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Regulatory Authorities and Decision-Making in Health Research

The Institutional Dimension

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21.1 INTRODUCTION

Institutional theories examine the way in which policies and decisions are structurally determined by institutions. 'Institutions' traditionally included state institutions such as the legislature and executive, but can also refer to embedded systems of rules, branches of law, etc. evident within particular organisational contexts. Institutional contexts or systems of rules and practice provide the foundation upon which decision-making within that context takes place. It is also within such institutional contexts that decision-making actors – including decision-makers within regulatory entities such as the Human Tissue Authority, Health Research Authority (HRA), Medicines and Healthcare Products Regulatory Agency and NHS trusts in the United Kingdom – operate. Institutional theories broadly suggest that institutions – and specific institutional contexts within which decision-making actors operate – influence and at times constrain decision-making actors in their decisions. Yet, while there is a body of research on organisational contexts and institutions within sociological studies and political science,[1] the discussion of the effects and influences of institutional contexts on downstream decision-making outcomes and actors is limited within mainstream legal literature. Instead, such questions of institutional effects are often confined to branches of legal theory,[2] and such institutional influences consequently remain largely under-explored in discussions of decision-making within medical law, including the health research regulation (HRR) context.

This chapter seeks to fill this gap. It argues that institutional influences give rise to engrained institutional predispositions within any decision-making context, which can significantly influence decision-making actors and hence the application of, *inter alia*, legal rules and professional guidance in practice. The chapter argues that the effect of institutional frameworks is particularly acute where discretion on the application or scope of a legal provision, guidance or rule is

[1] Within the sociological context, see e.g. J. W. Meyer and B. Rowan, 'Institutional Organizations: Formal Structure as Myth and Ceremony', (1977) *American Journal of Sociology*, 83(2), 340–363; F. C. Wezel and A. Saka-Helmhout, 'Antecedents and Consequences of Organizational Change: "Institutionalizing" the Behavioral Theory of the Firm', (2006) *Organization Studies*, 27(2), 265–286; P. DiMaggio and W. Powell, 'The Iron Cage Revisited: Institutional Isomorphism and Collective Rationality in Organizational Fields', (1983) *American Sociological Review*, 48(2) 147–160. Within the political context, see e.g. E. Amenta and K. Ramsey, 'Institutional Theory' in T. Leicht and J. Jenkins (eds), *The Handbook of Politics: State and Civil Society in Global Perspective* (Springer, 2010) pp. 15–39; P. Hall and R. Taylor, 'Political Science and the Three Institutionalisms', (1996) *Political Studies*, 44(5), 936–957.

[2] N. MacCormick, 'Norms, Institutions and Institutional Facts', (1998) *Law and Philosophy*, 17(3) 301–345.

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left to the decision-maker. Accordingly, the chapter argues that institutional factors and contexts should be very carefully scrutinised when adopting policy/legal changes, and particularly when drafting new provisions or guidance to be applied in any legal/regulatory context, including in the HRR context. Moreover, it will be argued that to achieve *effective* change within any context – 'effective' defined here as a change that fulfils the outcomes intended – it is not be sufficient merely to consider the text of a new provision to indicate how it is likely to be interpreted in practice. Instead, one must also consider the institutionalised context within which that provision or rule will operate.[3] It is only by considering a provision within its institutionalised setting that one will gain a more holistic picture of how the rule/provision is likely to be developed and applied by that decision-maker. To this one might argue that some rules leave no scope for discretion and hence must be applied in a regimented manner. This may be the case in some contexts; however, no context is static, and none should be viewed as such. This is because social or technological change often requires decision-makers to apply a rule in a situation for which the rule was not designed. Thus, discretion can emerge within contexts over time. Furthermore, the HRR context, by virtue of the constant developments within medicine and science, can be significantly affected by both social and technological change. Thus, the potential for institutional effects are vital to consider in HRR. Moreover, arguably laws/guidance must contain sufficient tolerance – in the sense of providing a space for the expansion of rules to new social/technological contexts – so that they can evolve to meet new circumstances over time.[4]

Furthermore, arguably, the effect of institutional factors cannot necessarily be accommodated or altered by training (of decision-making actors) from a top-down level. Guidance or training may help to move these decision-makers in a particular way in a particular context, but there is no guarantee that this guidance/training will be assimilated within an institutional framework to be used in other contexts. Instead, if the arguments are borne out, those designing and seeking to implement (legal/policy) change must be mindful of both the change suggested and also how this may be assimilated and interpreted within the institutional framework where decision-making bodies – responsible for the interpretation/implementation of such changes – are situated.

