Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

National Strategy for Accelerating Genetic and Genomic Medicine in Ireland

Minutes of Implementation Steering Group for Genetics and Genomics Meeting 003			
Date	21/09/23	**Time**	**13:30 - 15:00**
Location	MS Teams		
Attendees			
Dr Colm Henry (CH)		Dr Mark Bale (MB)	
Dr Richard Hagan (RH)		Eilish Hardiman (EH)	
Valerie Walshe (VW)		Oonagh Ward (OW)	
Triona McCarthy (alternate)		Ailish Kelly (AK)	
Aisling Cusack (AC)		Pauline Sargent (PS)	
Leah Dowdall (LD)		Margaret Cuddigan (MC)	
Christopher Ryan (CR)		Hannah Fox (HF)	
Maeve Smith (MS)		Claire McGeeney (CMcG)	
Apologies			
Prof Eileen Treacy (ET)		Martina Burns (MBs)	
Prof Risteárd Ó Laoide (ROL)		Dr. Eppie Jones	
Emma McCann (EMcC)		Marie Culliton (MCn)	
Dr Cliona Murphy (CM)		Prof Mary Day (MD)	

Deirdre McNamara (DMcN)	Phillippa Ryan Withero (PRW)
Eleanor Masterson (EM)	
Guest Speakers	
Brian Griffin (BG)	Fraser Thompson (FT)

Notes

1. Apologies, Minutes and Matters Arising

- MB welcomed members to the meeting, and gave an overview of the agenda for the meeting.
- MB noted the apologies and matters arising.
- MB commented that KM has had to step down from the role of patient representative and there are processes underway to source a suitable replacement candidate.

2. Genetics and Genomics Operating Model - Clinical Operating Model

- MB noted the action from the last ISG meeting, there was an action to develop an operating model, noted that over the summer work has been on-going to define and refine the core elements.
    - MB gave a high level overview of the main components within the operating model.
    - MB noted that the main point of focus at the moment is the clinical genetics service, but this will have a lot of relevance to the other components.
- MB spoke through the guiding principles, and noted that they align with Sláintecare, and while they were in the development stage, they had input from the Communications & PPI Working Group.
    - MB noted the consistency with Sláintecare principles, 'right care, right place, right time' and this includes the clinical care, the testing, the patient-centred care, and the alignment with other national programmes.
- MB spoke through the process which had been undertaken in an international best practice approach to review which models may be applicable to the Irish context.
    - MB noted that there is no one model which could be taken and used as is within Ireland, because every country is unique in its health service and how it interacts.
    - MB gave a high level overview of the operating models which have been identified through the international best practice exercise.
    - MB noted that as a result of the international best practice review, it was felt that the hybrid and decentralised models would not be suitable in the Irish context.
    - MB commented that this information was presented to the Communications and PPI Working Group, and also shared with respondents of the EoI survey to gain insights into how the public and patients would like to see genetic and genomic care delivered in the future.
- MB noted that a draft strawman has been developed after discussion and review of various components such as the international best practice work, Sláintecare, and other national programmes which have very defined care models and pathways, and is a combination of elements of each.
- MB gave an overview of the pathways presented, and noted that local delivery will be an important component, both referrals for testing, and responsibility for delivering care.

