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Unlocking the genomic landscape: Results of the Beyond 1 Million Genomes (B1MG) pilot in Belgium towards Genomic Data Infrastructure (GDI)

Tugce Schmitt *, Hélène A. Poirel, Emilie Cauët, Marie Delnord, Marc Van den Bulcke

Cancer Centre, Department of Epidemiology and Public Health, Sciensano, Rue Juliette Wytsmanstraat 14, Brussels 1050, Belgium

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ABSTRACT

Genomic medicine has great potential to offer insights into how humans' genetic variation can affect their health, prevention options and treatment responses. The Beyond 1 Million Genomes (B1MG) project was kicked off in 2020 with the aim of building a federated network of genomic data in Europe, in which Belgium took part as a piloting country. B1MG developed a framework to enable all interested countries to self-evaluate the level of maturity of national genomic medicine practices following a common matrix, called Maturity Level Model (MLM), that contained 49 indicators across eight domains: I. Governance and strategy; II. Investment and economic model; III. Ethics, legislation and policy; IV. Public awareness and acceptance; V. Workforce skills and organisation; VI. Clinical organisation, infrastructure and tools; VII. Clinical genomics guidelines and infrastructure; and VIII. Data management, standards and infrastructure. The ongoing Genomic Data Infrastructure (GDI) project aims to capitalise on the experience of B1MG piloting countries and their MLM results. In this paper, we present the qualitative and quantitative outcomes of B1MG MLM assessment in Belgium and discuss their relevance to GDI. The insights gained from this study can be helpful for steering future policy directions and interventions on genomics in Belgium and beyond.

1. Introduction

Genomics changes the way health systems provide care across the world [1]. Genomic medicine is an emerging interdisciplinary medical specialty that involves using genomic information about individuals and their family members as part of their clinical management [2]. As such, it has great potential to offer insights into how humans' genetic variation can affect their health, prevention options and treatment responses [3]. Over the past thirty years, the revolution in genomic technologies has fostered an increased understanding of the molecular mechanisms of diseases. It has also led to the widespread use of genomic information across all medical specialties as part of clinical care to determine disease risk, diagnosis and prognosis as well as to select treatment options [3]. This supported the development of precision medicine, which aims to tailor disease prevention, diagnosis and treatment by considering differences in people's genes, environments and lifestyles. It is expected that genomic technologies will soon not only predict diseases and optimise diagnoses and treatment options for individuals but also potentially help eliminate some genetic disorders entirely with gene-editing technologies [4].

Genomic medicine in Belgium has been well-established since 1987, with eight Centres for Human Genetics (CHGs) dedicated to both clinical and laboratory activities. Notably, substantial progress has been made since then in the country, especially in the field of rare diseases, cancer, precision medicine, and lately public health genomics – a novel discipline that combines genomics and public health. At the European level, Belgium has been involved in three consecutive initiatives, starting with the 1+ Million Genomes Initiative (1+MG) that was launched in 2018 to create a European data infrastructure for genomic data. Two years after the launch, the Beyond 1 Million Genomes (B1MG) project was kicked off in 2020, with the aim of building a federated network of genomic data in Europe. Lastly, in 2022, the Genomic Data Infrastructure (GDI) project began, building on the preparatory work of the 1+MG initiative and the B1MG project (Fig. 1). B1MG developed a framework to enable all interested European countries, including Belgium, to self-evaluate the level of maturity of their national genomic medicine practices following a common matrix, called Maturity Level Model (MLM). GDI aims to capitalise on the experience of B1MG piloting countries and their MLM results. In this paper, we present the qualitative and quantitative outcomes of B1MG MLM assessment in Belgium and discuss their

* Corresponding author.
E-mail address: Tugce.Schmitt@sciensano.be (T. Schmitt).

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relevance to GDI.

