financial risk sharing agreement be developed, covering the complex multi organisational / multi sectoral Genomic Medicine Centre and its associated workforce, estates and equipment and IT infrastructure.

One respondent commented that competition and co-production cannot co-exist.

Welsh Government Response

We agree that there is a need or better visibility for genomics in Wales, and our intention is that the business strategy will provide a framework to support this. We will work to ensure this has strong leadership. The Strategy provides medium term (five years) support to develop genomics capabilities in Wales, however, the taskforce will work to identify the longer-term requirements for genomics as the implementation develops. This will include consideration of the longer-term requirement and funding of the Wales Genomic Medicine Centre.

Co-production is central to the Prudent Healthcare Principles, and our intention is to ensure that these principles are adhered to in the genomic strategy.

Priority 2 - A Framework Agreement for Industry Engagement

Several respondents highlighted that there will be a need for transparency and clear, early communication of the benefits of industry partnerships with patients and the public. In particular, data sharing, data anonymisation and patient confidentiality will be a significant consideration.

Respondents also noted that it will be important to remove barriers to working across organisations.

Welsh Government Response

We are committed to working with patients and the public in the implementation of the Strategy. The action on co-production will include work with patients and the public to support the development of an open and transparent approach for data sharing, anonymisation and confidentiality, and this will link with, and inform, the development of strategic partnerships.

Priority 3 – Strategic coordination

Respondents commented that there are already good examples of partnership working between NHS Wales and Welsh Higher Education Institutions in this space, however, the appointment of a lead organisation for strategic partnerships is a positive move.

It was commented that the All Wales Medical Genetics Service needs to be able to maintain links with charitable and industry partnerships as well as UK, European and worldwide genomic research and development initiatives. However, one respondent queried if there is sufficient capacity in the service to absorb this additional work.

Many respondents that strategic partnerships should cover a broad range of partners to stimulate truly strategic partnership working. Managing multiple and board relationships will be key and there is a need to conduct capability analysis and mapping and have better understanding of the partner ecosystem.

One respondent commented that partnerships with companies that have a focus on streamlining services should be prioritised, whilst another suggested that software development is a key gap that Wales could look to address. One respondent noted that there is a need to develop partnerships with companies earlier in the development of new diagnostics.

One respondent commented that the Individual patient Funding Request process has led to a lack of trust between clinicians, patients with Duchenne Muscular Dystrophy and Welsh Government. There is a need for greater transparency in the process, particularly regarding exceptionality.

It was also commented that the Directors of Therapies and Health Sciences will work proactively with the All Wales Medical Genetics Service to ensure that the right numbers of appropriately trained healthcare scientists are available to support this

work whilst simultaneously retaining the highest standards of clinical and ethical governance.

Welsh Government Response

In the first year of implementation, the Welsh Government and genomics taskforce are committed to working with a wide range of partners to identify an organisation to lead on the strategic partnerships workstream. Resources have been earmarked to fund this work. We welcome the offer of insight and support and look forward to working with a broad range of partners to develop the work plan for strategic partnerships.

The Welsh Government held an independent review of the IPFR process and published a report in January 2017. The IPFR guidance for clinicians and IPFR panels has been updated to remove the exceptionality criterion, and this new guidance has been in use since June 2017.

Question 5 - We would like to know your views on the effects that the Genomics for Precision Medicine Strategy would have on the Welsh language, specifically on

i) opportunities for people to use Welsh and

ii) on treating the Welsh language no less favourably than English.

What effects do you think there would be? How could any positive effects be increased, or negative effects be mitigated?

Comments:

Respondents commented that Welsh should be as equally available as any other language in a modern Wales. Welsh speakers need to be given fair opportunities to take part, be this in accessing, interacting and developing services or through involvement, participation or engagement in clinical research. Healthcare documents, patient information sheets (and information more generally) should be available in the language of preferred choice. Additionally, patients should have access to counselling and receive reports in their preferred language. It was commented that appropriate training and resources are needed to encourage staff to learn Welsh and for Welsh speakers to deliver services in the patient's preferred language.

Welsh Government Response

The Genomics for Precision Medicine Strategy and accompanying written statement have been published in Welsh and English. The Genomics Taskforce will work with the All Wales Medical Genetics Service to support them in the development of services which are accessible to all patients, regardless of their language of choice.

Within the strategy we will encourage researchers in genomics to work with the Language Awareness Infrastructure Support (LLAIS) service, funded by Welsh Government via Health and Care Research Wales, to facilitate trial participation through the medium of Welsh wherever relevant.

LLAIS guides researchers with timely advice on embedding language awareness within key stages of the research process, including study design, sampling, recruitment, consent, data collection, administration of health measures, data analysis, report and dissemination.

Additionally, The Wales Genomic Medicine Centre will ensure that patients are able to be recruited to the 100,000 Genomes Project regardless of their language of choice. This means that patient information leaflets and generic counselling services will be available in Welsh and other languages.

Question 6 - Please also explain how you believe the Genomics for Precision Medicine Strategy could be formulated or changed so as to have

i) positive effects or increased positive effects on opportunities for people to use the Welsh language and on treating the Welsh language no less favourably than the English language, and

ii) no adverse effects on opportunities for people to use the Welsh language and on treating the Welsh language no less favourably than the English language.

Comments in response to question 6 largely duplicated the comments provided in Question 5. Additionally, respondents commented that locating the genetics laboratory outside south east Wales might improve Welsh language involvement. It was also noted that the most important consideration is that a clear and simple explanation of results is provided to all patients, and the language in which it is delivered is a secondary concern.

