Population Stratification for Public Health and the Ministry's Predictive Model: Constitutional Principles and Regulatory Developments*

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ABSTRACT:
Il contributo analizza le principali sfide giuridiche poste dai modelli predittivi per la stratificazione della popolazione e la predizione dell'evoluzione del fabbisogno sociosanitario. Si tratta di tecnologie potenzialmente in grado di assicurare una pianificazione dei servizi più in grado di rispondere ai bisogni, un'allocazione più equa delle risorse, nonché l'adozione di più efficaci misure di c.d. Sanità di iniziativa. Perseguendo questi obiettivi, essi inverano il principio di appropriatezza organizzativa e il complesso sistema di tutele costituzionali apprestato dall'art. 32 Cost. Prendendo le mosse da un caso di studio nazionale, cioè il modello predittivo sviluppato dal Ministero della Salute fin dal 2014, oggi parte del PNRR, l'analisi si concentra su come tale strumento si inserisce nella disciplina del finanziamento dei Livelli essenziali di assistenza, promettendo un riparto più equo delle risorse dell'(ex-) Fondo Sanitario Nazionale tra le regioni. Sullo sfondo dell'interconnessione

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fra dimensione organizzativa e clinica, emerge inoltre la tensione fra tutela della salute e protezione dei dati personali. A fronte di un contesto normativo che ha aperto la strada ai trattamenti per interesse pubblico, ma che risulta tuttora lacunoso, il Garante per la Protezione dei Dati Personali ha giocato e gioca un ruolo cruciale, che esercita anche in dialogo con il legislatore e con il Ministero della Salute, nella duplice veste di controllato e di normatore. Il contributo analizza infine le implicazioni dell'utilizzazione di sistemi di intelligenza artificiale per la predizione dell'evoluzione del fabbisogno sanitario alla luce delle norme europee sulle decisioni automatizzate e del Regolamento europeo sull'intelligenza artificiale. È restituito un quadro complesso, dove la digitalizzazione sembra in grado di contribuire a realizzare quell'inversione fra servizi e bisogni che è alla base delle più recenti riforme del Sistema sanitario nazionale solamente in un ordinamento giuridico che inveri la 'promessa' dell'art. 32 unitamente ai principi del cd. costituzionalismo digitale.

The paper analyses the primary legal challenges posed by predictive models for population stratification based on healthcare needs. These technologies have the potential to enhance service planning, ensure fair resource allocation and facilitate proactive healthcare initiatives. In pursuing these objectives, they implement the principle of organisational appropriateness and the intricate system of constitutional safeguards outlined in Article 32 of the Constitution. Beginning with a national case study, specifically the predictive model developed by the Ministry of Health since 2014 and now integrated into the National Recovery and Resilience Plan, the analysis delves into how this tool intersects with the legal framework governing the financing of the Italian healthcare system. Specifically, it examines it potential for facilitating a more equitable allocation among regions of the (ex-)National Health Fund financing Essential Levels of Care. Moreover, at the intersection of organisational and clinical public health domains, tensions between health protection and personal data protection arise. Although recent normative developments have enabled consent-free data processing, the legal framework remains incomplete, with the Italian Data Protection Authority playing a pivotal role and engaging in dialogue with the legislature and the Ministry of Health. The contribution also delves into the implications of using artificial intelligence systems in light of GDPR provisions on automated decision-making and the AI Act. Ultimately, the paper highlights how digitisation can contribute to realising the inversion between services and needs, a cornerstone of the most recent reforms of the Italian national healthcare system. However, to this end, a regulatory framework capable of fulfilling the 'promise' of Article 32, alongside the principles of digital constitutionalism, is imperative.

1. Predictive modelling for health: an introduction

In the digital age, it is crucial to delicately tread a fine line between exploring the potential of technological innovation and recognising the imperative to regulate it and safeguard fundamental rights. Striking this balance is particularly challenging when it comes to big health data analytics.

Similar to 'walking data generators', we continuously produce vast amounts of data, which we are able to analyse and subsequently exploit to extract new information.[1] The new

[1] The persistent and involuntary generation of data constitutes the first 'level' of 'datification' (or 'datafication'), one of the defining aspects of our contemporary era. Data analysis and data mining represent the second and third level of this

information extracted are often predictions. Predictive analytics can thus be defined as the use of data mining,[2] statistics, machine learning and artificial intelligence[3] to predict a certain event or behaviour. Prediction is a key aspect of the digital era and undoubtedly a significant turning point in the field of health. Predictive modelling holds the promise both to promote biomedical research and drug discovery and to support health professionals in the clinical management domain (e.g. predicting survival in certain conditions or the disease outcome following different clinical decisions)[4] and public institutions in the healthcare services domain. It stands as one of the most innovative aspects of the digital transformation in healthcare (e-Health).[5]

This contribution focuses on the realm of public health services, where predictive modelling is used for population-based risk assessment. Such modelling facilitates the development of risk stratification maps, often depicted as pyramids, illustrating the distribution of risk levels across the population: this enables the identification of groups of individuals with similar healthcare needs.[6] Risk stratification finds application both in the context of

data-driven transformation. See S. Calzolaio, *Protezione dei dati personali*, in R. Bifulco, A. Celotto, M. Olivetti (a cura di), *Digesto delle Discipline Pubblicistiche*, Milan, 2017, p. 598.

[2] I.e. automated techniques applied to analyse large and complex databases: S. Finlay, *Predictive analytics, data mining and big data*, London, 2014, p. 2 f.

[3] The demarcation between these concepts remains somewhat indistinct. Predictive analytics employs a diverse range of techniques, including probability theory, regression analysis, and machine learning methodologies such as artificial neural networks, decision trees, and support vector machines (V. Kumar, M.L. Garg, *Predictive Analytics: A Review of Trends and Techniques*, in *International Journal of Computer Applications*, no. 1, 2018, pp. 31 ss). Notably, deep learning techniques, a subset of artificial neural networks, are widely acknowledged as examples of artificial intelligence systems. In the draft presented by the Commission software developed with techniques listed in Annex I, encompassing machine and deep learning, statistical approaches, Bayesian estimation, and logic- and knowledge-based methods, is recognised as an AI system. These systems attain their AI classification by generating outputs such as content, predictions, recommendations, or decisions that influence the environments they interact with, aligned with specified human-defined objectives. In the draft agreement at the end of the trilogue operations Annex I is delated and a narrower definition of AI system is stated, aligning it more closely with OECD's definition: an AI system is thus «a machine-based system designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions influencing that can influence physical or virtual environments». In essence, AI systems are frequently applied for predictive modelling, with the option to use less advanced techniques for the same purpose.

[4] Predictive models could also be used in the clinical domain for classifying patients in the optimal healthcare tier «helping to define shared care arrangements between primary care and specialists», see I. Dueñas-Espín and others, *Proposals for enhanced health risk assessment and stratification in an integrated care scenario*, in *BMJ Open*, 2016, no. 4, p. 2.

[5] On the concept of e-Health cf. D. Morana, T. Balduzzi, F. Morganti, *La salute "intelligente": eHealth, consenso informato e principio di non-discriminazione*, in *Federalismi.it*, no. 34, 2022, pp. 128 f. Among the latest contributions on digitalisation of the Italian national healthcare system, which found its cornerstone in the introduction of the the Electronic Health Record (*Fascicolo sanitario elettronico*, FSE) and telemedicine, see at least M.C. D'Arienzo, *La trasformazione digitale della sanità tra problemi organizzativi e profili di responsabilità professionale*, in *Il diritto dell'economia*, no. 2, 2022, pp. 135 ff.; E. Catelani, *La digitalizzazione dei dati sanitari: un percorso ad ostacoli*, in *Corti Supreme e Salute*, no. 2, 2023, pp. 423 ff. Further bibliography *infra*, especially in footnote 77.

[6] I. Dueñas-Espín and others, *op. cit.*, 2. There is a wide array of internationally adopted stratification techniques.For a comprehensive literature review, see S.M. Girwar et al, *A systematic review of risk stratification tools internationally used in primary care settings*, in *Health Science Reports*, no. 4, 2021, pp. 329 ff.

specific diseases and in estimating the overall population health level also based on social determinants of health.[7]

Predictive modelling also provides the ability to observe how these risk levels might evolve over time and be influenced by epidemic events or public health policies. This facilitates, among other things, a more efficient allocation of resources, the customisation of territorial health infrastructures based on actual needs, the promotion of public health through targeted policies, and the adoption of proactive measures for specific clusters of patients. The study outlines the major legal issues raised by these innovative tools, focusing on an Italian case-study, i.e. the development of a predictive model of the evolution of healthcare needs by the Italian Ministry of Health. However, it must be noted that several programs at regional level (e.g. in Veneto, Lombardy, Emilia-Romagna and Tuscany) and at local level (single local health units, e.g. USL Friuli) have shown some interesting preliminary results.[8]

2. Ensuring the constitutional right to health, organisational appropriateness and the principle of substantive equality

As it is widely recognised, Art. 32 of the Italian Constitution is a multifaceted provision that encompasses various aspects of health protection.[9] It safeguards health as a (fundamental) collective interest and ensures the protection of health as a fundamental right. [10]

[7] In § 6 we will delve deeper into the impact of social determinants on health and how they could be incorporated into the stratification process.

[8] The already existing good practices at regional level have demonstrated the possibility of integrating informational flows and differentiated databases from those of the Revenue Agency (ISEE), INPS (Italy's National Institute of Social Security), and INAIL (Italy's National Institute for Insurance against Accidents at Work), to those related to citizens assisted by local social services, accredited third-party providers (such as associations, social cooperatives, Third Sector), socio-health services of the Local Health Authorities (AUSL), and other public and private providers «into a structured and interchangeable database accessible to all providers for a precise evaluation of the healthcare and social performance and consumption by the citizens of the considered territories». G. Banchieri, *Il Pnrr e la necessità della stratificazione dei bisogni delle popolazioni osservate*, in *Quotidianosanità.it*, 26th November 2021, URL: https://www.quotidianosanita.it/studi-e-analisi/articolo.php?articolo_id=100383.

[9] Of the vast constitutional literature on Art. 32 and its multifaceted nature see, at least: B. Pezzini, *Il diritto alla salute: profili costituzionali*, in *Diritto e Società*, 1983, pp. 21 ff.; B. Caravita, *Art. 32*, in V. Crisafulli, L. Paladin (a cura di), *Commentario breve alla Costituzione*, Padova, 1990, pp. 215 ff.; A. Simoncini, E. Longo, *Art. 32*, in R. Bifulco, A. Celotto, M. Olivetti (a cura di), *Commentario alla Costituzione*, Torino, 2006, pp. 655 ff.; R. Balduzzi, *Salute (diritto alla)*, in S. Cassese (dir.), *Dizionario di diritto pubblico*, VI, Milano, 2006, pp. 5394 ff.; C. Bottari, *Il diritto alla tutela della salute*, in P. Ridola, R. Nania (a cura di), *I diritti costituzionali*, II, Torino, 2006, pp. 1101 ff.; D. Morana, *La salute come diritto costituzionale*, 4° ed., Torino, 2021; M. Luciani, *Salute, I, Diritto alla salute - dir. cost.*, in *Enc. giur.,* XXVII, Roma, 1991.

[10] The term 'fundamental' refers both to the individual right and the collective interest, cf. V. Crisafulli, *In tema di emotrasfusioni obbligatorie*, in *Diritto e Società*., 1982, p. 564.

First of all, the preservation of health as a collective interest takes shape through several public interventions designed to 'objectively' safeguard health. These interventions are 'indivisible', i.e. they are directed towards the entire population collectively, especially in the context of preventing the spread of diseases, rather than being applied individually. However, this 'objective' safeguarding alone does not constitute a genuine right for individuals unless the failure or insufficient execution of these interventions leads to harm to an individual's health.[11]

Secondly, the fundamental right to health entails two different rights: on the one hand, the right to health as a freedom, which entails the expectation that every member of society, including public institutions, refrains from intervening in a set of interests designated for the enjoyment of its owner;[12] on the other hand, the right to health as a social right,[13] which derives from the constitutional provision stating the right of «the indigent» to obtain free healthcare. This provision is to be interpreted through the «lens»[14] of Law No. 833/1978, establishing the Italian national healthcare system (i.e. *Servizio sanitario nazionale*, Italian for National Health Service, from now on also 'SSN') based on the principles of comprehensive care, universal access, equal treatment, and uniformity of services. In other words, Art. 32 shifted from providing free care solely for the indigent to establishing a universal right for everyone to access medical services primarily funded by public resources.[15]

[11] D. Morana, *La salute*, cit., p. 3.