2. Materials and methods

To assess the adoption of genomic medicine practices in Belgium, a comprehensive evaluation was executed by using the B1MG MLM framework with a scale from 1 to 5, where 1 indicates the lowest (non-existing, not implemented) and 5 the highest level of maturity (fully implemented) [5]. In the first step, the B1MG project and the B1MG MLM exercise were presented to the national experts in May 2022. This facilitated an understanding of B1MG MLM, which has in total 49 indicators under eight distinct domains, as detailed below. Following this introductory meeting, the experts (Table 1) were invited to fill in the B1MG MLM survey and take part in two subsequent expert workshops aimed at reaching a consensus among the group on the survey results. After the completion of the survey, experts came together in June 2022 to find a joint decision on the maturity level of the first three domains of B1MG MLM: I. Governance and strategy; II. Investment and economic model; and III. Ethics, legislation and policy. The second and final joint decision meeting, conducted in July 2022, focused on the remaining five domains of B1MG MLM: IV. Public awareness and acceptance; V. Workforce skills and organisation; VI. Clinical organisation, infrastructure and tools; VII. Clinical genomics guidelines and infrastructure; and VIII. Data management, standards and infrastructure.

Initially, 63 country experts were invited from Belgium, of whom 26 accepted and confirmed their participation in our study. The survey served to familiarise the experts with the 49 indicators of B1MG MLM and give preliminary answers, setting a foundation for discussions in the workshops rather than beginning from scratch. The expert workshops played a crucial role in further scrutinising the survey results, gaining qualitative insights (reported in the Results section below), and resolving instances where indicators had received an equal number of votes by the experts in the survey. During the expert workshops, the consensus-finding process involved continuous modification of the maturity level of the indicators until no more objections were raised. Following the workshops, detailed meeting notes with outcomes were circulated among all workshop participants for the purpose of gathering any additional feedback; a step crucial for the validation of the consensus findings. No requests for modifications were made following the feedback round, indicating a unanimous agreement with the documented outcomes. The Results section below presents the qualitative and quantitative outcomes of the maturity level assessment of Belgium with 49 indicators following the workshops, based on a joint decision of the involved experts.

Table 1
Participants assessing B1MG MLM in Belgium.

Field	Number of experts
Academia / research organisation	9
National cancer centre	5
University hospital	3
National cancer registry	2
National Institute for Health and Disability Insurance (NIHDI)	2
Hospital	2
Industry	2
Federal Agency for Medicines and Health Products	1
Total	26

3. Results

The quantitative outcomes of the B1MG MLM assessment of Belgium are shown in Table 2. Following Table 2, we explain the reasons experts chose a specific maturity level as final, and thereby present the qualitative outcomes derived from the workshop discussions.

3.1. Domain I: Governance and strategy

Belgium has a total population of 11 522 440 and spends 10.7% of its Gross Domestic Product (GDP) on health, amounting to EUR 3 773 per capita (adjusted for differences in purchasing power) [6]. The health system covers a wide range of services, encompassing nearly the entire population; the financing primarily relies on social contributions that are proportionate to individuals' incomes. The responsibility to take policy decisions is divided between the Federal State and the federated entities. The Federal State, represented by the federal authorities, manages the national compulsory health insurance, determines the hospital budget and general organisational rules, regulates health products and activities, oversees healthcare professionals, and safeguards patients' rights. As two key federal-level authorities, the National Institute for Health and Disability Insurance (NIHDI) administers the compulsory health insurance, and the Ministry of Health (MoH) is accountable for the overall organisation and planning rules of the health system [7].

The experts participating in the B1MG MLM assessment agreed that despite the absence of a clear political plan, noticeable support for genomic medicine has been evident in Belgium. Concerted efforts are being made to develop and regularly update guidelines and best practices through the molecular genetics working group (BelMolGen) of the Belgian Society for Human Genetics (BeSHG) for inherited and rare disorders in close interaction with the College of Genetics, as well as at the Personalised Medicine Commission (ComPerMed) of Sciensano for