    - MB noted that this would have to work in conjunction with the existing local, and regional services.
    - MB noted that linking in with existing pathways would be a vital element to this local delivery aspect.
- MB noted that a two-way pathway between a national centre, local and regional centres is what the NGGO will be working out in more detail, and how this would work and look for patient care.
- MB explained the concept of a national clinical centre of excellence, and noted that it would have to link into the laboratory infrastructure.
    - MB did note that a national clinical centre of excellence would not have to be co-located with the laboratories, but that they would have to work closely together.
    - MB commented on the importance of the centre of excellence being able to work with academic institutions in Ireland, and internationally.
- MB gave a high level overview of the draft strawman, and what the main functions of the strawman would be.
    - MB commented that going forward, more work would be required, to bring this draft to a more comprehensive model.
    - MB noted that an approach to bring this draft to the next stage of completion, would be to use some example cases to work through the draft and to assess where pathways may need to be altered.
- MB gave a recap of the operating model, and spoke through the next steps in the process, highlighting some key dates which included the dates for the consultation workshops in October, and the dates for the finalised draft operating model for submission to the CCO in November, and to EMT in December.
- CH commented that this is an important piece of work, and noted that the location of the centre would not be decided today, as there are further actions required before this decision can be made.
    - CH noted that this would require a separate robust and transparent process.
- CR noted that he would not be able to stay for the duration of the meeting, but commented that he had some points relating to the laboratory operating model information which was circulated to ISG members before the meeting.
- CR noted that he had some points around how the laboratory operating model interfaces with the clinical operating model.
    - CR noted that there are particular gates in terms of capital investment, and the laboratory model may have additional capital investment requirements and that there are clear policies and procedures around procurement, and how this would and should progress.
    - CR voiced his concern that the Strategic Assessment Report short-listed an individual option as preferred option without any indication of the cost of implementing that option, as it pertains to capital investment required.
    - CR noted that usually a business case with a cost-benefit analysis on a short-list would determine the preferred option.
    - CR noted that it would be useful to have a conversation to understand the status of this piece of work and how it will relate to HSE capital investment planning.
    - CR commented that he would like to understand the piece of work, and how criteria were set and weightings applied within the report.
    - CR apologised that he would not be able to stay to ask the Deloitte team some of these questions, but that he would like to follow up with the NGGO regarding this in the coming weeks.
- CH suggested that it would be useful to set out the questions CR has regarding the decision-making processes within the report and its link to capital investment for further discussion.
- CR responded that he would be able to go through the report with capital investment colleagues to gain clarity around the proposal and how it would be developed.

- TMcC clarified that the tumour testing/somatic testing element of the NCCP operating model is based on the Norwegian model, but that the overall model for cancer testing is based on a centralised model.
- MB thanked TMcC for her comments, and noted that how Norway applies clinical genetics is different, and is a more decentralised model.
- MB responded that the NGGO would be happy to have conversations with CR, and the DoH about the next steps for the laboratory operating model.
    - MB commented that the infrastructure about informatics will be a big challenge for both the clinical and the laboratory operating model.
- CH commented on the next steps and key dates for the operating model.
    - CH noted that one of the key deliverables for this year was to have the operating model decided upon, and that this will allow for the evolution of the service going forward.
- MC wondered what the thought process around the suggested operating model was, and the understanding of the vision of improving IT infrastructure around genetics, and the laboratories, and possibly the usage of laboratories transferring information.
    - MC was keen to understand how this aspect would fit into the suggested operating model.
- MB responded informatics, and how it links in with wider HSE plans is one of the most crucial dependencies within the service.
    - MB noted that this is an area which will require further work and thought, and this work will be on-going into the next stages of the operating model.

3. Genetics and Genomics Operating Model - Laboratory Future Operating Model

- BG recapped on the project objectives, and highlighted the reliance and dependencies that are in play between services, and this was a key component to understanding the testing capacity, capabilities, knowledge and resources.
- BG noted that many of the countries chosen for appraisal were countries situated close to Ireland, however, many of these countries have utilised different operating models.
- BG commented that within the document and going forward, when referring to the operating model it refers to the core laboratory service, however, includes a range of critical supporting elements such as the test directory, the future workforce, and the bioinformatics service, and so it links to these other core component areas.
- BG gave an outline of the work conducted throughout the course of the review, noting that it ran from June to September.
    - BG noted that the team, with the NGGO held four workshops with some subject matter experts in attendance at some of the workshops.
    - BG also explained that laboratory site visits were conducted throughout July, and noted that this was to inform the teams understanding of local capability, challenges that the services are facing, and also to gain a sense from sites of the ambition expressed around participation and/or support of the future operating model.
    - BG noted that it was not an exhaustive review of the 'as is'.
- BG gave an overview of the key themes of the international comparators element of the project.
    - BG noted that there is a lot of diversity regarding the operating models which are in place within these countries, but there are some recurring themes, and spoke through the themes identified throughout the comparator review.
- BG then highlighted the challenges which were identified during site visits, and noted that recruitment, infrastructure and ICT were some of the key challenges identified.
    - BG commented that perhaps the recruitment challenges were identified as more pressing, and would be a challenge for fully implementing the future operating model.
    - BG noted that the infrastructure within these sites does not lend itself well to the expansion of service, and so this will be a challenge.