[12] We therefore subscribe to the theory that reconstructs freedoms as claims rather than faculties. Further on this debate, including references to the German theory of fundamental rights as '*Abwehrrechte*' and the Anglo-Saxon literature discussing the contrast between 'freedom from' and 'freedom to', see P. Grossi, *I diritti di libertà ad uso di lezioni*, I, 1, II ed., Torino, 1991, pp. 237 ff.

[13] Social rights shall be understood as 'rights to services' (*diritti a prestazione*), which inherently require state intervention for their realisation (see P. Grossi, *I diritti di libertà,* cit., pp. 274 ff.; Manlio Mazzotti di Celso had already addressed this point, as highlighted by A. D'Atena, *Lezioni di diritto costituzionale*, Torino, p. 13). According to this theory, freedom rights are 'self-sufficient' and capable of producing effects independently, as highlighted by Carlo Esposito in his discourse on freedom of expression in Rome in 1957, see C. Esposito, *La libertà di manifestazione del pensiero nell'ordinamento italiano*, Milano, Giuffré, 1958. However, it has been contended that freedoms require positive interventions aimed at ensuring their fullest exercise, as effectively highlighted by A. Pace, *Problematica delle libertà costituzionali. Parte generale: Introduzione allo studio dei diritti costituzionali*, 3° ed., Padova, Cedam, 2003). Furthermore, a distinction has been proposed within the same category of social rights between 'derivative' and 'original' social rights. The need for legislative intervention would apply solely to the former. Conversely, the latter could be directly enforced against the counterparty, and the judge would intervene to establish the scope of the performance if not explicitly specified by the legislator. (cf. C. Colapietro, M. Ruotolo, *Diritti e libertà*, in F. Modugno (eds), *Diritto pubblico*, Torino, pp. 690 f.). Some authors have emphasised, on one hand, the «ideological» influence of the liberal conception of the State on the idea of freedoms as self-sufficient and not needing public interventions to protect them. On the contrary, examples of necessary public interventions for ensuring freedoms would range from the repressive apparatuses of the State and the judiciary to the public infrastructures ensuring, for instance, the freedom of private economic initiative, freedom of expression, property protection, etc. On the other hand, the same authors contend that social rights do not always necessitate public interventions and the allocation of financial resources, as they may encompass elements of freedom themselves. See R. Bin, *Critica della teoria dei diritti*, Milano, 2018, pp. 11 ff.

[14] D. Morana, *La salute*, cit., p. 97.

[15] M. Luciani, *Salute,* cit., 8.

Now, it appears that predictive models used in the clinical field, especially for diagnostic purposes, primarily rise questions concerning the freedom of health. Consider, for example, the problem of obtaining informed consent from the patient when the diagnosis is made using automated diagnostic support devices.[16] Conversely, predictive modelling used in the public health domain primarily concerns the right to health as the right to obtain care and the 'objective' protection of health as a collective interest.

Further endeavours in interpreting the Constitution could offer additional insights into the matter. It has been asserted that healthcare services offered by the National Health Service must be deemed 'appropriate,'[17] in order to effectively safeguard health. The notion of 'appropriateness' encompasses both a 'clinical' and an 'organisational' dimension. To understand its meaning in those two different contexts, it is helpful to begin by considering its opposite. On the one hand, clinically inappropriate are healthcare services «whose effectiveness is not demonstrable based on available scientific evidence» or related to «individuals whose clinical conditions do not correspond to recommended indications». On the other hand, organisational inappropriateness entails forms of care that «while complying with the principle of clinical effectiveness, are (...) disproportionate in terms of timing, delivery methods, or the quantity of services provided, as well as interventions and services that can be replaced by others with a more satisfactory cost-effectiveness ratio».[18]

The organisational facet of appropriateness is, as we shall examine, of utmost significance within the scope of this contribution. To effectively uphold the right to healthcare as well

[16] On the interplay between informed consent and AI diagnostic devices, see: D. Morana, T. Balduzzi, F. Morganti, *La salute "intelligente"*, cit.; pp. 135 ff.; M. Granillo, *La sostenibilità giuridica dell'utilizzo degli algoritmi nei processi decisionali in ambito sanitario: il bilanciamento fra i benefici offerti dall'utilizzo delle nuove tecnologie e la regolamentazione in materia di trattamento dei dati personali,* in *IUS et SALUS*, 27th August 2021, p. 14; C. De Menech, *Intelligenza artificiale e autodeterminazione in materia sanitaria*, in *BioLaw Journal*, no. 1, 2022, pp. 181 ff. L. Scaffardi, *La medicina alla prova dell'Intelligenza Artificiale*, in *DPCE online*, no. 1, 2022, pp. 349 ff.,

[17] The term explicitly entered our legal system in 1997 through Art. 32, par. 9, lett. *a*) of Law No. 449/1997, «Measures for the stabilisation of public finances» (linked to the financial law for 1998). This law imposes obligations on regions, local health units, and hospital companies, in the exercise of their supervision and control powers to ensure the correct and effective use of resources. It mandates specific monitoring actions on hospital activities in terms of quality, appropriateness, accessibility, and cost. The evolution of appropriateness in the Italian legal system and the legislator's inconsistency in terminology is examined by R. Balduzzi, *L'appropriatezza in sanità: il quadro di riferimento legislativo*, in N. Falcitelli, M. Trabucchi e F. Vanara (a cura di), *Rapporto Sanità 2004*, a cura di Bologna, Bologna, 2004, pp. 73 ff., and, more recently, Id., *Le nuove frontiere dell'appropriatezza clinica e organizzativa, tra individualizzazione del trattamento e superamento di modelli tralatizi*, in F. Rescigno (a cura di), *Eguaglianza ed equità di cura. La risposta della Sex and Gender Medicine*, Bologna, 2023, pp. 36 ff. Organisational appropriateness is increasingly valued in light of recent regulations, as emphasised by the decree from the President of the Council of Ministers (DPCM) dated January 12, 2017, published on March 18, 2017. This decree updated the Essential Levels of Care (LEA), giving special attention to organisational considerations (see G. Fares, *Principi erogativi ed elementi organizzativi del Servizio sanitario Italiano. La prospettiva del giurista*, in C. Colapietro, M. Atripaldi, G. Fares, A. Iannuzzi (eds), *I modelli di welfare sanitario tra qualità e sostenibilità. Esperienze a confronto*, Napoli, 2018, p. 176).

[18] See the Health Plan 1998-2000 which indicates some examples of inappropriate services: «screening procedures and programs with an unfavourable cost-effectiveness ratio; numerous services currently provided in hospitalization that could be more appropriately provided in outpatient settings, day hospitals, or extra-hospital residential facilities». The Plan connects appropriateness with the notion of Essential Levels of Care, excluding from their realm those services deemed inappropriate from a clinical and/or organisational perspectiv.

as to ensure proper safeguarding of health as a collective interest, a healthcare system must be in place that ensures the delivery of high-quality healthcare services timely and through appropriate facilities. The organisation of healthcare involves decisions concerning the allocation of resources to adequately meet the healthcare needs of the population. These decisions may concern both the quantity of resources to allocate and the way they are utilised. The appropriateness of healthcare organisation should therefore be regarded as a corollary to the constitutional principles outlined in Art. 32 of the Constitution. This corollary guides the action of the Republic in fulfilling the task of safeguarding the right to healthcare.[19]

Regarding organisational appropriateness, two notable considerations emerge: the first is related to the allocation of responsibilities and legislative competences between State and regions, and the second involves the interplay between the Constitutional Court and the legislator, whether at the regional or national level.

Firstly, it is worth noting that 'healthcare organisation' is considered by the Constitutional Court to be an integral part of the concurrent legislative competence of the regions in the field of health protection, according to Art. 117, par. 3 of the Constitution.[20] This means regional competence is not exclusive; therefore, healthcare organisation is subject to the fundamental principles imposed by national legislation.[21]

Secondly, it is primarily the legislator's responsibility to determine the implementation modalities of healthcare services in accordance with the principle of appropriateness. The legislator acts as the primary interpreter of this principle, evaluating the concrete healthcare needs and ensuring an efficient allocation of resources. Consequently, the Constitutional Court's judgment should only extend to reviewing the reasonableness of the legislator's discretionary choices (whether at the national or regional level) regarding the acquisition of necessary resources and their appropriate allocation.[22]

[19] In these terms, D. Chinni articulated his views during his speech titled «*Effettività del diritto alla salute e appropriatezza della cura nella prospettiva costituzionalistica*» (Effectiveness of the Right to Health and Appropriateness of Care in the Constitutional Perspective) at the XXI National Health Law Conference themed «*Appropriatezza della cura e tutela della salute. Profili sistematici e applicative*» (Appropriateness of Care and Health Protection: Systematic and Applicative Profiles). The conference took place at the Department of Law, Roma Tre University, on October 12, 2023. During this event, Chinni also asserted that organisational appropriateness would find an additional constitutional foundation in Art. 117, par. 2, lett. *m*) of the Constitution: the determination of essential levels of (healthcare) services to be ensured nationwide – an exclusive competence of the State – necessitates the establishment, at the national level, of a suitable organisation for this purpose.

[20] According to various judgments, including decisions No. 54 of 2015 and No. 371 of 2008. Cf. F. Politi, *L'obbligo di vaccinazione per operatori sanitari ospedalieri afferisce alla "organizzazione dei servizi sanitari"? La Corte costituzionale detta alcuni criteri interpretativi circa le modalità di "lettura" della legge regionale in una questione relativa alla ripartizione di competenze fra Stato e Regioni in materia di diritto alla salute*, in *Corti supreme e salute*, no. 3, 2019, 3, pp. 412 ff.

[21] Contrary to what was initially asserted by Regions before the Constitutional Court. Further on the matter: G. Carpani, D. Morana, *Le competenze legislative in materia di «tutela della salute»*, in R. Balduzzi, G. Carpani (eds), *Manuale di diritto sanitario*, Bologna, 2013, 96 f.

[22] In these terms, once again, D. Chinni. For a comment on a constitutional court judgment regarding healthcare organisation that sanctioned a regional law in the context we are discussing here, i.e., «legislative discretion [turning] into

Population stratification and predictive modelling for public health can therefore be seen as a direct manifestation of the principle of appropriate care, implementing the Republic's (comprising both the State and regions) obligation to establish an efficient and cost-effective organisation. This discourse can certainly be extended to various other dimensions of digital healthcare, many of which are essential for stratification techniques and predictive models. Consider aspects such as the establishment of the Electronic Health Record (*Fascicolo sanitario elettronico*, FSE) and the interoperability among regional FSEs.[23]

Finally, another foundational principle must be briefly addressed: the principle of substantive equality.[24] It functions as a compelling force that should permeate every facet of health protection within the Italian legal system, ranging from a broader, more generalised perspective to increasingly intricate regulatory details.[25]

This tension is intrinsic to the right to health as a social right: those are rights which serve, by their very nature, as means to implement the principle of substantive equality.[26] Furthermore, it characterises the peculiar implementation of the right to health through the establishment of the Italian national healthcare system, anchored in the principles of comprehensive care, universal access, equal treatment, and service uniformity.[27] This influence extends to the financing system of the national public health service, funded through general taxation under the Beveridge system.[28] Additionally, the principle is evident in the

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arbitrariness», see A. Rovagnati, *Inadempienze regionali e controllo di legittimità costituzionale. Brevi considerazioni a margine di una (opportuna) decisione del giudice delle leggi in tema di (cattiva) organizzazione del servizio sanitario*, in *Le Regioni*, no. 1, 2009, p. 145. Furthermore, when the legislator's discretionary decisions involve highly technical content, the interplay between science and law tends to result in a gradual retreat of the latter compared to the former. See at least: A. Iannuzzi, *Il diritto capovolto. Regolazione a contenuto tecnico-scientifico e Costituzione*, Napoli, 2018, pp. 182 ff.; D. Servetti, *Riserva di scienza e tutela della salute, L'incidenza delle valutazioni tecnico-scientifiche di ambito sanitario sulle attività legislativa e giurisdizionale*, Pisa, 2019.