In making these arguments, the chapter is structured as follows: Section 21.2 sets out the nature of how institutions and institutional contexts are defined; Section 21.3 then draws on institutional theories to set out, in brief, a template of the main institutional influences in any decision-making framework – dividing these into key constraining and predictive influences. In doing so, it does not aim to provide an exhaustive list of all potential institutional influences in any context; rather, it sets out a template of key influences that are likely to form the core institutional scaffold of any context. Hence, such influences should be carefully considered when adopting decisions/changes in HRR. To demonstrate the practical significance of these arguments, examples of institutional influences within the HRR context are highlighted throughout this section. Section 21.4 concludes arguing that it is vital to take account of institutional contexts and their influence on decision-makers in HRR if we are to achieve the desired outcomes of policy and legal changes.

[3] This draws on the author's earlier work: A. McMahon, 'The Morality Provisions in the European Patent System: An Institutional Examination', PhD thesis, University of Edinburgh (2016).

[4] See also discussion in: T. T. Arvind and A. McMahon, 'Responsiveness and the Role of Rights in Medical Law: Lessons from Montgomery', (2020) *Medical Law Review*, 28(3), 445–477. See discussion in Part III (b) and role of responsiveness and functional suitability within law.

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21.2 BACKGROUND: DEFINING INSTITUTIONS AND INSTITUTIONAL CONTEXTS

Defining what is meant by the term 'institution' in any given theory can be a complex task[5] because several 'institutions' may be identified in any process, depending on the level of decision-making and influences investigated. As Weinberger argues, institutions are so varied it is 'impossible to set down a unified class of attributes to define all of them'.[6] Indeed, '[t]here is ... no commonly accepted view of what kinds of institutions exist, or what a typology of institutions ought to look like.'[7] Despite this diversity, there is a 'general agreement on a broad conception of institutions as systems of rules that provide frameworks for social action within larger rule-governed settings'.[8] Institutions are seen as incorporating formal procedures or norms within an organisational structure, and can also include informal aspects, such as aspects of culture within broader society or even within formal organisations'.[9] As North states, institutions are:

> ... the rules of the game in society or, more formally, are the humanly devised constraints that shape human interaction. In consequence they structure incentives in human exchange, whether political, social, or economic ... Conceptually, what must be clearly differentiated are the rules from the players. The purpose of the rules is to define the way the game is played. But the objective of the team within that set of rules is to win the game ...[10]

There is disagreement among institutional theorists about whether organisations – including e.g. international organisations, regulatory entities – are institutions.[11] Nonetheless, Hodgson argues that:

> Organizations involve structures or networks, and these cannot function without rules of communication, membership, or sovereignty. The unavoidable existence of rules within organizations means that, even by North's own definition, organizations must be regarded as a type of institution ...[12]

Moreover, for the purposes of this chapter, the question of a distinction between organisations and institutions is not crucial, because although a formal organisation *per se* may not be perceived as a specific institution under a given theory, the crux of these theories is still applicable. This is because, if an institution other than a formal organisation is the main site of investigation within a given theory, it is arguably merely taking a different level of analysis or emphasis as its starting point. For example, the EU could be viewed as the overarching amalgamation of the different institutions (of the type described) which, taken together, form the overarching framework for decision-making, within which a decision-making body such as the European Medicines Agency sits. Similarly, a hospital (clinical) ethics committee will sit within a broader hospital