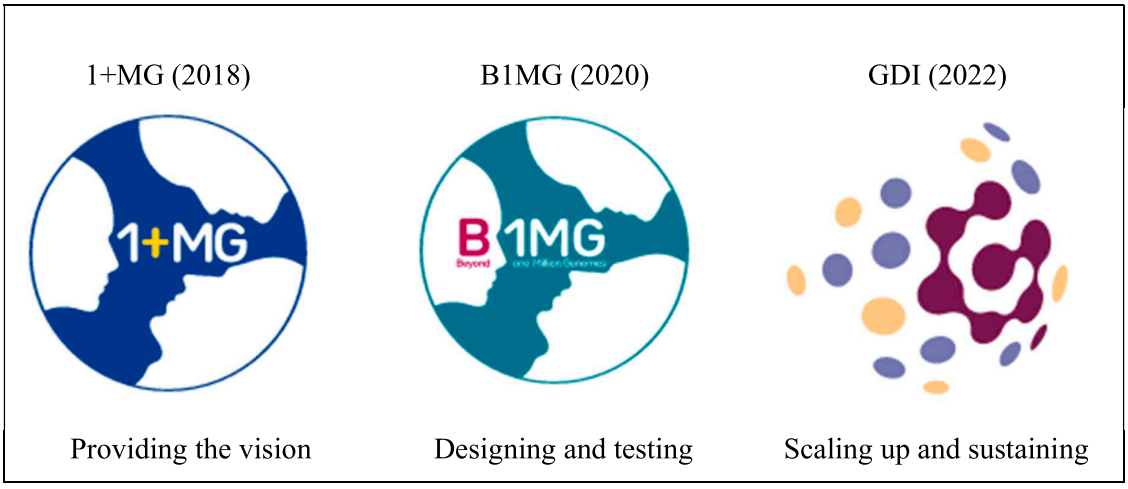

Fig. 1. Link between the 1+MG initiative, the B1MG project, and the GDI project.

Table 2
Quantitative results of the B1MG MLM assessment of Belgium.

Domain	Indicator	Maturity level				
I. Governance and strategy	Country/region has a dedicated governance for genomics in healthcare.	2				
	Genomics in healthcare is established as a priority at national/regional level.			4		
	There is a national/regional strategy for genomics in healthcare with a costed implementation plan.			3		
		Mean: 3				
II. Investment and economic model	There is an investment plan at the national and/or regional levels for genomics in healthcare, with public or mixed public-private funding models.			4		
	There is a framework for reimbursement or no-cost access plans for genomic tests, at the national or regional levels.					5
	There is a HTA framework to assess genomic tests in healthcare.					5
	There is a framework for cost-effectiveness assessment of genomic tests.		2			
	Societal benefits are considered in economic modelling for genomic medicine.	1				
		Mean: 3.4				
III. Ethics, legislation and policy	There are norms to protect and ensure the lawful, fair and transparent processing of personal data.			3		
	There are norms protecting the confidentiality of patient genetic/genomic test results, and specifically clarifying where family members may have rights to access these results.			4		
	There are norms limiting genetic/genomic testing to legitimate purposes and preventing misuse (e.g. no employer/insurer discrimination).					5
	There are norms to ensure appropriate consent is obtained and counselling is provided in relation to genetic/genomic testing.					5
	There are special rules to ensure that vulnerable groups have access to genetic/genomic testing, with counselling and appropriate protections to fully respect their rights and avoid their exploitation.					5
	There are norms ensuring the quality of genetic/genomic testing services (e.g. professional codes and self-regulatory bodies).			4		
	There are norms addressing the accreditation, registration, supervision, secure storage, and responsible use (including exchange and sharing) of human biological samples.			3		
	There is a national strategy for promoting health research and innovation, and associated data protection rules allowing sharing and further processing of health/genetic data for research or treating other patients.	1				
	There are norms facilitating genomic data sharing by researchers and/or healthcare providers, at the national and international levels.					5
	There are norms and processes ensuring the ethical practice and scientific integrity of genomic research.				4	
	There is a national (or regional if appropriate) research ethics committee or network to effectively and efficiently oversee the conduct of multicentre genetic/genomic studies.	1				
		Mean: 3.6				
IV. Public awareness and acceptance	There are literacy programmes or campaigns on genomic medicine with monitored impact on awareness.		2			
	Synergies with patient associations are well established.		2			
	There is a communication strategy for genomic medicine.		2			
			Mean: 2			
V. Workforce skills and organisation	Genomics is integrated in general university curricula for medical doctors.			3		
	Genomics is integrated in general curricula for nurses.	1				
	Genomics is integrated in general curricula for pharmacists.				4	
	There are officially recognised professional titles and career paths for genomic medicine.		2			
	There are training programmes for genetic counselling.		2			
	There are life-long or continuing education programmes in genomic medicine for different healthcare professionals.	1				
	There are programmes for policy makers and healthcare managers to raise awareness on genomic medicine and its implications for healthcare.	1				
			Mean: 2			
VI. Clinical organisation, infrastructure and tools	There are ICT tools supporting clinical interpretation of genomic results, clinical decision-making and communication with the patient implemented in public hospitals and clinics.			3		
	Clinical teams for genomic medicine are multidisciplinary and include ICT, biomedical and psychology experts.					5
	Adoption of novel technologies and software tools to support clinical decisions is fit-for-purpose.			3		
	There are processes established for the integration of the clinics with research outcomes.			3		
	There are effective partnerships with stakeholders from the industry sector.			3		
				Mean: 3.4		