[23] See, N. Maccabiani, *Tra coordinamento informativo e livelli essenziali delle prestazioni: il caso del Fascicolo Sanitario Elettronico*, in *federalismi.it*, no. 12, 2023, p. 259, who explicitly links the FSE and, in particular, interoperability, with care appropriateness and personalisation.

[24] Enshrined in Art. 3, par. 2 of the Italian Constitution. Regarding the absence of a similar provision in European and international legislation, and for some examples of provisions that nonetheless guide the actions of the European Union and its member states in specific sectors, see A. Giorgis, *Art. 3, 2° co., Cost.*, in R. Bifulco, A. Celotto, M. Olivetti (eds.), *Commentario alla Costituzione*, Milano, 109 ff.

[25] This is evident at a more general level within the legal system, even without succumbing to the excesses of turning Art. 3, par. 2, into a kind of «supernorm» (see G.P. Dolso, *art. 3*, in S. Bartole, R. Bin (eds.) *Commentario breve alla Costituzione*, Padova, II ed., p. 33). Further on Art. 3, the 'sincerity' of the Constitution and the «model of society it anticipates», U. Romagnoli, Art. 3, in G. Branca (eds.) *Commentario della Costituzione, Principi Fondamentali*, 162 ff.

[26] Regarding the relationship between social rights and the principle of substantive equality, see M. Mazziotti di Celso, *Diritti sociali*, in *Enciclopedia del Diritto*, XII, Milano, 1964, p. 805. According to Mazziotti social rights «achieve a synthesis between freedom and equality, in a word an *equal freedom*». See also M. Luciani, *A proposito del «diritto alla salute»*, in *Diritto e società*, 1979, 410 ff. On the long journey of social rights, from their acknowledgment as inviolable to their interconnection with the principle of budgetary balance amidst the crisis of the welfare state, cf. C. Colapietro, *La giurisprudenza costituzionale nella crisi dello stato sociale*, Padova, 1996, 351 ff.

[27] Concerning the relatively recent crisis in the nexus between the principle of equity and the establishment of the National Health Service, see I. Ciolli, *La salute come diritto in movimento. Eguaglianza, universalismo ed equità nel sistema sanitario nazionale, oggi*, in *BioLaw Journal*, no. 2, 2019, pp. 13 ff.

[28] See, once again, I. Ciolli, *La salute come diritto*, cit., p. 15, also for further bibliography.

adoption of Essential Levels of Care (*Livelli Essenziali di Assistenza*, LEA), which contribute to achieving more uniformity amidst regional distinctions, albeit in tension with the principle of regional autonomy.[29] Finally, as we will explore in depth in the following, the principle of substantive equality is embedded in the criteria for distributing financial resources among regions. A fairer allocation relies on better aligning it with the genuine needs of each region's population.

In summary, from the broadest legislative and administrative decisions to the minutest details, all aspects of health protection are affected by the principle of substantive equality. Predictive models may serve as a significant stride towards implementing this principle, as we will delve into shortly.

3. The blurred boundary between the clinical and the public health domains

Delineating the constitutional framework aids in capturing the core legal questions related to predictive modelling and population stratification in the clinical and public health domains. However, as we are going to demonstrate, the boundary between these two domains remains blurred, giving rise to intertwined legal concerns.

Said interconnection is particularly evident in Ministerial Decree No. 77/2022,[30] i.e. the regulation for the reorganisation of healthcare and implementing the Italian National Resilience and Recovery Plan (PNRR), from now on 'DM 77.'[31] DM 77 explicitly asserts that

[29] Same goes, more generally, for the adoption of Essential Levels of Services (*Livelli essenziali delle prestazioni*, LEP) pertaining to civil and social rights, as per art. 117, par. 2, lett. *m*), Cost. Further on LEP as «economic measure of equality» in F. Saitto, *La legge delega sul "*federalismo fiscale*": I livelli essenziali delle prestazioni come* misura economica dell'eguaglianza, in *Giur cost.*, no. 5, 2010, 2827 ff. Se also M. Belletti, *I "livelli essenziali delle prestazioni" alla prova del "coordinamento della finanza pubblica". Alla ricerca della "perequazione" perduta*, in M. Sesta (a cura di), *L'erogazione della prestazione medica tra diritto alla salute, principio di autodeterminazione e gestione ottimale delle risorse sanitarie*, Rimini, 2014, pp. 101 ff. On LEA, see, at least, M. Luciani, *I livelli essenziali delle prestazioni in materia sanitaria tra Stato e Regioni*, in E. Catelani, G. Cerrina Feroni, M. C. Grisolia (eds), *Diritto alla salute tra uniformità e differenziazione. Modelli di organizzazione sanitaria a confronto*, Torino, 2011; F. Pizzetti, *La ricerca del giusto equilibrio tra uniformità e differenza: il problematico rapporto tra il progetto originario della Costituzione del 1948 e il progetto ispiratore della riforma costituzionale del 2001*, in *Le Regioni*, no. 4, 2003, 599 ff.; L. Trucco, *Livelli essenziali delle prestazioni e sostenibilità finanziaria dei diritti sociali*,

[30] Regulation «containing the definition of models and standards for the development of territorial healthcare in the National Health Service».

[31] It is divided into a normative and a descriptive part. On the state of the art of the implementation of Mission 6 of PNRR see Aa.Vv., *La nuova sanità territoriale: realtà o illusione?*, in *Corti Supreme e Salute*, no. 2, 2023, pp. 301 ff.: in particular for critical remarks on DM 77 see M. D'Arienzo, *Verso un sistema di unità sanitaria? Luci e ombre del DM 77/2022*, in *Corti Supreme e Salute*, no. 2, 2023, pp. 309 ff. Further on the PNRR-driven healthcare reform and prospective trends in e-health F.G. Cuttaia, *Il recupero della centralità del diritto alla salute. Prospettive di riforma del Servizio Sanitario Nazionale*, Torino, 2022, pp. 125 ff.

risk stratification is pivotal to «*Medicina di Popolazione*»[32], which translates to Population Health Management or Population Health Improvement. These two terms are frequently used interchangeably to characterise actionable public health policies, aiming at optimising the overall health of a population.[33] DM 77 refers to *Medicina di Popolazione* as an approach to the delivery of efficient healthcare services which «promotes the well-being of the entire population, including those who may not actively seek healthcare», thus linking Population Health Management/Improvement to the concept of so called «*Sanità di iniziativa*» (i.e. Proactive Healthcare). This approach emphasises taking early and preventive actions to maintain and improve one's health, implying prevention, education, early intervention, case finding and conducting targeted screenings, contrary to the traditional model of healthcare, involving patients seeking medical assistance only when they have developed illnesses.[34]

[32] DM 77 defines *Medicina di popolazione* as a method aimed at «promot[ing] the health of the target population through the use of stratification models and the identification of health needs based on data», see Annex I, § 3 titled «Population stratification and demographic conditions of the territories as a tool to analyse healthcare needs, aimed at planning and care management».

[33] Uncertainty in terminology affects both literature and official documents. According to M. Swarthout and M.A. Bishop the term Population Health Improvement emphasises the necessity of «reach[ing] patients who do not seek healthcare through traditional delivery models and includes greater emphasis on factors traditionally unrelated to healthcare, including education, employment, and the physical environment». On the other hand, Population Health Management is frequently defined as the effective allocation of a predetermined budget to provide healthcare, concentrating on customising interventions for patients according to their risk levels. Population Health Management is concerned with the entire patient population, ranging from those with minimal health risks to those with complex health conditions. Its objective is to slow down the progression of risk within the patient population while simultaneously diminishing costly healthcare services, such as visits to the emergency department. M. Swarthout, M.A. Bishop, *Population health management: Review of concepts and definitions*, in *American Journal of Health-System Pharmacy*, no. 18, 2017, p. 1408. Along with Population Health Management and Population Health Improvement several other terms commonly employed in the field would benefit from a universally accepted definition. Consider the term Predictive Healthcare (English equivalent for '*medicina predittiva*') which is used to refer to «an approach that, before and/or after birth, aims to discover and evaluate probabilistically the factors that, for a specific person in a given context, may predispose to the onset of a disease», according to the Italian Ministry of Health's website (URL: https://www.salute.gov.it/portale/gard/dettaglioContenutiGard.jsp?id=1644&area=gard&menu=attivita). Predictive Healthcare appears thus to be more closely tied to the clinical domain rather than to the realm of public health services, expressing «the possibility of identifying different levels of risk and communicating them accurately in the patient-care relationship» R. Balduzzi, *Protezione e tutela della persona: lo sguardo delle scienze giuridiche*, in F. Anelli, A. Cesario, M. D'Oria, C. Giuliodori and G. Scambia (eds), *Persona e medicina. Sinergie sistemiche per la Medicina Personalizzata*, Milano, 2021, p. 270. In this view, Predictive Healthcare forms a «segment» of Personalised Healthcare, i.e. the approach that leads to the centrality of the specific person in the field of contemporary healthcare services and systems, shifting «from the evaluation in terms of 'categorical' appropriateness [of care], which is related to classes of patients/treatments, to appropriateness linked to the specific individual situation» (*ivi*, p. 269; appropriateness, in this context, is to be understood as clinical appropriateness). 'Preventive Healthcare' or 'Preventative Healthcare' is normally placed within the clinical domain and, like Predictive Helathcare, is a segment of Personalised Healthcare. It is true, in fact, «that not everything can be demanded of prevention since there is a different individual predisposition to risk factors and situations – and therefore preventive healthcare should not, rightly, be understood as a term overlapping with personalised healthcare – [but] it is accurate that, by drawing on genetic knowledge, appropriate preventive care can be provided, and therefore prevention (primary, secondary, tertiary) cannot be ignored» (*ivi*, pp. 269 f.).

[34] Notably, DM 77 defines *Sanità di iniziativa* as «an assistance model for the management of chronic diseases based on proactive care for individuals, from prevention and health education phases to early and advanced stages of the medical condition».

In summary, providing a thorough understanding of the evolving health needs of a population, risk stratification techniques serve a dual objective. Firstly, they aim at attaining a more efficient distribution of resources among different territorial and functional sectors of public health services and improving the overall health of the population through public health policies tailored to specific clusters. This is in line with the more 'managerial' aspect of Population Health Management/Improvement. Secondly, these techniques can facilitate targeted initiatives for individuals through a proactive approach, thus entailing engagement with general practitioners at an individual level and enhancing personalised care.[35] This is explicitly pointed out in DM 77 where it states that risk stratification techniques should help structuring the individual «*Progetto di Salute*» (Health Plan), allowing for «an evaluation that operates on two levels: the individual level, where the Health Plan and its related interventions are defined for each person; and the population level, which is useful for the planning and assessment of the results achieved by healthcare and social healthcare services within the reference community».

Now, the blurred line between clinical and public health sectors gives rise to intricate legal issues: the dimensions of the right to health as a freedom and as a social right, as well as the 'objective' protection of health as a collective interest are ultimately all to be considered. Moreover, while predictive models for public health primarily serve the organisational aspect of appropriateness, they may also uncover insights relevant to the evaluation of clinical appropriateness. This is particularly evident with regards to data-driven healthcare preventive measures.

As previously underlined preventive measures primarily contribute to the objective protection of health. It is important to note that this aspect remains unchanged even as preventive measures evolve from general population-based approaches to more targeted and personalised strategies. In other words, while care becomes more customised through Population Health Management and Proactive Healthcare tools, it does not automatically translate into an individual entitlement to these services from healthcare institutions and professionals. Nevertheless, the enhancement of organisational and clinical protective standards through innovative tools is consistent with the gradual implementation of Art. 32, aligning with its programmatic nature.[36]

[35] For a definition of Personalised Healthcare, see *supra*, footnote 33.