[5] J. Bengoetxea, 'Institutions, Legal Theory and EC Law', (1991) *Archiv fur Rechts-und Sozaphilosophie*, 67(2), 195–213.
[6] O. Weinberger, *Law, Institution and Legal Politics. Fundamental Problems of Legal Theory and Social Philosophy* (Dordrecht: Kluwer Academic Publishers, 1991), p. 155.
[7] Ibid., p. 158.
[8] D. Ruiter, 'A Basic Classification of Legal Institutions', (1997) *Ratio Juris*, 10(4), 357–371, 358 referring to E. Ostrum, 'An Agenda for the Study of Institutions', (1986) *Public Choice*, 48(1) 3–25 and D. Ruiter, 'Economic and Legal Institutionalism: What Can They Learn from Each Other?' (1994) *Constitutional Political Economy*, 5(1), 99–115.
[9] Amenta and Ramsey, 'Institutional Theory', p. 17.
[10] D. North, *Institutions, Institutional Change and Economic Performance* (Cambridge University Press, 1990), pp. 3–5 as cited in G. M. Hodgson, 'What Are Institutions?', (2006) *Journal of Institutional Economics*, 40(1), 1–25, 9.
[11] See Hodgson, 'What Are Institutions?', 8–9.
[12] Ibid., 9.

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management system, which then sits under an overarching NHS context (in the UK). Under such conceptions, the primary argument remains the same, i.e. that the overarching organisation/ institution – which may have sub-organisations or entities – comprises a framework peculiar to that entity and within which decision-making actors are situated.

Bearing in mind the foregoing definitional points, the chapter argues that such institutional frameworks offer embedded influences on decision-maker(s) within that body who apply/ interpret (legal/ethical/professional guidance) provisions. Therefore, the role of institutional contexts should be carefully scrutinised in the development of effective systems of HRR.

21.3 INSTITUTIONAL FACTORS AND DECISION-MAKING: A TEMPLATE OF INFLUENCES

As Immergut states: 'institutions . . . act as filters that selectively favour particular interpretations either of the goals toward which political actors strive or of the best means to achieve these ends'.[13] Institutional frameworks provide the scaffold within which decisions are taken; yet, these factors are often ignored or viewed as neutral within the decision-making context. This section challenges this view, arguing that such institutional influences can be highly significant. It argues that two main types of institutional influences can be identified, namely: (1) *prescriptive* (constraining) influences that legally constrain the scope of a decision-maker's actions, e.g. the legal competences of an adjudicative body and (2) *predictive* influences – e.g. political influences on a decision-making body; such influences, although not legally constraining, can be used to predict and/or explain the way in which decision-makers may act, particularly in relation to controversial issues.[14] Under the categories of prescriptive and predictive influences, four main institutional influences can be discerned (described below) and can be applied to any decision-making framework. Such influences, depending on the legal context applicable, can oscillate between being merely predictive to prescriptive. The template highlights two primarily *prescriptive* influences, namely: the central objectives of an institution and the path dependencies (this factor may be either constraining or predictive in nature depending on the context); and two primarily *predictive* influences, namely, the composition, decision-making structure of an institution and the inter-institutional influences (again, this factor may be constraining or predictive in nature).

21.3.1 *Central Objectives of the Decision-Making Body*

A central factor of influence for any decision-maker is the main objective of the overarching institution within which it sits, and, if relevant, the core objective of the legal provision/ guidance it is responsible for applying. MacCormick's account of institutions of law highlighted the importance of having a grasp of the function or main point of an institution.[15] He stated: 'an explanation of any institution requires an account of the relevant rules set out in light of its point'.[16]

[13] E. Immergut, 'The Theoretical Core of New Institutionalism', (1998) *Politics and Society*, 26(1), 5–34, 20.

[14] See A. McMahon, 'The Morality Provisions', Chapter 2, for a detailed justification of this categorisation.

[15] N. MacCormick, *Institutions of Law* (Oxford University Press, 2007), p. 36; see also his discussions in: N. MacCormick, *Practical Reason in Law and Morality* (Oxford University Press, 2008); MacCormick, 'Norms, Institutions and Institutional Facts'.

[16] MacCormick, *Institutions of Law*, p. 36.