(*continued on next page*)

Table 2 (*continued*)

Domain	Indicator	Maturity level
VII. Clinical genomics guidelines and infrastructure	Genomic centres are established.	5
	Guidelines for sequencing are defined.	5
	Guidelines for genomic data analysis are defined.	5
	Guidelines for sequence-associated-metadata structure to support clinical interpretation are established.	2
	Guidelines for clinical interpretation of genomic results are defined.	5
	Guidelines for clinical reporting of genomic results are defined.	5
		Mean: 4.5
VIII. Data management, standards and infrastructure	Infrastructure and policies for data security are established.	2
	Guidelines for structuring metadata for datasets are established.	2
	Data access governance framework is established.	2
	Data sharing policies and data flows are established.	2
	Guidelines for record level data structure are established.	2
	Guidelines for dataset structure are established.	2
	Data sharing infrastructure is established using a federated model.	1
	Services for data reception to support interoperability are established.	2
	Computational and data infrastructure for medical reuse and secondary data analysis is available.	2
		Mean: 1.9

cancer prevention and care. Based on the recommendations of these professional bodies and expert groups, the health system continually revises reimbursement policies concerning the genomic testing.

3.2. Domain II: Investment and economic model

Reimbursement policies for genomic medicine (genetic counselling as well as genetic testing) are in place to address the specific needs of individuals with rare or inherited diseases within the eight CHGs, established according to the Royal Decree of 14 December 1987 and focused on the diagnosis of constitutional genetic disorders. This was subsequently complemented by the Royal Decrees in 1988 and 1989 to foster the growth of the eight CHGs and to confine the reimbursement of genetic consultations and analyses to accredited centres [8]. Revisions then followed in 2012 and 2018 to integrate the reimbursement of complex genomic tests. Reimbursement of targeted gene tests has been established for acquired haematological malignancies and solid tumours that can be performed in other molecular labs besides human genetic centres. Additionally, a Health Technology Assessment (HTA) framework, such as the next-generation sequencing (NGS) convention for oncology, has been implemented, and ComPerMed serves as a renowned committee to consolidate scientific expertise in the field of precision medicine. It assumes the responsibility of developing guidelines, which subsequently provide recommendations to NIHDI for annual revisions of the reimbursement scheme. The current reimbursement schemes for genomics in Belgium encompass a range of provisions: i) molecular test for inherited disorders, Article 33, NIHDI [9]; ii) molecular test for cancer, Article 33bis, NIHDI [10]; iii) Predictive Tests for a Therapeutic Response (PITTER), Article 33ter, NIHDI [11]; iv) companion diagnostic test platform NIHDI, CDx [12]; and v) NGS convention, which is currently under revision [13].

However, the assessment of cost-effectiveness for genomic tests in Belgium is still in its early stages, with only limited comprehensive evaluations conducted thus far. This holds particularly true for precision medicine, where the evidence for cost-effectiveness remains uncertain. Although data registration mechanisms exist in the health system, these are not fully used for evaluative purposes. Moreover, the consideration of societal benefits in economic modelling for genomic medicine is still lacking; no specific analytical models focused on societal benefits have been applied or are known to the experts in Belgium.