[36] Cf. the thoughtful considerations on the risk of underutilising AI in public health and the Republic's obligation to offer technologically advanced services by U. Pagallo, *Il dovere alla salute. Sul rischio di sottoutilizzo dell'intelligenza artificiale in ambito sanitario*, Sesto San Giovanni, 2022, pp. 10 ff.

4. The Italian Ministry of Health's predictive model: first steps and state of the art

The implementation of a stratification system and a predictive model to forecast the evolution of healthcare needs in Italy has been on the Ministry of Health's agenda for some time. Within the framework of the strategy outlined in the National Operational Programme on Governance and Institutional Capacity (PON GOV) 2014-2020,[37] the project «Analysis of production factors for resilience and development of the National Health Service»[38] was indeed initiated. It concluded in November 2020 after approximately two years of activity, during which the General Directorate of Health Programming at the Ministry of Health conducted a complex preparatory work by building a prototype version of the model. Subsequently, in a second project phase – contingent upon the legal possibility of accessing information flows from the New Healthcare Information System (NSIS)[39] – the Ministry developed the Predictive Model 2.0,[40] completing it in September 2022.[41]
The continuation of this project's objectives is currently part of the National Recovery and Resilience Plan.[42] To implement the PNRR the Ministry of Health issued the already mentioned DM 77 which adopts a national unique risk stratification model. Given that stratification methodologies developed at the academic, international, and regional levels are

[37] The National Operational Programme on Governance and Institutional Capacity is one of EU Cohesion Policy instruments devised for the 2014-2020 cycle, financed through the European Structural and Investment (ESI) Funds. It supports the implementation of strategic priorities in the field of public administration enhancement and innovation.

[38] The official website of the project can be found at the following URL: https://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=5600&area=programmazioneSanitariaLea&menu=progetti.

[39] Further on the NSIS and data protection *infra*, § 7.

[40] The official website of the follow-up project can be found at the following URL: https://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=5987&area=programmazioneSanitariaLea&menu=progetti.

[41] This preliminary work achieved some important results, including: «the study of major predictive and/or population stratification models developed at the regional, academic, and international levels; the examination of all health prevention and promotion programs aimed at improving the quality of life for both chronic and non-chronic individuals; the development of a prototype model for classifying the chronic population and stratifying those receiving care, designed to be fed by NSIS data flows and adaptable for identifying prevalent pathological profiles based on resource utilisation or socio-assistance risk class […]; an initial outline of the 'logical map' of the Predictive Model, with a particular focus on defining the 'trend scenario' to create a forecast for the overall evolution of the national healthcare system in its 'inertial situation.' Additionally, there is an initial analysis and design of the new components constituting the 'programmatic scenario'». Cf. General Director's Decree of April 18, 2023, approving the Operational Plan of the General Directorate of Health Programming (DGPROGS) for Mission 6 'Health,' Component 2 - Investment 1.3.2: "*Technological Infrastructure of the Ministry of Health and Data Analysis and Predictive Model to ensure Italian Essential Levels of Assistance (LEA) and Health Surveillance and Oversight. Sub-investments: Conceptualization of the Predictive Model*."

[42] In particular, Sub-investment 1.3.2. of Mission 6, Component 2. As stated in the Ministerial Decree of April 1, 2022, from the Ministry of Health outlining the allocation of investments and sub-investments for the National Recovery and Resilience Plan, sub-investment 1.3.2.3 allocates 77 million euros for «Ministry of Health's technological infrastructure and data analysis, predictive model for LEA monitoring», of which approximately 22 million euros, according to Sub-investment 1.3.2.3.1, are designated for the «conceptualization of the model, development of the algorithm, and project governance of the simulation and forecasting model for medium and long-term scenarios in the SSN».

very diverse, the adoption of a single national stratification model – and thus a «uniform language» – is key for «equitable access and homogeneous care management».[43]
Moreover, the model stratifies population according to their «level of healthcare and social needs» («*livello di bisogno socioassistenziale*») based on «information on clinical and social condition and further individual needs and preferences». The aim of population stratification as set out by DM 77 is clear: a holistic assessment of individual needs, taking into account health conditions as well as social, economic, and also environmental factors, in line with the so-called Planetary Health approach.[44]
This model consists of six risk levels, ranging from Level I (healthy individuals) to Level VI (end-of-life individuals). For each cluster the model identifies the type of clinical/social condition, the level/intensity of care needed, and the type of actions that the SSN must undertake (from primary prevention actions to coordinated multi-professional care actions). One of the main short-term challenges for the Ministry[45] is to adapt the prototype version of the predictive model to the six-levels stratification model outlined in DM 77. Preliminary

[43] DM 77, p. 17.

[44] The concept is undoubtedly related to the 'One Health' paradigm. One Health was defined in June 2021 by the One Health High-Level Expert Panel and the Quadripartite (Food and Agriculture Organization of the UN, the World Organisation for Animal Health, the UN Environment Programme, and WHO) as «an integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals, and ecosystems. It recognizes the health of humans, domestic and wild animals, plants, and the wider environment (including ecosystems) are closely linked and interdependent. The approach mobilizes multiple sectors, disciplines, and communities at varying levels of society to work together to foster well-being and tackle threats to health and ecosystems, while addressing the collective need for healthy food, water, energy, and air, taking action on climate change and contributing to sustainable development». Zoonosis, a fundamental aspect of One Health studies, has been brought to the forefront by the Covid-19 pandemic. Consequently, it is not coincidental that the term One Health has been integrated into programmatic plans and legislative proposals presented to the Italian Parliament since 2020. Specifically Italian documents refer to the concept of Planetary Health as «the more advanced vision of the One Health approach» (cf. the National Prevention Plan 2020-2025, p. 22) or an «evolution» of the One Health integrated approach (cf. Art. 27, par. 2, D.L. No. 36/2022, so called 'PNRR2 Decree', converted in Law No. 79/2022). Although the two terms remain close, their distinction appears to lie in the fact that while the One Health approach remains more focused on the relationship between humans, animals, and the environment, Planetary Health – closer to the idea of sustainable development embodied by the Agenda 2030 – sheds light on socio-economic factors and how they influence the relationship between the three, «emphasising the importance of safeguarding the needs of communities and vulnerable individuals or those in vulnerable situations, in alignment with principles of equity and proximity» (Art. 27, par. 2, PNNR2 Decree). Refer to G. Ragone, *One Health and the Italian Constitution, between eco-centric impulses and new perspectives for the protection of human, environmental, and animal health*, in *Corti Supreme e Salute*, n. 3, 2022, p. 822, and *ivi* for additional insights into the concept of One Health in the PNRR and its implementation, particularly through the establishment of the National System for Prevention and Health from Environmental and Climatic Risks (*Sistema nazionale prevenzione salute dai rischi ambientali e climatici*). See also S. Rossa, *Riflessioni giuspubblicistiche in merito alle teorie Nudge e One Health*, in *Corti Supreme e Salute*, n. 2, 2023, pp. 836 ff. and further contributions in the same dedicated special section of *Corti Supreme e Salute*, n. 3, 2022, "One World, One Health…Wich law?". Cf. also L. Violini (eds), *One Health. Dal paradigma alle implicazioni giuridiche*, Torino, 2023; C.D. Butler, J. Dixon, A.G. Capon (eds), *Health of People, Places and Planet. Reflections based on Tony McMichael's four decades of contribution to epidemiological understanding*, 2015, ANU Press.

[45] The implementing entities for the sub-investments related to the construction of the predictive model are the General Directorate of Health Programming (DGPROGS) and the General Directorate of Digitalization, the Healthcare Information System, and Statistics (DGSISS). The DGPROGS is identified as the implementing entity for the conceptualization of the model, algorithm development, and project governance (sub-investment 1.3.2.3.1), while for the design and construction of the tool (sub-investment 1.3.2.3.2), the implementing entity is DGSISS, with the support of DGPROGS.

steps include the implementation of the National Health Register (FSE) and the National Register of Beneficiaries (*Anagrafe Nazionale Assistiti*)[46] and the adoption of new informational flows both included in the NSIS (e.g., with reference to primary care, territorial rehabilitation, community hospitals, and counseling centers) and extra NSIS (such as cancer registries, disease registries, population surveillance on behavioral risk factors, and prevention programs).[47]

5. *Segue*: a multifaceted aim

Some further reflection deserves the aim of this ambitious and long-term project. Upon reviewing the opinion dated March 5, 2020 released by the Italian Data Protection Authority[48], it becomes apparent that the objective of the Ministry's stratification tool and predictive model is fundamentally twofold: firstly, to aspire towards a more equitable allocation of the National Health Fund (*Fondo Sanitario Nazionale*, FSN) among ordinary regions, a distribution at the time predicated solely upon a notably imprecise proxy of healthcare needs, namely, age.[49] Secondly, to fulfil «additional purposes [...] related to the concepts of 'predictive healthcare or 'proactive healthcare'».

Setting aside the previously underscored uncertainty in terminology,[50] upon examining this opinion alongside DM 77, it becomes apparent that continuity is explicitly granted to the second objective. DM 77 clearly states that the core objective of the ongoing project is to evaluate the outcomes conducted by healthcare and social services and allow for the monitoring of Essential Levels of Care, which must be ensured across the entire territory to facilitate targeted and timely interventions through proactive initiatives and well-structured planning. Furthermore, it explicitly mentions the concepts of Population Health Management/Improvement and Proactive Healthcare initiative, emphasising their tight correlation. Conversely, the first objective, though it has been on the agenda of the Ministry during the first phases of the project, conducted in the framework of PON GOV 2014-2020, is not

Refer to the already mentioned decree of the General Director of DGPROGS dated April 18, 2023, and the decree of the General Director of DGSISS dated March 18, 2022, wherein they approved the respective operational plans.

[46] Established by art. 62-*ter*, D.L. No. 82/2005 and DPCM June 1, 2022 (which received the Garante's greenlight on February 24, 2022).

[47] In these terms Stefania Vasselli, an executive at DGPROGS, spoke at the final national gathering for the dissemination of the results of the Joint Action JADECARE (Joint Action on the implementation of person-centered integrated care supported by digital technologies), held in Rome on September 20, 2023.

[48] Refer *infra* for further details on this opinion.

[49] See *infra* for an in-depth analysis of the public health financing system and recent normative changes regarding the allocation formula.

[50] In Italian «*medicina predittiva o di iniziativa*»; on these concepts see *supra*, footnote 33. It is noteworthy that in the passage, the use of the disjunction ('or') suggests that Predictive Healthcare and Proactive Healthcare are synonyms or very closely related concepts, whereas there are some fundamental differences.

explicitly stated in DM 77. The latest ministerial decrees implementing the PNRR emphasise that the goal is to create a «predictive healthcare planning dashboard» by 2026, which will allow for: *i*) analysing and monitoring the performance of the SSN at both central and regional/local level, integrating all available databases and monitoring tools,[51] and simulating the impact of healthcare planning interventions (e.g. normative interventions, hospital network reorganization, spending limit adjustment); *ii*) projecting the 'inertial' health demand and healthcare costs over a 20-30 year time horizon, taking into account the demographical, epidemiological and lifestyle changes, and simulating the impact of new measures on specific clusters of diseases and value-based public health policies.[52]
However, the original aim of ensuring a more equitable allocation of State's resources among regions addresses a crucial aspect of the Italian decentralised healthcare system: the tension between holding individual regions accountable for efficient resource utilisation and bridging the enduring gap between southern and northern regions.[53] As mentioned above, the pursuit of a fairer distribution of the National Health Fund is in line with the calls for equity that inspired the very establishment of the National Health Service.[54] These reasons underscore the imperative for a thorough examination of the topic.

6. Funding of the Italian healthcare system: significance of healthcare needs indicators and potential role for predictive models

The financing of the Italian healthcare system and the distribution of the National Health Fund have long been based on the criterion of 'historical expenditure', i.e. how much regions have spent in the past to provide healthcare services. The financing mechanism is currently regulated by Legislative Decree No. 68/2011 (from now on, D.lgs. No. 68/2011)[55] which implemented so-called 'fiscal federalism':

[51] information (including databases and existing monitoring tools, e.g. LEA and the New Guarantee System, funding, healthcare mobility, waiting lists, outcomes, networks, healthcare infrastructure, etc.),

[52] See the already mentioned General Director's Decree of DGPROGS dated April 18, 2023, p. 6.