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According to MacCormick, this does not mean that institutions cannot be used for a variety of purposes. However, if used for other purposes, then 'it is the institution that normally functions towards a given broadly-stated end – its 'final cause' – that is so adapted'.[17] As a corollary, arguably, if the institution is not adapted, tensions can arise between the new purpose and how this is carried out, and whether it aligns with the core purpose. If a new purpose moves too far from the core broadly stated aim of the institution, that new purpose unlikely will be achieved without institutional change/adaptation. Put simply, the institutional context is not fit for purpose in such contexts.

Several factors can be used to assess the final cause/objective within an institutional context, including the mission statements, self-descriptions of the overarching institution and the text/articles of founding treaties/legislation that the decision-making body is responsible for applying.

An example of this in HRR could include a scenario whereby the HRA adopted policies that went beyond its initial – albeit broadly defined – remit. These policies may be watered down in practice, as their interpretation will likely be interpreted in a way that aligns with HRA's core purpose. Similarly, if the HRA is perceived by the public/stakeholders as over-stepping its remit in adopting a new policy, the HRA's actions could be challenged/criticised and knowledge of this may also influence policy change within HRA or other bodies, particularly in areas where its remit is not entirely clear. A 'conservative' approach to policy change may be adopted to maintain its 'acceptability'.

Thus, in setting out the remit of a body in HRR, steps should be taken to ensure that its defined remit provides scope to take actions where needed or can be amended if uncertainty arises related to a body's remit. Moreover, because institutional theories suggest that the actions of decision-makers will be influenced and applied in furtherance of their central objectives, when legal change or adaptation is sought, one must consider how such change is likely to align with the overarching aims of the framework within which decision-makers are situated.

21.3.2 Institutional Structure, Role and Composition of the Decision-Making Body and Overarching Institution

Second, a key predictive influence is the institutional structure, role and composition of the decision-making body within which that decision-maker sits. This influence draws particularly on March and Olsen's work, who have argued that institutions 'are constitutive rules and practices prescribing appropriate behaviour for specific actors in specific situations'.[18] They emphasise how the internal rules of operation or structural elements within decision-making bodies impact upon decision-making outcomes.

The institutional structure is significant as it facilitates access to, and participation in, the decision-making process. This influences aspects such as the level of external opinion in the decision-making process and the types of actors involved or consulted by decision-making actors, thereby shaping the contours of decisions. Furthermore, the avenues in which decisions are structurally made, and shaped (and by whom), can help predict the types of issues likely to be considered by decision-makers. Key factors include (a) the decision-making structure within

[17] MacCormick, *Institutions of Law*, p. 37. See also MacCormick, 'Norms, Institutions and Institutional Facts'.

[18] J. March and J. Olsen, 'Elaborating the "New Institutionalism"' in R. Rhodes et al. (eds), *The Oxford Handbook of Political Institutions* (Oxford University Press, 2006), pp. 3–8, p. 3.

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each institution, the composition of decision-makers, the levels of appeal (if any), and (b) the level – and avenues – of consultation, including mechanisms for public/external participation in the decision-making process.

Furthermore, the role and composition of the decision-making actors themselves may prove influential as it feeds into what Stanley Fish[19] termed an 'interpretative community'.[20] This is a community 'working with a shared set of assumptions, understandings, conventions and values that settles issues and problems of interpretation'[21] within the given system. In short, the decision-making community operates with shared understandings – depending on the composition of that decision-making body – and uses such understandings to interpret rules/provisions applicable by them in HRR and other contexts.

Support for this is gleaned by Powell and DiMaggio's work, which draws on the concept of isomorphism: a mimicking or homogenisation arising across organisations in a similar field. The authors conceptualise isomorphism as 'a constraining process ... [which] forces one unit in a population to resemble other units that face the same set of environmental constraints'.[22] One category of isomorphism is normative isomorphism whereby organisations within a field become composed of groups of similar professionals, creating:

> ... a pool of almost interchangeable individuals who occupy similar positions across a range of organisations and possess a similarity of orientation and disposition that may override variations in tradition and control that may otherwise shape organizations.[23]

Accordingly, similar ways of thinking may develop within an institutional context such that decision-making actors act in ways they are familiar with, reinforced or validated by similar groups working in parallel organisations with similar thinking styles. This can lead to similar patterns of action or outcomes across decision-making bodies in the same field – even when faced with different environmental factors such that the resulting outcome is unsuitable to their environment.