3.3. Domain III: Ethics, legislation and policy

Certain norms in the Belgian health system exist to ensure the confidentiality of patients' genetic/genomic test results, such as guidelines describing the circumstances in which family members may be entitled to access the genetic/genomic test results according to international guidelines. The prevailing practice adheres to the principle of informed consent, which may not necessarily be in written form but ensures that individuals possess a comprehensive understanding of the relevant information before making decisions regarding genetic/genomic testing. Moreover, norms are in place to restrict genetic/genomic testing to legitimate purposes while controlling their potential misuse. National legislation clearly mandates that patient information is exclusively shared with insurers, ensuring that it remains confidential and protected from patients' employers. Data sharing for research purposes occurs within controlled frameworks, and individuals are informed regarding the specific purposes and locations where their data are used. Further norms are in place to uphold the quality of genetic/genomic testing services, supported by various mechanisms such as professional codes and self-regulatory bodies. The health system ensures equal access to services for all individuals, making special rules to guarantee access for vulnerable groups superfluous.

However, the existing norms to safeguard and ensure the lawful, fair and transparent processing of personal data in the field of genomics may need improvement. Although numerous software packages are available, accessing genomics data for researchers remains challenging. The practice of open access (OA) is not widely adopted. Notably, robust regulations exist to ensure secure storage, accreditation and responsible use of patient samples. However, the existence of numerous regulations intended to safeguard data security may also inadvertently impede practicality and hinder the goal of being fit-for-purpose. The rigorous compliance requirements associated with data protection rules impose significant time and financial burdens on the meaningful use of data for genomic medicine. A national strategy for promoting health research and innovation would be useful, in line with data protection regulations facilitating the sharing and subsequent utilisation of health/genetic data for research or treatment purposes. To create such a strategy, the establishment of a steering committee comprising key stakeholders in health and research policies would be instrumental.

From a regulatory perspective, a national committee has been established in Belgium to oversee the implementation of the General Data Protection Regulation (GDPR). Within each CHG, informed consent forms have been implemented in accordance with the recommendations of BelMolGen for germline testing. These consent forms are readily available on the respective CHG websites [14]. The quality of genetic testing services is regulated through the Belgian Accreditation Body (BELAC), and it is legally prohibited to conduct germline testing outside the framework defined by the Royal Decree in 1987 nomenclature. However, the absence of a centralised national committee or a network specifically dedicated to overseeing the conduct of multicentre genetic/genomic studies is noteworthy. It would be essential to assess the feasibility of establishing such a comprehensive committee or network. Considering the logistical challenges of coordinating efforts at the

national level, taking the first step at the sub-federal level could be a viable approach to streamline the efforts and avoid an inconsistent and fragmented infrastructure in the country.

3.4. Domain IV: Public awareness and acceptance

In Belgium, the availability of communication materials concerning specific topics in genomic medicine, such as brochures to raise awareness, is inconsistent and sporadic. Similarly, the establishment of a comprehensive communication strategy for genomic medicine remains irregular. While initiatives involving patient associations do exist (particularly for rare diseases where patient representatives are consistently engaged in European Reference Networks; ERNs), a systematic collaboration at the national level is lacking. Nonetheless, several noteworthy practices deserve attention. Firstly, there are well-established patient organisations that actively engage in the field of human genetics as well as of solid tumours and haematological malignancies. Secondly, the BeSHG plays a significant role in disseminating information regarding the DNA-Day, an event organised by the European Society of Human Genetics (ESHG). Lastly, the ComPerMed secretariat, situated within the Cancer Centre at Sciensano, takes the initiative to conduct several citizen dialogues [15].