[53] See C. Abbafati and F. Spandonaro, *Costi standard e finanziamento del Servizio sanitario*, in *Politiche sanitarie*, vol. 12, no. 2, 2011, p. 47. Furthermore, the 2023 report from the Centre for Applied Economic Research in Health (CREA Sanità) on "Regional performance" provides an analysis of the performance of regions in health protection based on indicators such as equity, outcomes, appropriateness, innovation, economic-financial dimension, and social dimension. It is important to highlight that disparities in morbidity and mortality are to be found also at the regional and sub-local level: consider, for example, urban peripheries, cf. V. Molaschi, *La tutela della salute nelle periferie*, in *Nuove Autonomie*, no. 3, 2016, pp. 455 ff.

[54] See *supra* § 2 on the multi-level implementation of the principle of substantive equality.

[55] Implementing Law no. 42/2009 which delegated the Government to adopt a legislative decree on fiscal federalism according to Art. 119 of the Constitution. Among the earliest contributions on the topic, see G. Rivosecchi, *La legge delega sul federalismo fiscale e il coordinamento della finanza pubblica e del sistema tributario: la difficile quadratura del cerchio*,

Notably, within the realm of healthcare, the departure from a distribution method based on how much regions historically spent to provide healthcare services had already occurred long before 2011.[56] During the latter half of the 1990s, a budget distribution system was already instituted which made a shift in the financing criterion: from an orientation based on supply to one centred on demand, distributing finances through a 'weighted' *per capita* allocation. This implies that, for estimating healthcare needs and the resources required to meet them, each region should receive resources proportional to its population size; however, corrective criteria are also applied to align the estimate of healthcare needs with the actual demand.

Notably, it has been contended that this system has not substantially changed following the introduction of the new financing system of D.lgs. No. 68/2011. The intricate procedure implies calculating the 'standard cost'[57] which embodies the weighed mean *per capita* expenditure at an aggregate level across three benchmark regions.[58] Several economists have contended that the outcome of the distribution of the National Health Fund[59] remains

in A. De Petris (eds), *Federalismo fiscale "*learning by doing*": modelli comparati di raccolta e distribuzione del gettito tra centro e periferia*, Padova, Cedam, 2010, 134 f.

[56] See E. Caruso and N. Dirindin, *Costi e fabbisogni standard nel settore sanitario: le ambiguità del decreto legislativo n. 68 del 2011*, in *Quaderni del Dipartimento di Economia, Finanza e Statistica*, no. 100, 2011, pp. 7 ff.; G. Crisafi, *Fascicolo sanitario elettronico: "profilazione" e programmazione sanitaria*, in *federalismi.it*, no. 5, 2021, pp. 112 ff. The previous system gave rise to inefficiencies and budgetary deficits. Such inefficiencies also occurred because the state did not establish the essential levels of services, thus shifting decision-making centers of expenditure onto local authorities: indeed, «[o]nly the pursuit of uniform standards at a central level can help bridge the gap between determining services and calculating needs» (G. Rivosecchi, *La determinazione dei fabbisogni standard degli enti territoriali: un elemento di incertezza nella via italiana al federalismo fiscale*, in G. Campanelli (eds), *Quali prospettive per il federalismo fiscale? L'attuazione della legge delega tra analisi del procedimento e valutazione dei contenuti*, Giappichelli, Torino, 2011, p. 184 f.). See also C. Pinelli, *Sui "livelli essenziali delle prestazioni concernenti i diritti civili e sociali" (art. 117, co. 2, lett. m, Cost.)*, in *Diritto pubblico*, 2002, 883 f.; R. Balduzzi (eds), *La sanità italiana alla prova del federalismo fiscale*, Bologna, 2012.

[57] The 'standard cost' is calculated separately for each of the three macro-levels (collective care 5%, district care 51%, and hospital care 44%).

[58] The three benchmark regions are selected in consultation between the State and Regions, from amongst five regions identified by the Ministry of Health and the Ministry of Economy and Finance, all of which either attain or approximate economic and financial equilibrium. We could very approximately state that the standard cost is how much every region, if it were virtuous, should spend on average to address the healthcare needs of one resident. However, this assumes that if the benchmark Regions are in financial equilibrium, then the other Regions should also be able to achieve it (for some critical remarks, see C. Abbafati and F. Spandonaro, *Costi standard*, cit., p. 49. See also A. Brancasi, *Uguaglianze e diseguaglianze nell'assetto finanziario di una Repubblica federale*, in *Diritto pubblico*, no. 3, 2002, pp. 909 ff. who highlights that to produce identical performances from both a qualitative and quantitative perspective, local authorities incur different costs). Once the standard cost is determined, it is then applied to each regional population weighed through the already mentioned corrective criteria. The result is a percentage distribution of resources known as 'regional standard needs'. Finally, the regional standard need is multiplied by total amount of resources necessary for guaranteeing the Essential Levels of Care which has been determined at the initial stage through a negotiation between the State and Regions, known as 'standard national healthcare needs'. The total expenditure is thus determined *ex ante* based on macroeconomic considerations (C. Abbafati and F. Spandonaro, *Costi standard*, cit., p. 49. Similarly, E. Caruso and N. Dirindin, *Costi e fabbisogni standard*, cit., p. 11). Thus, the number of resources allocated to each region is calculated.

[59] *Rectius*, of the 'standard national healthcare needs', cf. footnote 58.

indifferent to which regions are designated as benchmarks depending the result ultimately on the criteria employed to weigh the *per capita* allocation.[60]
According to art. 34 of Law No. 662/1996 said criteria may include factors such as «resident population, healthcare utilisation rate categorised by age and gender, mortality rates, linked to specific territorial circumstances deemed valuable in delineating the healthcare needs of specific regions and territorial epidemiological indicators».[61]
From the mid-1990s to 2005, factors such as age structure of the population, infant and perinatal mortality, and population density were utilised as correction factors for regional needs. However, starting from 2006, the allocation formula was modified by eliminating factors related to mortality and population density.[62] Consequently, the only applied criteria were based on healthcare utilisation rate and the age factor.[63]
The corrective criterion of age assumes that older cohorts necessitate increased healthcare; a premise that holds true. However, it functions as a somewhat imprecise proxy of healthcare needs. Several additional factors, including mortality rates, as well as socio-economic elements such as educational achievements, employment status, and underprivileged housing conditions, can contribute to healthcare disparities, consequently amplifying the need for healthcare services.[64] Hence, these factors should be taken into account to attain a more equitable distribution of financial resources among regions.
The pursuit of aligning funding with actual needs suggests an interpretation of Essential Levels of Care as «constructed as rights», contrasting with a view of essential levels «as entities of supply».[65] When viewed as entities of supply, meeting the Essential Levels of Care implies an obligation on public powers to deliver a specific standard of relevant services. Conversely, when considered as rights, essential levels mandate the service provider to

[60] See E. Caruso and N. Dirindin, *Costi e fabbisogni standard*, cit., p. 21 and C. Abbafati and F. Spandonaro, *Costi standard,* cit., p. 48, also for further economic bibliography on the subject.

[61] As stipulated in Art. 1, par. 34, Law No. 662/1996, which also states that the definition of the weights to be assigned to these factors is decided by the Interministerial Committee for Economic Planning (CIPE), upon the proposal of the Minister of Health, in agreement with the Permanent Conference for Relations between the State, the Regions, and the Autonomous Provinces of Trento and Bolzano. This provision is referred to in Art. 27, par. 7, D.lgs. No. 68/2011, which establishes that «Starting from the year 2015, the weighs are defined by decree of the Minister of Health, in agreement with the Minister of Economy and Finance, after consultation with the Permanent Conference for relations between the State, regions, and the Autonomous Provinces of Trento and Bolzano, based on the criteria provided for in Article 1, paragraph 34, of Law 23 December 1996, No. 662».

[62] E. Caruso and N. Dirindin, *Costi e fabbisogni standard*, cit., p. 8.

[63] The situation has recently changed following the publication of the Ministerial Decree issued on December 30, 2022, see *infra*.

[64] On social determinants of health and their impact on health inequalities, see at least the Report of the World Health Organisation's Commission on Social Determinants of Health's report published in 2008, link: https://www.who.int/publications/i/item/WHO-IER-CSDH-08.1. Further on the Commissions' genesis, method of work and the lesson it provided about the nature of global governance for health in R. Bell, S. Taylor, M. Marmot, *Global Health Governance: Commission on Social Determinants of Health and the imperative for Change*, in *Journal of Law, Medicine and Ethics*, 2010, pp. 470 ff.

[65] Referring to Essential Levels of Services, see A. Brancasi, *Uguaglianze e diseguaglianze*, cit., pp. 927 f.

fully meet the demand for services, regardless of its magnitude, provided that the demand meets conditions required by the law. Consequently, this implies an overall expenditure proportionate to the demand for services and, therefore, to the needs that these services aim to satisfy. Since needs vary among different communities, the financial burdens each local authority must bear are diverse. Financing systems must, therefore, incorporate mechanisms capable of responding to the varying allocation of needs.

Following this approach, a more accurate indicator of healthcare needs, rather than solely relying on age, has been identified in what is known as the 'deprivation' index. This index signifies the «absence of a range of cultural, social, and economic resources essential for maintaining good health».[66] After considering age and gender, it emerges as the most significant proxy for assessing health needs. [67]

To accomplish this goal, the key would be classifying National Health Service users based on their individual health status, associated with their economic and social situation: in a word, the answer would be population stratification. This implies interconnecting information streams from the healthcare system – which are already mandated by Art. 27, par. 2 of D.lgs. No. 68/2011 to serve as an information source for determining the 'regional standard costs' and 'regional standard needs' – with a number of other information sources from other public administrations, e.g. income information available through the tax registry, mortality records from the National Institute of Statistics (Istat), and regional databases containing exemption codes for medical conditions. This operation undeniably raises a series of ethical and legal issues – primarily concerning privacy and the protection of personal data – that will be analysed in the following paragraph.

In a recent effort to better align the allocation of the National Health Fund with actual healthcare needs, there has been a revision in the allocation formula. On March 13, 2023, the Ministerial Decree issued on December 30, 2022, titled «Definition of new criteria and weights related to the allocation of the national health standard need», was officially published in the Official Journal. Alongside the «resident population» and the «healthcare utilisation rate categorised by age», this decree introduces two novel criteria: the «mortality rate» (among the population under 75 years) and «indicators linked to specific territorial circumstances deemed valuable in delineating the healthcare needs of regions». The latter should reflect the «socio-economic conditions of the population, considered a proxy for healthcare needs». The decree thus identifies these indicators in *i*) individual relative poverty, *ii*) the level of low education in the population, and *iii*) the unemployment rate.[68]

[66] AGENAS, *Riflessioni sui criteri da utilizzare per il riparto del fabbisogno sanitario. Relazione commissionata dalla Conferenza delle regioni e delle province autonome*, Roma, 30 aprile 2010, p. 34.

[67] *Ivi*, p. 5. See also L. Cuocolo, *I "costi standard" tra federalismo fiscale e centralismo*, in R. Balduzzi (eds), *La sanità italiana alla prova del federalismo fiscale*, Bologna, p. 112.