Considering the composition of decision-making actors can provide valuable lessons, as in some cases, the greater the similarity of the backgrounds of individuals on a decision-making body, the greater the likelihood for institutional pre-dispositions in favour of certain outcomes. Engrained patterns of thinking may develop and become difficult to shift.[24] Arguably, this provides a strong justification for ensuring, where possible, a multi-disciplinary approach within HRR decision-making contexts. Such an approach is crucial to help ensure conversations do not become engrained within aligned or shared understandings to the extent that broader considerations are missed by decision-makers.

[19] S. Fish, *Doing What Comes Naturally: Change, Rhetoric and the Practice of Theory in Literary and Legal Studies* (Durham, NC: Duke University Press, 1989).

[20] There have been criticisms of Fish's usage of this term, including: R. B. Gill, 'The Moral Implications of Interpretive Communities', (1983) *Christianity & Literature*, 33(1), 49–63; R. Scholes, 'Who Cares about the Text?', (1984) *A Forum on Fiction*, 17(2), 171–180; W. A. Davis, 'The Fisher King: Wille zur Macht in Baltimore', (1984) *Critical Inquiry*, 10(4), 668–694.

[21] P. Drahos, 'Biotechnology Patents, Markets and Morality', (1999) *European Intellectual Property Review* 21(9), 441–449, 441–442.

[22] P. DiMaggio and W. Powell, 'The Iron Cage Revisited: Institutional Isomorphism and Collective Rationality in Organizational Fields', (1983) *American Sociological Review*, 48(2), 147–160, 149.

[23] C. Perrow, 'Is Business Really Changing?', (1974) *Organizational Dynamics*, 3(1), 31–44 as cited in DiMaggio and Powell, 'The Iron Cage Revisited', 152.

[24] Also work on 'thought styles' by M. Douglas, *How Institutions Think* (Syracuse University Press, 1986).

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This argument is not a criticism of the need for, or role of expertise, within the HRR context or elsewhere. Indeed, expertise is vital. However, arguably, within any regulatory context, if decision-making actors are drawn from similar backgrounds, we must be conscious that this can lead to 'stickiness',[25] or a failure to question traditional lines of thinking and engrained institutional predispositions towards certain decision-making avenues/outcomes.

Two main related challenges arise from the foregoing from an HRR perspective:

1. *Issues of accountability and risk aversion*: As each level of decision-making is accountable to the next level within the overarching institutional structure, this can lead decision-makers to adopt risk averse behaviours with positive and negative effects. On the one hand, within HRR, adopting risk-averse strategies can mean that health research bodies insist on strict compliance with research policies, such as requiring strict adherence with data protection guidance for participants. This can assist in maintaining high standards within health research. However, it can also mean that decision-makers asked to, for example, share a health dataset for research in a context where promotion of research is not explicitly part of that organisation's mission statement, may be reluctant to do so. Such decision-makers may fear reprisal if they allow data use and if there is a lack of explicit institutional policies around how data should be shared to promote health research. The 'safest' option for a decision-maker in such a context in terms of protecting itself from potential challenge/liability, is to maintain the *status quo* and refuse to share datasets. This may be entirely contrary to the public interest but could be seen by some institutions as a safer self-preservation strategy.