3.5. Domain V: Workforce skills and organisation

Training in genomics is accessible at universities in the medical field (usually within the genetics discipline), although this is rather limited to Bachelor's programmes and has not yet been fully integrated into Master's courses. The clinical genetic specialty was created in Belgium in 2017, and trainings are organised among the eight CHGs. Genomics is somewhat better incorporated into the general curricula for pharmacists compared to medical doctors; gaps in coverage are periodically identified in a decentralised manner, with professors taking decisions about curricula. Although there is a need for improvement to ensure a more centralised and comprehensive approach, genomics training into pharmacy is widely integrated, which is not the case for medical students and nurses. In Belgium, there is no professional title as genomic medicine; instead, the specialty is acknowledged under the title of clinical geneticist. Unlike some other countries, Belgium does not have a (sub-)specialty in genomic medicine that is separate from clinical genetics. The emergence of the title molecular pathologist is underway, although formal approval is still pending. Currently, post-graduate training is provided by the eight CHGs [14], allowing professionals to obtain a certificate in human genetics. The programme details can be found on the website of BeSHG [16]. There are no life-long or continuing education programmes in genomic medicine for healthcare professionals, nor are there formal programmes for policymakers and healthcare managers to raise awareness on genomic medicine and its implications for health. Finally, while national training programmes for genetic counselling are currently not in place, working groups of BeSHG make meaningful contributions, e.g. on genetic counselling and molecular genetics.

3.6. Domain VI: Clinical organisation, infrastructure and tools

Regarding the information and communication technology (ICT) infrastructure, accredited clinical support tools are primarily implemented within laboratory settings. Moreover, the Clinical Genetic Bioinformatics and IT working group of BeSHG (BelGenBioIT) actively engages in assessing ICT tools that facilitate clinical interpretation of genomic results and improve patient communication [17]. However, there is still room for improvement, particularly in the field of predictive medicine. In the context of multidisciplinary clinical teams, genetic counsellors collaborate with geneticists specialising in various disciplines, following established guidelines to facilitate the process. Bioinformaticians play a significant role in these teams. Although the presence of ICT and psychology experts in decision-making processes may vary, the teams generally maintain a multidisciplinary approach in the hospitals involved in genomics.

The adoption of emerging technologies and software tools to enhance clinical decision-making in Belgium is primarily driven by sub-federal, decentralised initiatives rather than a federal, centralised strategy. Nevertheless, the implementation of novel technologies occurs within relatively a short time frame. This is facilitated by established plans and processes to guide the integration of these advancements into clinical practice. However, the public funding for translational research aimed at integrating research outcomes into clinical practice is relatively constrained, with initiatives predominantly occurring at the local or regional level. Similarly, various stakeholders and hospitals effectively engage in collaboration with the industry; these partnerships, however, primarily operate at the regional level.

3.7. Domain VII: Clinical genomics guidelines and infrastructure

Several genomic centres have been established in Belgium, operating in adherence to shared guidelines and policies, such as guidelines created by the College of Genetics [18], BelMolGen of BeSHG [19] and NGS guidelines of ComPerMed [20]. Notably, the clinical interpretation of genomic results is facilitated through ERNs, BelMolGen and ComPerMed working groups, fostering a comprehensive and interconnected network. National best practices and guidelines govern the clinical reporting of genomic results, although it would be important to note that these practices are not coercive in Belgium. The guidelines are regularly updated to incorporate technological advancements and ethical considerations, and their implementation is through 'soft enforcement' rather than being obligatory, taking into account evolving ethical and technological contexts.

3.8. Domain VIII: Data management, standards and infrastructure

Regarding the guidelines for structuring metadata for datasets, the situation varies depending on the organisation. Primarily, such guidelines are not established at the national level but rather at the local level. Additionally, while datasets do exist, they may not cover every domain or area of interest. Finally, translational research might not be in place. For instance, a particular data access governance framework has recently been established in Belgium for genomic data, which is stored and organised at the local level [13]. However, experts are unaware of any specific approach to its clinical use at present. Data sharing policies and data flows have been established in the country; yet data sharing predominantly occurs through individual agreements and is not systematically integrated into the electronic health records of patients. Guidelines pertaining to reporting information or data management plans exist within universities, providing a structured approach. However, an overarching national policy specifically addressing this matter is currently absent. Nonetheless, the monitoring of guideline utilisation for dataset structure has recently been initiated in Flanders [21]. While the practice is still in its early stages and not yet fully developed, it might be an encouraging start. Data sharing infrastructures are commercial; experts are unaware of any specific strategy concerning a federated approach.