[68] Subsequently, the decree assigns weights to these criteria, allotting 98.5% of resources based on resident population and healthcare utilisation rates, calculated through the standard cost procedure outlined in Art. 27 of D.lgs. 68/2011. Fur-

The newly introduced criteria will need further assessment concerning their effectiveness in genuinely promoting a more equitable distribution of the National Health Fund. However, the Ministerial Decree also offers useful insights regarding the criteria omitted in the allocation – and the reasons behind such exclusions. The omitted criteria encompass that of «healthcare utilisation rate categorised by gender» and «territorial epidemiological indicators». In the first case, the inability to incorporate this criterion into the decree stems from the fact that «the New Healthcare Information System provides data exclusively classified by age groups and not by gender». In the second scenario, the obstacle is of a legal nature, specifically related data protection: the absence of a legal basis for processing those personal data.[69]

Once again, the crucial importance of data is underscored and the imperative to address the privacy risks for data subjects. This is especially pertinent in the context of population stratification and the creation of predictive models, considering that most of the data involved are health-related data[70] and possibly genetic data[71] – falling under the special category data with heightened safeguards as per Art. 9 of the General Data Protection Regulation (GDPR). Furthermore, the very link between those data a data of other sources to construct clusters of people it is ultimately profiling based on social economic and health status and the use of automated processing techniques suggests that Art. 22 GDPR concerning automated decision making could apply. To gain a thorough understanding of how population stratification and predictive modelling are regulated is therefore necessary to delve further into this aspect.

7. Striking the balance between data protection and public health: inadequacy of the regulatory framework and role of the *Garante*

As previously indicated, population stratification and the development of predictive models of healthcare needs require data from which to extract information about health status and social and economic situation. Unsurprisingly, the development of the Ministry's predictive model is rooted in a broader healthcare digitalisation project, aiming at creating a complete, accessible, interoperable information system. Cornerstone of the project is

thermore, 0.75% of resources are assigned based on the mortality rate, and 0.75% is determined by the comprehensive data resulting from the aforementioned socio-economic indicators, with each indicator carrying equal weight.

[69] Since the Minister of Health's decree outlined in Art. 7, par. 2 of Legislative Decree 34/2020 has not yet been enacted: see *infra* § 7.

[70] Defined by No. 15 of Art. 4 of the General Data Protection Regulation (GDPR).

[71] Defined by No. 13 of Art. 4 GDPR.

the establishment of the New Healthcare Information System (*Nuovo Sistema Informativo Sanitario*, NSIS).[72]

The NSIS is the primary source of information for determining 'regional standard costs' and 'regional standard needs' as explicitly stated by Art. 27, par. 2 of D.lgs. No. 68/2011. In broader terms, the NSIS aims to assist Regions and the Ministry of Health in the exercise of their functions by providing comprehensive, exhaustive, and timely information. Specifically, it supports the Ministry in ensuring the uniform application of Essential Levels of Care across the national territory.

The data flows of the NSIS encompass both the managerial, organisational, and economic aspects of the National Health Service, as well as analytical data documenting individual healthcare utilisation. The integration of the NSIS data flows is gradually shaping a comprehensive system of individual healthcare information. The interconnection of (pseudonymised) individual data at a national level for public health purposes was then implemented by Ministerial Decree No. 262 of 2016.[73]

Providing the NSIS with individual health information is primarily entrusted to the Electronic Health Record (*Fascicolo sanitario elettronico*, FSE). The FSE extends throughout the patient's lifetime and undergoes continuous updates by healthcare professionals and regional actors of the Italian National Health Service.

The evolution of the FSE and its regulation over time[74] demonstrates a rather slow but steady advancement which was then expedited by the COVID-19 pandemic and subse-

[72] The National Health Information System (NSIS), founded on Art. 87 of Law No. 388/2000 (Financial Law for 2001), became operational through the Framework Agreement between the State, Regions, and Autonomous Provinces of Trento and Bolzano stipulated on February 22, 2001.

[73] See Art. 7 of Ministerial Decree 262/2016. Governance purposes are identified referring to Art. 12, par. 2, lett. *c*) of Legislative Decree No. 179/2012. Thanks to this regulation, the Ministry of Health has assigned a unique national code to each beneficiary, allowing them to track their healthcare journey across various healthcare settings.

[74] Formally introduced at a national level by Art. 12 of Legislative Decree No. 179/2012 (from now on, D.L. 179/2012), the FSE has multiple objectives, including «healthcare planning, care quality and healthcare evaluation» (lett. *c*), par. 2, Art. 12 mentioned above). Before 2012 many regions had already initiated projects for local Electronic Health Records (FSE) systems. Hence, it is not surprising that prior to 2012 both the Italian Data Protection Authority (2009) and an interinstitutional table led by the Ministry of Health (2010) had adopted guidelines (the latter aiming at creating a nationwide unified model for Electronic Health Records). Notwithstanding these efforts, interoperability among different FSEs across regions was still the primary challenge. Hence, Prime Ministerial Decree No. 178/2015 (from now on, D.P.C.M. No. 178/2015), regulating the FSE as per Art. 7 of D.L. No. 179/2012, established that each region and autonomous province should implement the FSE through a technological infrastructure ensuring accessibility throughout the national territory and interoperability with other regions. Subsequently, the Budget Law for 2017 (Law No. 232 of 2016) expedited FSE's implementation nationwide. Notably, Art. 1, par. 382, amending Art. 12 of D.L. No. 179/2012, introduced Art. 15-*ter* to simplify the interoperability of regional FSE systems: the National Infrastructure for Interoperability (INI) was created, with design entrusted to Italian National Agency for Regional Healthcare Services (AGENAS) in collaboration with the Agency for Digital Italy, the Ministry of Health, the Ministry of Economy and Finance, and the regions and autonomous provinces. The use of FSE for governmental purposes was thus regulated by the aforementioned D.P.C.M. 178/2015, with Art. 19 specifying that the data may be used only if stripped of direct patient identifying information, adhering to the principle of data minimisation. Specific personal data of patients are explicitly excluded from processing for governmental purposes (e.g. name and surname, fiscal code, ID number, address). Then, the '*Rilancio*' Decree (Legislative Decree No. 34 of May 19, 2020) introduced significant reforms concerning the FSE in response to the Covid-19 pandemic. Notably, the requirement for data subjects' consent to feed the FSE was abolished, while consultation by authorised

quent reforms and EU fundings. Despite this momentum, regional disparities and structural differences still impede data circulation and interoperability, which inevitably hinders the National Health Service's e-Health ambitions.

In this evolution the Italian Data Protection Authority (*Garante per la protezione dei dati personali*, from now on, *Garante*) has played and continues to play a crucial role in calling for a fair balance between privacy and public health. Numerous decisions made by the *Garante* revolve around population stratification and predictive modelling initiatives carried out by various regions or local health units. For instance, the *Garante* provided opinions on the draft legislation and implementing regulations regarding Proactive Healthcare proposed by the Autonomous Province of Trento between May and October 2020.[75]

parties (doctors) remained contingent upon explicit patient consent. The FSE is thus automatically updated with data and documents related to healthcare events occurring after May 19, 2020. With the adoption of the National Recovery and Resilience Plan (PNRR), the enhancement of the FSE became a pivotal element of Investment 1.3, Component 2, Mission 6. Among the 4 main objectives of the FSE outlined in the FSE Working Group's Guidelines of March 27, 2022 (the relevant implementing body of M6 C2 Investment 1.3.1) is the establishment of a national database on the health status of the population to support health institutions and personalising clinical data. Finally, the most recent legislative changes (Art. 21 of Legislative Decree No. 4/2022, converted with modifications by Law No. 25/2022) amended Art. 12 of D.L. No. 179/2012, mandating the inclusion of data in the FSE within 5 days of healthcare provision. This requirement applies to both public and private (accredited or authorised) institutions, with potential sanctions for non-compliance. Furthermore, it is now explicitly stated that the FSE contributes to feeding the Health Data Ecosystem (*Ecosistema Dati Sanitari*, EDS). Legislative changes have also autonomously emphasised processing for prevention purposes (lett. a-*bis*), par. 2, Art. 12 of D.L. No. 179/2012) and included a reference to international prophylaxis (lett. a-*ter*) of the above-mentioned provision). In light of the numerous amendments to Art. 12 of D.L. No. 179/2012 after its implementation through D.P.C.M. 178/2015, it became imperative to implement those changes issuing a new regulation. The Ministry drafted a decree, which, after intense inter-institutional dialogue (and a negative opinion of the Garante on August 22, 2022) was greenlighted by the Garante on June 8, 2023, and was then issued on September 7, 2023, becoming known as the FSE 2.0 Decree. Of the vast literature on the FSE and data protection issues cf. at least L. Califano, *Fascicolo sanitario elettronico (Fse) e dossier sanitario: il contributo del Garante privacy al bilanciamento tra diritto alla salute e diritto alla protezione dei dati personali*, in *Sanità pubblica e privata*, no. 3, 2015, pp. 1 ff.; G. Comandé, L. Nocco, V. Peigné, *Il fascicolo sanitario elettronico: uno studio multidisciplinare*, in *Rivista italiana di medicina legale*, 2012, pp. 105 ff.; P. Guarda, *Fascicolo sanitario elettronico e protezione dei dati personali*, Trento, 2011; L. Ferraro, *Il Regolamento UE 2016/679 tra Fascicolo Sanitario Elettronico e Cartella Clinica Elettronica: il trattamento dei dati di salute e l'autodeterminazione informativa della persona*, in *BioLaw Journal*, no. 4, 2021, pp. 91 ff. On the latest regulatory innovations concerning the FSE cf. at least N. Posteraro, *La digitalizzazione della sanità in Italia: uno sguardo al Fascicolo Sanitario Elettronico (anche alla luce del Piano Nazionale di Ripresa e Resilienza)*, in *federalismi.it*, no. 26, 2021, pp. 189 ff.; G. Crisafi, *Fascicolo sanitario elettronico*, cit.; A.M. Gambino, E. Maggio, V. Occorsio, *La riforma del fascicolo sanitario elettronico*, in *Diritto Mercato Tecnologia*, 22 July 2020, pp. 1 ff. Focusing on the impact of the implementation of FSE on the division of competences between State and regions, cf. also C. Silvano, *La digitalizzazione dei servizi sanitari alla luce del riparto di competenze tra Stato e Regioni. Il caso del Fascicolo Sanitario Elettronico*, in *federalismi.it*, no. 26, 2023, pp. 228 ff.; N. Maccabiani, *Tra coordinamento informativo e livelli essenziali delle prestazioni: il caso del Fascicolo Sanitario Elettronico*, no. 12, 2023, pp. 250 ff.

[75] The opinion on the draft legislation from the Autonomous Province of Trento regarding Proactive Healthcare was dated May 8, 2020; while the opinion on the draft implementing regulations thereof was dated October 1, 2020. This legislation states that Proactive Healthcare should rely on profiling patients through algorithms. In this context, it was highlighted that the collection and processing of health data to create a health risk profile for individuals with specific conditions constitutes separate processing from treatments for care and diagnosis. Therefore, it is contingent upon the data subject's informed consent, as it involves automated processing not strictly necessary for health treatment purposes (see Artt. 9, par. 2, lett. *a*), and 22 of the GDPR).

Additionally, it imposed sanctions on the Local Health Unit of South-East Tuscany in December 2020,[76] and on three local health units in Friuli-Venezia Giulia in December 2022.[77] Notably, at national level, the *Garante* has issued an opinion addressing the predictive model developed by the Ministry of Health.[78] More precisely, the Italian Data Protection Authority was tasked with assessing the Ministry's proposal for a new allocation method of the National Health Fund among regions, which is based on population stratification. This assessment was necessary to determine if the proposal complied with data protection rules.[79] According to the *Garante*, population stratification based on health status and economic circumstances is ultimately a particular data processing, i.e. profiling, employing data from several different sources.[80] The *Garante* lamented that there was no valid legal basis for this profiling activity: Neither in Law No. 662/1996 (which outlines FSN distribution criteria), nor in D.lgs. No. 68/2011 (introducing the standard costs and standard needs system), nor in other legal provisions. Additionally, the *Garante* called for an impact assessment as per art. 35 GDPR and emphasised the need to adhere to principles regarding automated decision-making, particularly if the Ministry intends to implement Proactive Healthcare initiatives.[81]

Following the *Garante*'s opinion,[82] a legal basis for data processing for predictive purposes was introduced in Art. 7 of the '*Rilancio*' Decree.[83] The provision specifically regarded health-related data within the information systems of the national health service. Notably, during the conversion into law reference to income data of the data subject and their fam-

[76] In the decision issued on December 17, 2020, the *Garante* does not sanction the USL Toscana Sud Est Company, specifically in relation to the absence of a valid legal basis, despite mentioning the problem alongside the opinions provided to the Autonomous Province of Trento. The injunction addresses other matters, including the lack of a processing activities register, the failure to conduct a Data Protection Impact Assessment, and deficiencies in the information provided to patients regarding healthcare-related treatments.