2. *Public v Private Duties*: Relatedly, there is an inherent tension within HRR between how to protect individual rights in health research and maintaining the public interest in conducting scientifically sound and ethically robust research which effectively promotes human health. This duty to promote both individual and public interests is enshrined within UK law,[26] but the two goals can be in tension within HRR.[27] Where tension arises, arguably the HRA will lean back on a default of protecting individual interests over public interests because institutional incentives may be stacked in this way, given that: (1) it is more likely for challenges to arise from a failure to protect named/groups of individuals, than a duty to promote the 'public interest', which often has limited teeth in practice and (2) historically, the focus within health research has been to protect individuals to avoid many of the scandals of the past. Hence, there may be engrained institutional preferences for individual interests over broader public interests. This chapter recognises the intentions behind such approaches as laudable, but we must be aware of its shortcoming in terms of promoting public interests.

In short, understanding the role and composition of the decision-making bodies within any institutional context is vital to discerning the interpretative community evident. This allows consideration of normative biases that may develop, how these may affect the provision being interpreted and ways to mitigate this where deemed necessary.

[25] See discussion in patent context: S. Thambisetty, 'The Learning Needs of the Patent System: Implications from Institutionalism for Emerging Technologies Like Synthetic Biology', (2013) *LSE Law, Society and Economy Working Papers 18/2013*; see also: Boettke et al., 'Institutional Stickiness and the New Development Economics', (2008) *American Journal of Economics and Sociology*, 67(2), 331–358

[26] Care Act 2014, Section 111(2).

[27] See E. Dove, *Regulatory Stewardship of Health Research: Navigating Participant Protection and Research Promotion* (Cheltenham: Edward Elgar, 2020).

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21.3.3 Path Dependencies and Historical Influences

Path dependency is generally understood within institutional theories as the influence of historical actions on present acts.[28] At the most general level, it implies that 'what happened at an earlier point in time will affect the possible outcomes of a sequence of events occurring at a later point in time'.[29] It implies that the way a particular issue – or analogous issue – has been dealt with in the past by the institution will be influential, but not necessarily determinative, of present action(s). Within institutional theories, individual decision-makers are seen as influenced not just by past actions of the institution within which they are situated, but also by their own past actions and experiences.

In a legal/regulatory context, this influence can be either prescriptive or predictive in nature. Prescriptive or legally constraining influences can include, for instance, the principle of *stare decisis*, whereby in a common law context 'reliance upon binding precedents leads courts to begin every case with an examination of the past'.[30] If one is looking to how legal changes might be interpreted by courts, an examination of the relevant judicial/quasi-judicial context requires an investigation of how the case law on similar provisions developed in the past, whether any pattern can be discerned, analogies likely to be drawn and mapping a trajectory of influences based on what precedents are likely to bind decision-makers. Similarly, HRR decision-making bodies would likely look to their past findings/decisions for future decisions to ensure consistency in decision-making (e.g. to protect itself from review/appeal).

For example, the HRA's Confidentiality Advisory Group (CAG),[31] in developing its own approach to advising on whether to approve requests for researchers to use patient-level data for 'secondary' health research purposes within the public interest, made public its decisions in this context as precedents for its future work, and to guide future applicants.

Furthermore, past actions of a body can be relevant as suggestive of predictive influences. For instance, the past experiences and criteria for appointment (related to Section 21.3.2) of decision-makers may be instructive to the type of experiences actors in that decision-making body have. Arguably, if decision-makers are unaccustomed to taking decisions on ethical issues, they may be more reluctant to exercise discretion in such areas.[32] Furthermore, past failures in regulatory contexts may affect future decisions as decision-makers strive to ensure this does not happen again. However, as noted, this can have unwarranted effects. For example, the UK's Alder Hey organ retention scandal in the 1990s related to the storing of organs of deceased adults/children without families' knowledge or consent in many cases, and led to the adoption of strict legal reform and extensive guidance on organ donation/retention under the Human Tissue Act 2004. Such change was undoubtedly warranted, but placing issues of transplantation under this same Act arguably conflated the purposes and potentially could be viewed as having led to overly

[28] See O. Hathaway, 'Path Dependence in the Law: The Course and Pattern of Legal Change in a Common Law System', (2001) *Iowa Law Review*, 86(2), 601–665.

[29] W. H. Sewell Jr., 'Three Temporalities: Toward an Eventful Sociology' in T. McDonald, (ed) *The Historic Turn in the Human Sciences* (University of Michigan Press, 1996), pp. 245–280, pp. 262–263.