Welsh Government Response

As above in response to Question 5.

Question 7

Many respondents reiterated their broad support for the Strategy. However, some requested further information on the timescales for implementation and the budget allocated for the Strategy. Additionally, it was commented that the Strategy needs a form of evaluation, to determine if the proposed actions are having a meaningful impact on patient care. Furthermore, some respondents noted the need for high level, highly qualified leadership and accountability for the Strategy.

It was also commented that precision medicine does not always require high technologies, but requires healthcare staff to have sufficient time to engage with patients to gain a fuller understanding of their condition. Additionally, clinicians require more time for training, and one respondent felt that training should be provided to better understand and analyse the range of possible patient outcomes to support patients in making the best decisions regarding their care.

One respondent also commented that ethical constraints on the plan are ignored, in regard to sharing patient identifiable data. Another commented that the Research and Impact section was highly focused on laboratory-based genomics expertise, and noted that there is excellent work undertaken in Wales on the broader ethical, legal,

social and workforce implications of genomics – for example, at the Genomics Policy Unit at the University of South Wales.

Some respondents commented that Wales needs to ensure strong links are maintained with other UK organisations and services, for example NHS England and NICE. It was also commented that medical research charities play an important role as an honest broker between Government, NHS, patients and the Public. Another respondent commented that the Strategy needs to recognise impact that professional bodies such as the Clinical Genetics Society (CGS) and the Association of Genetic Nurses & Counsellors (AGNC) have had.

Welsh Government Response

The strategy now includes an indicative set of timelines and budget for the work. Additionally, an evaluation strategy will be developed to run alongside the strategy. A set of process, output and outcome indicators will be developed, and this work will be conducted in partnership with members of the public, patients and clinicians.

The sharing and use of patient data is an important element of the strategy and will be considered alongside other Welsh Government programmes regarding the use of patient data. This work will consider the important ethical, legal and social considerations of genomic data and be conducted openly and transparently with the public.

Working with stakeholders both in Wales and nationally is vitally important in order to progress the national strategy. This is recognised in the Strategic Partnerships chapter, which outlines how we will work with a wide range of organisations. The AWMGS will continue to work with NHS England and UK partners in the provision of genetic and genomic services.

We recognise the impact that professional groups such as Clinical Genetics Society (CGS) and the Association of Genetic Nurses & Counsellors (AGNC) and we are keen to learn from them during the implementation of the Strategy. We are also aware of the excellent work of the Genomics Policy Unit at the University of South Wales and this is now recognised in the Research and Innovation section of the Strategy. We welcome the offer of support from our partners both in the NHS and externally and we welcome the opportunity to work with you on the exciting new development in Wales.

3. Next steps

A steering group will be established to develop a more detailed implementation plan. The group will regularly monitor progress and publish annual reports against key actions highlighted in the Strategy.

The Strategy outlines the initial steps necessary to develop the genomics for precision medicine infrastructure in Wales and lays the foundations for the routine application of genomic technologies to support precision medicine approaches in Wales. In doing this, it enables patients and the public of Wales to benefit from better

healthcare and underpins a bright future for the application of cutting-edge genomic technologies in NHS Wales.

Annex 1: List of respondents

No	Name	Organisation
1	Anonymous	N/A
2	Dhavendra Kumar	The Genomic Medicine Foundation
3	Mark Temple	N/A
4	Anna Evans	Cystic Fibrosis Trust
5	Dr Cath O'Brian	Welsh Blood Service
6	Emma Thomas	British In Vitro Diagnostics Association
7	Jane Coppard	Roche Diagnostics
8	Mark Donovan	Atos
9	Cerys Jones	North Wales Community Health Council
10	Anonymous	N/A
11	Joanne Ferris	ABPI Cymru wales
12	Anonymous	N/A
13	Lowri Jackson	Royal Collage of Physicians Wales
14	Philippa Brice	PHG Foundation
15	Adam Jones	Public Health Wales NHS Trust
16	Stephen Hoffmann	Action Duchene
17	Kirsty Henderson	Cancer Research UK
18	Anonymous	N/A
19	Dr Emma Tonkin	Genomics Policy Unit, University of South Wales
20	Elen Jones	Royal Pharmaceutical Society
21	Chris Coslett	Welsh Health Specialised Services Committee
22	Craig Rhodes	Intel Health and Life Sciences
23	Andrew Senior	Institute of Medical Genetics, University Hospital of Wales
24	Anonymous	N/A
25	Anonymous	N/A
26	Anonymous	N/A
27	Anonymous	N/A
28	Anonymous	N/A
29	Anonymous	N/A
30	Anonymous	N/A
31	Anonymous	N/A
32	Richard Ebley	N/A
33	Anonymous	N/A
34	Anonymous	N/A
35	Anonymous	N/A
36	Andrea Edwards	All Wales Medical Genetic Service, University Hospital of Wales
37	Anonymous	N/A
38	Anonymous	N/A
39	Rachel Butler	All Wales Genetics Laboratory
40	Anonymous	N/A
41	Clive Morgan	Director of Therapies and Health Science on

		behalf of Cardiff and Vale University Health Board
42	Clive Morgan	On behalf of NHS Wales Director of Therapies and Health Science Peer Group
43	Jonny Savage	Prostate Cancer UK
44	Rhianedd Ellwood-Thompson	Institute of Medical Genetics, University Hospital of Wales
45	Caroline Pottinger	AWMGS (North Wales)
46	Anonymous	N/A
47	Jayne Spink	Genetic Alliance UK