[77] On December 15, 2022, the *Garante* fined each of the 3 Friulian Health Units €55,000 for breaching GDPR regulations in handling patient data. This violation was related to a project aimed at assessing Covid-19 risk among various patient groups. The sanctions were challenged in the Courts of Udine, Pordenone, and Trieste based on territorial competence. The Pordenone Court (ruling on October 13, 2023) and the Udine Court (ruling on September 21, 2023) annulled two of the *Garante*'s measures, arguing that the Health Units could not be deemed data controllers. Notably, the Udine Court also deemed secondary processing of health data for preventive purposes acceptable, stating its compatibility with the care and diagnosis processing. Alternatively, it stated the possibility of finding legal base in art. 9, lett. *i*) concerning public interest reasons. These ongoing legal cases will help to shed light on the balance between public health interests and personal data protection.

[78] Previously analysed with regards to the aim of said model, see *supra* § 5.

[79] The Ministry initially sought the opinion of the Council of State, but since the request fell within the *Garante*'s jurisdiction, the Council redirected it to the *Garante* for evaluation.

[80] Namely, the NSIS, the tax registry, mortality records, the Italian National Institute of Statistics (Istat), and regional exemption code registries.

[81] On the principles applicable to automated decision-making, see *infra* § 8.

[82] The *Garante* was also invited to participate in an interinstitutional working group aiming at developing the predictive model, alongside the Ministry and representatives from seven regions and one autonomous province (Lazio, Emilia-Romagna, Lombardy, Piedmont, Puglia, Toscana, Veneto, and the Autonomous Province of Bolzano),

[83] Legislative Decree No. 34, of May 19, 2020. Cf. *supra* footnote 77.

ily was omitted, thus excluding their processing from the scope of legal basis. The legislation refers to a regulation to be issued by the Minister of Health, which has not yet been adopted nor submitted for the necessary approval to the *Garante*.[84]

A couple of years later, the *Garante* was also involved in the transfer of data by eight regions[85] participating the Ministry of Health's project. Those regions were asked by the Ministry to provide aggregated health datasets of the relevant regional population. The *Garante* issued eight separate decisions dated February 24, 2022, sanctioning them for processing and aggregating a dataset without a proper legal basis.[86]

Meanwhile the regulatory framework for stratification had undergone further changes. Decree-Law No. 139/2021[87] introduced a provision (par. 2-*bis*) in Art. 7 of the '*Rilancio*' Decree which allows the Ministry of Health to engage in activities related to classifying chronic diseases present in the Italian population. This activity is limited to constructing preliminary analytical models for the development of predictive models for the population's health needs.

The same Decree-Law no. 139/2021[88] also allowed the Ministry of Health to process non-health data whenever necessary to the development of predictive systems for the evolving population health needs also mentioned above. To this end, interconnection between the FSE and information streams from other public administrations is permitted. This provision similarly references the regulation to be issued by the Ministry of Health. Without its issuance, there exists a potential risk that the data processing outlined in the article may lack a solid legal foundation.

The legal framework has been further enriched by the introduction of a provision[89] in Art. 2-*sexies* of the Privacy Code[90] which provides a legal basis for the processing and interconnection of pseudonymised health-related data by the Ministry of Health and various other institutions within the National Health Service, when functional to the pursuit of their own institutional objectives. However, also the implementation of this provision hinges on the issuance of regulations by the Ministry of Health. These regulations will outline the per-

[84] This regulation is meant to specify the types of personal data that can be processed for the purpose of developing predictive models of the evolution of population's health needs, the permissible operations, methods for data acquisition from the information systems maintained by data-holding entities, and the necessary measures to safeguard the rights of data subjects.

[85] More precisely, seven regions (Puglia, Veneto, Piemonte, Emilia-Romagna, Toscana, Lazio, Lombardia) and the autonomous province of Bolzano.

[86] It is crucial to underline that the law provides exclusively the Ministry of Health with a legal basis for processing personal data collected within the information systems of the National Health Service for developing predictive methodologies to understand the evolving health needs of the population. Importantly, this remains unchanged despite legislative interventions in 2021, as discussed further in the main text.

[87] Converted into L. 205/2021.

[88] Adding paragraph 1-*bis* to Art. 7 of the '*Rilancio*' Decree.

[89] Again, it is a paragraph 1-*bis*.

[90] Legislative Decree No. 196/2003. Art. 2-*sexies* implements Art. 9, par. 2, lett. *g*) GDPR.

missible types of data processing, the methods employed, and the necessary safeguards to uphold fundamental rights.[91]

From the examination of the data protection framework governing predictive modelling for public health several noteworthy aspects emerge: *i*) There is a discernible shift from a regulatory approach centred on data protection towards one that advocates for data governance and circulation when necessary for ensuring higher quality health services; *ii*) Within this evolving landscape, a constructive dialogue between the Data Protection Authority and the legislator is evident; *iii*) Given that legislative provisions often necessitate implementation through regulations crafted by the Ministry of Health, a robust exchange takes place between the Ministry and the *Garante*; in this interaction, the Ministry serves a dual role: subject to oversight by the Authority while also functioning as the regulatory body seeking guidance on data protection issues from the Authority; *iv*) However, due to delays in the Ministry's enactment of these regulations, significant gaps persist within the legal framework. We will now delve deeper into each of these points.

Firstly, legal literature highlights the transition from data protection to data governance occurring across various fields, including health.[92] This shift involves moving away from a consent-centric approach towards alternative legal bases outlined in Art. 6 of the GDPR, which are linked to exemptions under Art. 9 GDPR. Italian legislative initiatives closely mirror the evolving landscape at the European level, as articulated in the European Strategy for Data and corresponding regulations. This transition signifies a departure from a sole focus on data protection towards a broader framework of data governance, aiming to uphold robust safeguards for fundamental rights while embracing a human-centric approach. Key legislative instruments propelling this transition include the Data Governance Act,[93]

[91] Art. 2-*sexies* was recently amended by D.L. No. 19/2024, which was subsequently converted into Law. No. 56/2024. Several adjustments concerned par. 1-*bis* of Art. 2-*sexies* and a new paragraph 1-*ter* was introduced, which appears to largely rephrase the second part of the former paragraph 1-*bis*. Paragraph 1-*ter* stipulates that one or more decrees issued by the Ministry of Health will regulate the interconnection of information systems, including the FSE, among health institutions outlined in par. 1-*bis* and «other public administrations that need to adapt their information systems for this purpose». These decrees will establish «a secure processing environment where anonymous or pseudonymised data is made accessible to serve the institutional objectives of each entity». Further on health data processing for public interest: L. Durst, *Il trattamento di categorie particolari di dati in ambito sanitario*, in R. Panetta (eds.), *Circolazione e protezione dei dati personali, tra libertà e regole del mercato*, Milano, 2019, pp. 65 ff.; F. Pizzetti (eds.), *Protezione dei dati personali in Italia tra GDPR e Codice novellato*, Torino, 2021, 114 ff.; G. Lofaro, *Dati sanitari e e-Health europea: tra trattamento dei dati personali e decisione amministrativa algoritmica*, in *medialaws*, no. 3, 2022, pp. 179 ff.

[92] See, *ex multis*, A. Iannuzzi, *La governance europea dei dati nella contesa per la sovranità digitale: un ponte verso la regolazione dell'intelligenza artificiale*, in *Studi parlamentari e di politica costituzionale*, 2021, pp. 31 ff.; F. Giacomo, *Governance and processing of personal data in the Italian healthcare system in the light of EU principles,* in *Actualidad Juridica Iberoamericana*, no. 20, 2024, pp. 1052 ff.

[93] The Data Governance Act entered into force on 23rd June 2022 and is applicable since September 2023.

the Data Act,[94] and, notably within the healthcare domain, the European Health Data Space.[95]

Secondly, the evolution of data processing regulation for predictive modelling for public health underscores the emergence of a dialogue between the *Garante* and the legislator. For instance, legislative innovations such as those found in the '*Rilancio*' Decree and D.L. No. 139/2021 have followed the *Garante*'s remarks on the absence of a valid legal basis. Notably, legislative actions have been characterised by their emergency nature and reliance on decree-laws originating from the government as per art. 77 of the Italian Constitution.

However, delving into the third point, many of these legislative advancements alone are inadequate to fully establish the legal framework for the interconnection, stratification, and predictive activities of the Ministry of Health and other entities within the National Health Service. This is primarily because the implementation of these provisions often hinges on regulations by the Ministry of Health, subject to approval by the *Garante*. Consequently, the *Garante* has initiated a close dialogue with the Ministry of Health, which assumes a dual role. On one hand, the Ministry engages with the *Garante* as an autonomous data controller which profiles users within the national healthcare system. On the other hand, the Ministry acts as a regulatory authority seeking advice from the *Garante* in detailing the types of data that can be processed, the methods of processing, and the security measures necessary to protect the rights of data, as required by legislative provisions. This inter-institutional dialogue increasingly seeks to pre-empt unfavourable opinions, ensuring a privacy-by-design and privacy-by-default approach from the earliest drafting stages. Nevertheless, the pivotal role of the *Garante* is occasionally impeded. Legislative requirements mandating prior consultation of the *Garante* regarding ministerial and governmental regulations are sometimes disregarded. An illustrative case is the Ministry's implementation of DM 77 without obtaining the required opinion from the Data Protection Authority.

The failure in issuing the above-mentioned decrees by the Ministry of Health leads to the fourth point, i.e. the persistent inadequacy of the legal framework for stratification and predictive modelling. Many of those decrees are either still pending enactment or face challenges in obtaining approval from the *Garante*. Consider the opinion issued on June 8, 2023, regarding the FSE 2.0 Decree.[96] The *Garante*'s greenlight came after two unfavourable opinions in August 2022, one regarding the draft FSE 2.0 regulation and the other concerning the Healthcare Data Ecosystem, which triggered extensive interinstitutional dialogue between the *Garante* and the Ministry of Health. The FSE 2.0 Decree vividly illustrates the inadequacy of the legal framework, by excluding at least three crucial

[94] Which entered into force on 11th January 2024.

[95] The Proposal for a Regulation on the European Health Data Space was presented by the Commission on 3rd May 2022 (COM (2022) 197 final). On 15th March a political agreement between the European Parliament and the Council occurred and the text was adopted by the Parliament on 24th April.

[96] See footnote no. 74.

aspects from its scope. Firstly, it states that a separate decree will determine the specific components of the FSE used for developing predictive methodologies, as outlined in Art. 7 of the '*Rilancio*' Decree. Secondly, it specifies that another distinct decree will determine the specific components of the FSE subject to planned interconnections with other healthcare information systems, as indicated in Art. 2-*sexies*, par. 1-*bis* of the Code.[97] Lastly, in response to concerns raised by the *Garante* in the opinion of August 2022, the FSE 2.0 Decree also excludes processing for healthcare governance from its scope. As a result, these aspects continue to be regulated by the previous FSE Decree[98] until further specific decrees are adopted.[99]

8. Automated public health decision-making: from the GDPR to the Ai Act

It is crucial to note that, while the major privacy issues raised by risk stratification and predictive models for public health have been addressed by the legislator or can reasonably be expected to be addressed in the short to medium term by the Ministry of Health through its regulatory powers, the Italian Data Protection Authority will continue to play a pivotal role and closely monitor the subsequent developments of the Ministry's project. The GDPR contains indeed some provisions on automated decision making, which constitute the first albeit incomplete discipline of AI systems.[100]

Leaving a more comprehensive exploration to future studies, we thus wish to touch upon an aspect that has so far remained in the background, i.e. the applicability of regulations concerning automated decision-making and artificial intelligence (AI) to the subject matter of this study.

In absence of a comprehensive regulatory framework, the Italian Council of State was the first to address automated administrative decision-making. Unsurprisingly, in deriving three key principles indications from «supranational principles», it primarily referred to Art. 22 and Recital 71 of the GDPR. These three principles are: non exclusivity of the automated decision, knowability and understandability of the algorithm, and non-discrimination.[101]

[97] Now par. 1-*ter* following the entering into force of D.L. No. 19/2024 (see *supra* footnote 91).