[30] Ibid.

[31] An advisory group which advises approving bodies such as HRA whether to approve requests to access confidential patient information without patient consent for research purposes. See Health Research Authority 'Confidentiality Advisory Group', (HRA), www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/.

[32] For a discussion of marginalisation of ethical issues in patent law in this context see A. McMahon, 'Gene Patents and the Marginalisation of Ethical issues', (2019) *European Intellectual Property Review*, 41(1), 608–620

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restrictive policies in some contexts – such as deferring to families in practice even if the deceased consented to donation.[33]

21.3.4 *Inter-institutional Influences*

Finally, inter-institutional influences and relationships/agreements between over-arching institutions and external institutions can be highly significant on the application of rules/provisions. Sociological institutionalism highlights that institutions can affect each other, akin to a form of institutional peer pressure amounting to a potential for diffusion or homogenisation of norms/policies across institutions operating in the same area.[34] The urge for homogenisation may be driven by types of isomorphism (discussed earlier) at play, namely:

1. *Coercive* isomorphism, whereby coercive forces exert pressure on decision-makers, such as legally or politically mandated requirements from external sources on that institution;[35]
2. *Mimetic* isomorphism, whereby in cases of uncertainty 'when the goals are ambiguous or when the environment creates symbolic uncertainty, organizations may model themselves on other organizations'.[36] This may be particularly acute within the HRR context as both societal/technological changes cause uncertainty for regulators;
3. *Normative* isomorphism whereby similar experiences/backgrounds of decision-makers lead to homogenisation given similarities in thought processes.

Understanding homogenisation across institutions is important to consider for HRR, as homogenisation may not deliver the best interests of those regulated, or public interest(s), objectively defined. Inter-institutional effects can be either constraining or predictive in nature, depending on the hierarchical legal relationships – if any – between the institutions in question. For example, a regulatory body may have legal obligations under EU law or under the European Convention on Human Rights (ECHR) system. Such influences will permeate how that body carries out its decision-making processes, particularly if it fears legal sanction for failing to abide by law. However, if the body perceives itself as having discretion in how it can apply rules to conform with EU/ECHR obligations, or if such obligations have not been strictly monitored in the past, this may limit the effect of the overarching institution's influence.

Relationships between institutions may also be highly persuasive, such as where institutions are not in a hierarchical relationship *per se*, but may seek to align functions for broader political reasons. For example, in the HRR context, section 111(4) of the Care Act 2014 imposes a legal obligation on multiple regulatory authorities to co-operate with each other to achieve a co-ordination and standardisation of UK HRR practices.

21.4 CONCLUSION

Institutional influences act as scaffolds for decision-making, and in so doing, shape and influence outcomes. Yet, these influences are often ignored and overlooked. This chapter

[33] See e.g. S. Harmon and A. McMahon, 'Banking (on) the Brain: From Consent to Authorisation and the Transformative Potential of Solidarity', (2014) *Medical Law Review*, 22(4), 572–605.

[34] DiMaggio and Powell, 'The Iron Cage Revisited', citing L. Coser et al., *Books: The Culture and Commerce of Publishing* (New York: Basic Books, 1982).

[35] DiMaggio and Powell, 'The Iron Cage Revisited', 151, referring to Milofsky's work on neighbourhood organisations; C. Milofsky, 'Structure and Process in Community Self-Help Organizations', (1981) *Yale Program on Non Profit Organizations, Working Paper 17*.

[36] DiMaggio and Powell, 'The Iron Cage Revisited', 151.

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has argued that institutional influences require much deeper consideration within HRR and in other health contexts. Their effect is particularly acute where decision-makers have discretion on rules/provisions and can lead to engrained pre-dispositions in favour/against certain changes. Moreover, as the health context is one where social/technological change is constant, discretion and/or uncertainty on the application of provisions/rules is always evolving. Hence, we must take more seriously the effect of institutional influences on decision-making. Such influences must be actively considered and accounted for in legal/policy change in HRR and other contexts.

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