4. Discussion

In this paper, we examined Belgium's participation in the B1MG project, which has been one of the most significant international initiatives focused on the development of genomic data infrastructure in Europe to establish a federated network of genomic data across the continent. For our evaluation, we utilised B1MG MLM, which was created to enable European countries to assess the maturity level of their national genomic medicine practices. As a result, we provided an in-depth analysis with qualitative and quantitative outcomes. At the

current stage, authorities in Belgium are increasingly recognising the significance of genomics, leading to the establishment of infrastructures for genomic medicine at the local level. The existence of advanced clinical genomics guidelines and infrastructure is especially noteworthy, as evidenced by the B1MG MLM assessment results (see the mean value of Domain VII: 4.5, Table 2). However, on the other side of the spectrum, the self-assessment results also show that there is a great need for improvement concerning data management, standards and infrastructure for genomics in the country (see the mean value of Domain VIII: 1.9, Table 2). Additionally, workforce skills require further investments (see the mean value of Domain V: 2, Table 2). Moreover, our results suggest concerted efforts would be needed to raise public awareness and foster acceptance of precision medicine among the public (see the mean value of Domain IV: 2, Table 2). When designing policy strategies, the peculiarities of Belgium with three different regions (the Brussels-Capital Region, the Flemish Region and the Walloon Region) should be taken into account. Ultimately, there is a pressing dilemma between centralisation and regionalisation in this field, highlighting the need to strike a balance between local access, quality and cost-efficiency amidst the democratisation of genomic medicine for public health genomics.

It can be concluded that Belgium is currently standing at a critical moment, well-positioned to unlock the possibilities of genomic medicine while confronting some intricate challenges. The genesis of genomic medicine in Belgium was initially concentrated on the diagnosis and treatment of rare diseases, and it has gradually expanded its scope to encompass both cancer prevention and therapeutic interventions [8]. The literature in this field points towards different bottlenecks in the implementation of precision medicine in Belgium such as the limited NGS registration, storage and data management for cancers [22]; the budget to be provided for data-storage, analysis and interpretation after NGS [23]; citizens' concerns about the risk of abuse and harm in the context of genomic data sharing [24]; and their high-level of demand for knowing more about the use and purpose of (donated) genomic and health information, which ultimately influences the public trust when collecting and sharing genomic data [25].

Experience from other European countries indicates that even with a solid evidence base for public health genomics, there is still a significant amount of work to be accomplished in translating this evidence into clinical practice and health policies [26]. Initiatives such as 1+MG and the B1MG project have successfully paved the way for the wider implementation of public health genomics in Europe, including Belgium. The 1+MG initiative launched the 1+MG Framework website and the 2023–27 Roadmap in November 2023 to advance genomics in personalised healthcare and research across Europe. Whilst the Framework compiles EU experts' recommendations, guidelines and best practices for secure genomic and health data access, the latter outlines the detailed steps towards these goals [27]. The 1+MG Framework will continue to evolve, in alignment with the European Health Data Space (EHDS) [27]. As widely known, the European Union (EU) is creating EHDS to enable the exchange and sharing of health data, including electronic health records and genomics, aiming to enhance primary care, develop new treatments and ensure individuals have control over their own health data [28]. Future studies could focus on how the genomics data exchange within the EU may be better coordinated in the upcoming European structures like EHDS. Such studies hold the potential to shed light on how genomics research can be optimally used to enhance healthcare practices and policies at both national and European levels.

The need for further research and evidence in genomic medicine is crucial, just as the international collaborations. While conducting this research, the GDI project has introduced a Starter Kit, which constitutes an important initial step in the development of a comprehensive system for the sharing of genomic data within Europe [29]. Belgium is among a group of six countries that have initiated the use of the GDI Starter Kit. This is an important step given that the GDI Starter Kit establishes the groundwork for countries to set up infrastructure that can become functional and integrate into the 1+MG framework. Intended to aid national data centres, as well as to pave the way for future involvement by public and private sectors, the GDI Starter Kit focuses on enhancing the organisation, accessibility and sharing of genomics data. As such, it streamlines the setup process and offers the ability to share vital genomics data, including synthetic datasets on cancer and rare diseases, across European countries [29]. These endeavours under GDI not only improve the field of genomics but also strengthen the cooperation within the EU, which are essential for pioneering advancements in precision medicine in Europe.