[98] D.P.C.M. 178/2015.

[99] In accordance with Art. 12, par. 7, of D.L. No. 179/2012.

[100] See *ex multis* F. Pizzetti, *La protezione dei dati personali e la sfida dell'Intelligenza Artificiale*, in id (eds.), *Intelligenza artificiale, protezione dei dati personali e regolazione*, Torino, 2018, pp. 5 ff.

[101] See the decision of the Council of State, December 13, 2019, No. 8472. These principles have now been coded in the new Public Procurement Code (Legislative Decree No. 36/2023) at art. 30. Of the vast literature on these principles see at least A. Simoncini, S. Suweis, *Il cambio di paradigma nell'intelligenza artificiale e il suo impatto sul diritto costituzionale*, in *Rivista di filosofia del diritto*, no. 1, 2019, pp. 87 ff. On algorithmic administrative decision-making, see, *ex multis*, A. Masucci, *L'automatizzazione delle decisioni amministrative algoritmiche fra big data e machine learning*.

Predictive modelling for the evolution of the population's health needs challenges all these principles. Concerning human autonomy and non-exclusivity, policymakers are anticipated to increasingly depend on these predictive models for resource allocation, territorial healthcare services organisation, and proactive healthcare measures. Therefore, it is not too early to address the issue of ensuring non-exclusivity of the decision in practical scenarios: the challenges posed by automation bias, which inherently incline individuals to rely on the outcomes presented by machines, are widely recognised.[102] Additionally, knowability of the algorithm must be ensured, allowing healthcare decision-makers to understand the logic behind specific outputs. Similarly, when public health domains intersect with the clinical domain,[103] ensuring transparency is crucial for health practitioners and patients too. Finally, consistent challenges are posed to the principle of non-discrimination which are ultimately linked to the choice of health needs indicators as outlined *supra* in § 6.
The *Garante* will closely monitor the implementation of those principles, with a particular focus on the possible utilisation of artificial intelligence systems. Starting from the GDPR provisions on automated decision-making and the close nexus between data protection, secondary use and the development of AI software, the Italian Data Protection Authority has articulated the fundamental principles governing artificial intelligence:[104] consider, for example,

Verso l'algocratic governance?, in *Diritto e processo amministrativo*, no. 2, 2022, pp. 265 ff.; R. Rolli, M. D'Ambrosio, *L'algoritmo nella Pubblica Amministrazione. L'innovazione tecnologica come strumento di contrasto del virus Covid-19 e la necessità di una visione antropocentrica*, in *Il Diritto dell'economia*, no. 3, 2021, pp. 189 ff. Further on the constitutional principles governing AI: M. Fasan, *I principi costituzionali nella disciplina dell'Intelligenza Artificiale. Nuove prospettive interpretative*, in *DPCE online*, no. 1, 2022, pp. 181 ff.; C. Casonato, *Costituzione e intelligenza artificiale: un'agenda per il prossimo futuro*, in *BioLaw Journal*, Special Issue , no. 2, 2019, pp. 711 ff. Focusing on AI applications in the health sector, see also A. Spina, *La medicina degli algoritmi: Intelligenza Artificiale, medicina digitale e regolazione dei dati personali,* in F. Pizzetti (a cura di), *Intelligenza Artificiale, protezione dei dati personali e regolazione*, Torino, 2018, pp. 319 ff.; G. Fares, *Artificial intelligence in social and health services: A new challenge for public authorities in ensuring constitutional rights*, in M. Belov (eds.), *The IT revolution and its impact on State, constitutionalism and public law*, Oxford, 2021, pp. 269 ff.; D. Morana, T. Balduzzi, F. Morganti, *La salute "intelligente*, cit., 179 ff.; P. Guarda, L. Petrucci, *Quando l'intelligenza artificiale parla: assistenti vocali e sanità digitale alla luce del nuovo regolamento generale in materia di protezione dei dati*, in *BioLaw Journal*, no. 2, 2020, pp. 425 ff.; E.A. Ferioli, *L'intelligenza artificiale nei servizi sociali e sanitari: una nuova sfida al ruolo delle istituzioni pubbliche nel welfare italiano?*, in *BioLaw Journal*, no. 1, 2019, pp. 163 ff.; P. Guarda, *"Ok Google, am I sick?": artificial intelligence, e-health, and data protection regulation*, ivi, pp. 359 ff.; F. Aperio Bella, *L'accesso alle tecnologie innovative nel settore salute tra universalità e limiti organizzativi (con una postilla sull'emergenza sanitaria)*, in *Persona e PA*, no. 1, 2020, 219 ff.

[102] See at least W.N. Price II, *Medical AI and Contextual Bias*, in *Harvard Journal of Law & Technology*, no. 1, 2019, pp. 100 ff.

[103] See *supra* § 3.

[104] The future of the *Garante*'s role in regulating AI depends on whether it becomes the supervising authority for the Ai Act. This was advocated not only by the *Garante* itself but also by the European Data Protection Board and the European Data Protection Supervisor in their joint opinion on the proposal for an Artificial Intelligence Regulation (June 18, 2021). This proposed solution could yield numerous benefits. Primarily, it could contribute to greater regulatory harmonisation, enabling the *Garante* to define a coherent interpretation of the entangled regulatory framework for AI development. Additionally, it could streamline procedures for citizens and companies, who could then turn to a single authority. Furthermore, it could ensure a reduction in administrative, financial, and time burdens in implementing the Regulation, leveraging the *Garante*'s expertise in the field.

with regards to the health sector, the *Garante*'s decalogue published in September 2023.[105] Lastly, some initial observations will be addressed regarding legislative advancements in predictive modeling for public health following the approval of the long-anticipated AI regulation of the European Union, known as the AI Act.[106] First of all, it should be assessed whether those predictive models fall within the definition of AI systems according to the Ai Act. This definition has been highly debated and changed multiple times during the trilogue negotiations. After examining both the initial proposal[107] and the final text,[108] it seems reasonable to conclude that most predictive models of the evolution of health needs, are likely to be considered AI systems under the Ai Act.[109]

However, the EU regulation envisages a multi-level risk-based regulatory architecture, dividing AI systems into 4 categories: *i*) Unacceptable risk systems, which are banned; *ii*) High-risk systems, which are subject to a list of strict obligations before they are put on the market; *iii*) Limited risk AI systems, which are subject to transparency requirements; *iv*) Minimal or no risk systems, which are not bound to special obligations.[110] It is therefore crucial to provide some preliminary considerations on the level of risk of those predictive models. While medical devices typically fall into the high-risk category, meeting certain criteria outlined in Art. 6, par. 1 of the Ai Act,[111] those predictive models could hardly fall

[105] In point 4 of the decalogue the three principles of knowability, non-exclusivity and non-discrimination are reaffirmed.

[106] The "Regulation laying down harmonised rules on artificial intelligence (and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828, (Artificial Intelligence Act)" was approved in its first reading by the European Parliament on March 14, 2024 and is now awaiting the Council's first reading position.

[107] The proposal originally presented by the Commission provided a broad definition of AI systems, accompanied by a list of approaches and techniques, which was meant to be updated by the Commission periodically. This list encompassed a variety of techniques, ranging from machine learning to «statistical approaches». Among «statistical approaches» logistic regression was included, which appears to be commonly used for risk stratification. For critical remarks concerning the inclusion of such relatively explainable and transparent techniques, see for example the position paper on the Ai Act's proposal by the Association of Consumer Credit Information Suppliers (ACCIS), at the following URL: https://accis.eu/wp-content/uploads/2022/06/ACCIS-Position-paper-on-the-EUs-Artificial-Intelligence-Act-2022-31012022.pdf.

[108] The final text approved by the European Parliament on March 14, 2024, eliminates the list of techniques, circumscribing the general definition. According to Art. 3, par. 1, point (1), «artificial intelligence system» is «a machine-based system designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such predictions, content, recommendations, or decisions that can influence physical or virtual environments». However, it remains a rather broad definition, encompassing machine learning approaches that learn from data how to achieve certain objectives, and logic- and knowledge-based approaches that infer from encoded knowledge or symbolic representation of the task to be solved» (Recital 12 Ai Act).

[109] Notably, the Ministry of Health itself on the official website of Predictive Model 2.0 announces the enhancement of machine learning and artificial intelligence tools for its predictive model.

[110] But whose providers and deployers are subject to could voluntarily adhere to codes of practice (Artt. 56 ff.) and must «ensure, to their best extent, a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf» (Art. 4 Ai Act).

[111] Medical devices would be high-risk systems because they fulfil both conditions of Art. 6, par. 1 of the AI Act («(a) the AI system is intended to be used as a safety component of a product, or is itself a product, covered by the Union harmonization legislation listed in Annex II; (b) the product whose safety component is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment with a view to the placing on the market or putting

under the definition of medical devices. However, the Ai Act appears to provide special protection to AI systems concerning healthcare, medical assistance, and triage and patient selection for healthcare services[112] and several norms imply that Ai systems to be employed in public health management could be categorised as high-risk.[113] We could therefore conclude that predictive models of the evolution of health needs are likely to be considered high-risk AI systems, although a case-by-case evaluation remains necessary.[114] At the conclusion of the journey undertaken in this contribution, a framework extremely rich in complexity and continually evolving emerges. Predictive models for public health determining the population health needs contribute to the inversion between needs and services, which lies at the heart of Component No. 1 of the Health Mission of the National Recovery and Resilience Plan.[115] However, they also raise several ethical and legal questions which need to be timely addressed to fulfil the 'promise'[116] of Article 32 together with the principles of so-called digital constitutionalism.

into service of that product pursuant to the Union harmonization legislation listed in Annex I») being subject either to the Medical Devices Regulation, i.e. Regulation (EU) 2017/745 or the In Vitro Devices Regulation, i.e. Regulation (EU) 2017/746.

[112] See also the *Garante*'s aforementioned Decalogue on AI in healthcare, p. 3.

[113] Consider Recital 27 which suggests that high-risk AI systems should be limited to those that have «a significant harmful impact on health». Furthermore, in Recital 37, systems which deserv special consideration are those limiting «the access to and enjoyment of certain essential private and public services and benefits necessary for people to fully participate in society or to improve one's standard of living […] namely […] healthcare services». Notably, among the high-risk systems listed in Annex III, sixth paragraph, point (a) are those «intended to be used by public authorities or on behalf of public authorities to evaluate the eligibility of natural persons for essential public assistance benefits and services, including healthcare services, as well as to grant, reduce, revoke, or reclaim such benefits and services». Finally, consider Annex III, sixth paragraph, point (c) which appoints as high-risk those AI systems «intended to evaluate and classify emergency calls by natural persons or to be used to dispatch, or to establish priority in the dispatching of emergency first response services, including by […] medical aid., as well as of emergency healthcare patient triage systems».

[114] Some authors have highlighted that the Ai Act's final version includes a «filter provision» (see P. Friedl, G.G. Gasiola, *Examining the EU's Artificial Intelligence Act*, in *Verfassungsblog.de*, February 7, 2024) according to which systems shall not be considered high-risk, despite falling into one of the eight listed high-risk areas, «if they do not pose a significant risk of harm, to the health, safety or fundamental rights of natural persons» (Art. 6, par. 3). This «shall be the case» if the system is intended to: *a*) «perform a narrow procedural task»; *b*) «improve the result of a previously completed human activity»; *c*) «detect decision-making patterns or deviations from prior decision-making patterns and is not meant to replace or influence the previously completed human assessment, without proper human review»; *d*) «perform a preparatory task».

[115] Regarding the inversion of the order between services and needs, where needs precede services, as envisioned by the healthcare reform, cf. R. Balduzzi, *Gli standard (e il modello) dell'assistenza sanitaria territoriale: prime considerazioni*, in *Corti Supreme e Salute*, no. 2, 2022, p. 1 f.

[116] Reference is made to the «promised revolution» of social rights, according to the well-known expression coined by Piero Calamandrei.