    - BG also stated that ICT infrastructure and systems currently in place would not have the capabilities to deliver the ambition of the national strategy, and so would involve reasonable investment to achieve the level of integration that the operating model would require.
- BG commented that there was strong ambition among some of the sites visited regarding future goals and remit, and fostering this ambition and building it into the model would be important.
- FT spoke through the evaluation process which was utilised during the future operating model assessment.
    - FT explained that the team constructed a series of eight different options with respect to the configuration of the laboratory network.
    - FT noted that they came up with 4x centralised models, 3x hybrid models, and 1x decentralised model.
    - FT that there was a two-step evaluation process, the first part which was a minimum qualification criteria, which was a set of essential, non-negotiable items that all models to be considered should meet.
    - FT noted that the second step of the evaluation was a multi-criteria assessment, which consisted of nine parameters which were agreed as part of the workshops, and were given different weightings depending on their level of importance with respect to the future operating model.
- FT noted that a centralised model emerged as a preferred model for the future operating model and specifically a hub and node model, which is closely aligned with the HSE Health Regions.
    - FT spoke in more detail about this preferred model, and explained some of the rationale for the suggested sites for testing.
    - FT explained that there is a proposal for a new National Centre of Excellence, in line with strategy, which would serve as the central hub within the laboratory and bioinformatics partnership network.
    - FT gave an overview of the areas which the national centre would be responsible for.
    - FT explained that the centre would be supported by a series of nodes, and the nodes would be located within acute hospital facilities and would capitalise on existing services.
    - FT noted that where possible, there should be a consolidated number of nodes to ensure a centralised model. FT commented however, that this aspect of the model would require further exploration in conjunction with other national offices and services.
- FT commented in relation to the governance aspect to the laboratory operating model, the nodes would be governed by the HSE Health Regions in which they are situated
    - FT noted that the National Centre of Excellence would have to be re-visited at a later date, and would depend on where the centre is located.
    - FT stated that the role of the NGGO would not be to provide clinical governance for these facilities, but rather an oversight, guidance and strategic role.
- FT explained the proposed approach to funding, and quality assurance.
- FT noted that the clinical genetics service would need to be integrated into the laboratory model, and commented that the National Centre of Excellence could serve as a hub for this service.
- FT gave a high-level summary of the recommendation within the report, and noted that there were close to 30 recommendations which pertain to 6 different areas.
    - FT commented that the area of staffing and professional development was an area which was highlighted numerous times during the laboratory site visits as being a key barrier to maintaining, and also expanding the services, and which would require specific attention going forward.
- TMcC queried the number of nodes, and whether this has been decided yet, or are there further considerations in relation to this.
    - BG responded that it would be an approach of less nodes, rather than more nodes, and this would be guided by the evidence as seen from the comparator reviews and

consultations.
    - BG commented that this is a key design element of the laboratory operating model which will require attention.
- CH queried the next steps for the laboratory operating model.
    - BG responded that there is a roadmap outlined within the report for indicative purposes, however, this would require further work to create a more detailed implementation plan.
    - BG did note that there are some design elements such as the number of nodes that would need to be addressed sooner rather than later.
- MB responded that there are many interdependencies with the clinical operating model, and that the estimates and capital process will need to be discussed further with the DoH.
    - MB also noted the approach for communicating this work with professionals is key to ensure there is transparency and fairness around the location of the centre.
- BG responded that the idea of an interim operating model was introduced within the report, and that a more enduring model would require further work.
    - BG noted that the short-term focus would potentially be on the nodes, and supporting them to scale up and deliver a more comprehensive, integrated service.