Admittedly, the methodology applied in our study offers several strengths and potential limitations. Among its strengths, the study employed a comprehensive evaluation approach, using a detailed maturity scale, which can provide nuanced insights into the adoption of genomics practices in the Belgian health system. The internationally acknowledged and structured B1MG MLM tool, with its 49 indicators spanning eight domains, provides an extensive overview of a large number of elements that impact genomic medicine adoption. Engaging country experts throughout our investigation ensured that the survey data were collected by individuals with a detailed knowledge of genomic medicine in Belgium. The expert workshops not only allowed for an understanding and refining of survey responses, but also added a layer of validation, especially through the consensus-based approach. As such, our methodology sought to reduce individual biases and the negative effect of potential outliers through survey responses. As exemplified through the diversity among our workshop participants, this research underscores the importance of interdisciplinary collaboration between experts in genomics, healthcare delivery and policy to address the challenges and opportunities presented by the evolving field of genomic medicine.

However, there are certain inherent limitations to our methodology. Relying on expert opinion may introduce subjective biases, even when a consensus approach is used. While the expertise of the participants can be seen as an asset, the number of available experts and their professional backgrounds might influence their perceptions and evaluations. Moreover, it is acknowledged that the consensus-finding method may include the potential for groupthink and the inadvertent exclusion of certain viewpoints, possibly also influenced by the limitations in participant availability. Additionally, the B1MG MLM primarily evaluates the presence and maturity of processes and systems, but not necessarily their effectiveness in practice. The B1MG MLM, while comprehensive, might not capture all nuances of the complex landscape of genomics practices adoption in health systems. For this reason, our study should be considered in combination with other health policy research focusing specifically on the Belgian health system to better contextualise our findings given that public health issues and the available solutions in precision medicine are mostly influenced by country-specific contexts [30]. Last but not least, in a rapidly evolving field such as genomic medicine, the assessments like B1MG MLM should be done more regularly to capture the latest developments.

To the best of our knowledge, there are also other scholars who applied and shared the outcomes of their B1MG piloting experience in Europe [31]. In our research, the consensus-building approach adopted by the country experts proved beneficial. Distributing the B1MG MLM indicators through a survey to stimulate some initial thoughts and further elaborate on these preliminary outcomes during the expert workshops was an effective strategy. In this study, we gave efforts to contextualise our findings when giving recommendations and suggest that countries interested in using the methods from this paper should also reflect on their results based on their specific health systems and national settings. Ultimately, it is our hope that this study paves the way for improved healthcare delivery, not only in Belgium but also on a European scale.

5. Conclusion

Genomic medicine stands as a transformative force in healthcare, offering precise clinical management and proactive disease prevention. The intricate nature of genomic medicine necessitates continued international collaboration, especially in Europe. Belgium's involvement in international projects, such as B1MG, offers critical insights into optimising its genomic infrastructure and practices. By capitalising on the B1MG MLM findings, Belgium can drive the development, deployment and operation of a sustainable data-access infrastructure under GDI. This study can help identify points of attention and make evidence-informed decisions for improving the infrastructure and organisation of genomic medicine in Belgium in a way that is harmonised and interoperable with other European countries.

CRediT authorship contribution statement

Tugce Schmitt: Conceptualization, Methodology, Data curation, Formal analysis, Investigation, Writing – original draft. **Hélène A. Poirel:** Investigation, Writing – review & editing. **Emilie Cauët:** Writing – review & editing. **Marie Delnord:** Writing – review & editing. **Marc Van den Bulcke:** Conceptualization, Funding acquisition, Project administration, Resources, Supervision.

Declaration of competing interest

The authors have no conflict of interest to declare.

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