4. 1+MG Meeting Update

- LD gave an overview of the recent meetings which have taken place, and gave a high level summary of these meetings.
- LD noted that the first meeting of the 1+MG Workstreams took place in Brussels in September, and outlined some of the key takeaways from these meetings.
- LD commented that the next meeting of the /irish National Mirror Group is on November 6th, and the main objective of this meeting is to prepare ahead of the next meeting of the 1+MG Special Group on 14-15th November.
- LD provided a high-level overview of the key takeaways from the 1+MG meeting in Brussels.
    - LD commented that the integration of the 1+MG into the EDHS was an important piece of work as it connects to the legal framework, and also has implications on Ireland's approach, and how Ireland structures its GDI project.
    - LD also noted that there was significant progress made on cancer and rare disease test cases, but there are still some questions around balancing research and use cases moving forward.
- LD highlighted that the 1+MG roadmap will be finalised, and will be brought to the National Mirror Group, and will be signed off at the next Special Group Meeting.
- LD noted that a draft of the framework is being developed, and invited members to view the website which outlines the revised framework.
- LD spoke about some of the considerations for Ireland moving forward, and gave a high-level overview of; implementation, national activity, legislative issues and maximising funds through EU grants and joint actions.

5. WorkStream Updates

- MB gave an overview of the recruitment of frontline posts, and noted that the NGGO have been in contact with hospital sites.
    - MB noted that is it important to ensure progression of the recruitment of these posts to ensure there are no risks of losing the funding which was secured at the beginning of the year
- MB noted that a series of workshops and webinars have been developed in collaboration with the RCSI and the RCPI, and commented that this educational series will be aimed at improving knowledge around genetic and genomic medicine for healthcare professionals.
- MB gave an overview of the key priorities for the rest of 2023, and invited AC to comment on workstream 2, Communications and Stakeholder Engagement, and Richard Hagan to comment

on workstream 3, Testing Guidance and Directory.
    - AC noted that the EoI form worked very well in establishing a database of interested persons for future PPI and engagement activities.
    - AC commented that the NGGO are looking forward to inviting people from this database, along with a range of other stakeholders to the consultation workshops in October.
- RH noted that there has been good engagement around the development of a Testing Guidance document, and there is an upcoming meeting in October to progress this piece of work.
- MB noted that the NGGO have been having discussions with the EU GDI Project in Ireland, to ensure there is no duplication in the bioinformatic elements of the strategy.

6. Closing Remarks/AOB

- LD commented that the DoH are receiving a lot of parliamentary questions (PQ's) about workforce resourcing, and that it would be very beneficial to see the status of the availability to fill these frontline roles.
    - LD noted that this information would be useful when finalising estimates so as not to include roles where there is not capacity/resources to fill them.
    - LD noted that it is important to highlight critical skill areas, so that these can be progressed as professions/skills where there is a need for investment for future recruitment.
- MB commented that career pathways, registration and training capacity also needs to be reviewed, and noted that there is work on-going regarding the laboratory workforce, and crucial skills.
- EH commended the work which has been completed to date, and noted that further work on the laboratories in the border sense is important to ensure there is alignment with this work and the work of the NGGO.
- MB spoke through the next steps for the strategy implementation, and highlighted that there will be consultation workshops in October to allow stakeholders to give feedback on the proposed clinical operating model.
- MB noted that the NGGO would be progressing implementation activities, and would keep ISG members updated.
- CH thanked members for their time, and participation.

END

New Actions				
#	**Action**	**Action Owner**	**Status**	**Notes**
1.	Arrange meeting with DoH regarding Future Laboratory Operating Model Strategic Assessment Report	PS	Closed	
2.	ISG members to provide feedback on Future Laboratory Operating Model Strategic Assessment Report and strawman of genetics and genomics clinical operating model presented at ISG.	ISG Members	Closed	
3.	Circulate meeting minutes	PS	Open	
4.	Send meeting 4 slides to ISG members	PS	Closed	