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The Regulation of Medical Device Representatives: A Question of Trust?

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Abstract

The introduction of new technologies in medical treatment has led to innovation in medical devices that are highly technical in their application and operation. The medical technology landscape is changeable and healthcare providers often turn to the medical device representatives (MDRs), employed by device manufacturers to help navigate the shifts and uncertainties. While the relationship between MDRs and healthcare providers can be a positive one focusing on appropriate use, selection and safety of devices, it is one that has evolved over time and is not independently regulated. In addition, patients, for the most part, are usually unaware of the involvement of MDRs in their healthcare. It is this knowledge gap with regard to the role of MDRs that is the focus of this paper.

We argue that trust is at the heart of healthcare relationships and explore the nature of trust alongside the models of regulation of the medical device industry. We argue that MDRs may currently present a threat to both the interpersonal and the institutional trust of patients, and that regulation and policy responses are appropriate ways to address this risk. We consider potential regulatory frameworks and identify transparency and communication as the crucial characteristics of an appropriate response. We recommend that the polycentric nature of Australian healthcare regulation be cultivated through a multilayered approach, and that a positive obligation to inform the patient of the role of MDRs in their clinical care be established.

Keywords: Medical devices; Medical device representatives; Healthcare; Trust, Regulation.

Introduction

The introduction of new technologies in healthcare has led to the introduction of medical devices that are highly technical in their application and operation. The medical device representatives (MDRs) employed by device manufacturers to promote these devices to healthcare practitioners have specialist expertise in their operation. Healthcare practitioners often rely on MDRs for direct assistance and to improve their understanding of how to operate the devices. In a constantly changing therapeutic environment, this practitioner–MDR relationship has the potential to be beneficial in facilitating safe and competent use of new devices, thereby contributing to successful patient treatment.

However, equally, the existence of these relationships has the potential to generate harms and impact patients' trust in the health system overall as well as in their treating practitioner. Where MDRs are present in a clinical setting, particularly in hospital surgical environments, their role may be somewhat unclear within the healthcare team, and the nature of their relationship with patients may be unspecified. Although patients may be advised to some extent about the technical nature of the medical device itself, they may not be aware of the presence or active involvement of the MDR in their surgery. Significantly, they will have little insight into the nature of the relationship between the MDR and their healthcare team.

In this article, we argue that the presence of MDRs—as currently managed in Australia—presents a threat to both the interpersonal and institutional trust of patients, and that regulation and policy are appropriate ways to respond to this threat. We draw on concepts of distributed interpersonal trust and trustworthy systems in health delivery to address these concerns about MDRs in clinical settings. Our approach is multifaceted and focuses on transparency about the role and actions of the MDR seeking to avoid potential harm to patients, practitioners and the health system itself, which may arise out of the existing opaque nature of the role of the MDR in surgery. Patients are more likely to trust a healthcare system involving the clinical presence of MDRs if they are duly informed and satisfied that there is appropriate external scrutiny and accountability of MDRs that go beyond their immediate relationship with the surgeon and healthcare team.

Importantly, we place our dialogue within the existing practice of MDRs entering the clinical space and advising healthcare professionals directly. We acknowledge that this arrangement is itself open to challenge, and there are alternate models in which health systems have decreased or eliminated their dependence on MDRs. In some cases, hospitals have shifted away from allowing doctors' preferences to drive the selection of devices and implants, as these are shaped by surgeons' training, comfort, and their relationships with MDRs rather than evidence. Evidence-based device formularies, which contain a limited number of implants and accompanying instrumentation kits for each type of surgery, are one potential alternative. In-house medical engineers, nurses and technicians can then develop the requisite in-house expertise to support safe, quality and efficient surgeries. However, these models are outside the scope of the present discussion, which focuses on addressing the existing pattern of MDR relationships and their impact on patient trust.

MDRs and Clinicians: A Potentially Troubled Relationship?

The role of MDRs in the clinical environment has evolved incrementally over time and is not yet subject to any formal regulatory oversight. The role has developed into one governed by a complex mix of commercial, advisory and educational imperatives. For example, the relationship between surgeons and MDRs has been characterised as a 'symbiotic' one,[1] representing a merging of clinical and commercial imperatives. However, this may be to the detriment of all participants in the clinical relationship, including patients, healthcare providers and their institutions. The potential harm at stake is rarely of the traditional legally relevant type, which is usually readily identifiable and tangible (such as physical injury or financial loss). Rather, the harm is intangible and is best characterised in terms of reputational damage, breakdown of relationships and, ultimately, as we are arguing here, decline in both interpersonal and institutional trust. Specifying these harms is challenging, because quite often a patient will be given appropriate medical treatment, suffer no physical damage and perhaps be healthier than they previously were. MDRs are frequently, and perhaps increasingly, the sole source of knowledge about the safe and appropriate use of new technologies, and they serve as gatekeepers to expert communities,[2] thus, potentially improving patient outcomes.

However, if details emerge of the existence of conflicts of interest concerning medical devices, or of a deliberate veiling of the nature of the MDR role or relationship, patient trust may suffer or be compromised. Similarly, the inclusion of an unknown non-clinical participant in the surgery, or knowledge that healthcare practitioners do not have the requisite expertise to perform their role independently of MDRs, may also affect patient trust. Patients undergoing surgical procedures are highly vulnerable: they are largely sedated and/or unconscious, without advocates in the form of family or other caregivers, and are at risk of complications such as infection in addition to other adverse events. The physical presence of an MDR, particularly without the patient's knowledge or consent, heightens this vulnerability. Given these features, our concern is that patients may lose trust and, in the future, become less willing to comply with medical advice, ultimately leading to more tangible harm.

The breach of trust may begin with a lack of information provided to patients regarding the role of the MDRs. Good medical practice requires effective communication with patients; this includes an overview of the clinical intervention, the individuals involved in that intervention, and the known risks and benefits. It also includes ensuring valid informed patient consent, which requires that patients have enough information to make a meaningful choice. However, the lack of transparency around the involvement of MDRs means that the patient is often unaware that 'salespeople working on commission are frequently present and sometimes even advise the clinical team during surgery.'[3] The prevalence of this practice also means that patients may not have a meaningful or viable alternative, including access to a second opinion if any alternative available surgeon likewise works closely with MDRs. If, after the treatment is concluded, the patient discovers that a sales representative was present without their knowledge or consent, and does not understand the risks or benefits of their involvement in the procedure, suspicion is likely to be aroused and the crucial relationship of trust between the clinician and patient will potentially be undermined. One

[1] Gagliardi, " 'We Can't Get Along.' "
[2] Nicolini, "The Changing Nature of Expertise."
[3] Farmer, "Sales Reps," para. 2.

such situation, in which a patient later found out about the presence of an MDR at her surgery, arose in relation to investigations into the now infamous urogynaecological[4] or transvaginal surgical mesh products. Allegedly, one of the claimants discovered that an MDR was present during her procedure. Investigative journalist Joanne McCarthy reported the story in *The Newcastle Herald*, in July 2017, and claimed that 'NSW Health is investigating how a male pelvic mesh company representative was in a private hospital operating theatre during a woman's intimate pelvic mesh surgery, without her knowledge or approval.'[5]

It is well beyond the scope of this paper to discuss in detail the issues raised by the mesh cases.[6] However, we note that the significant responses by both federal and state governments[7] did not pick up on this discrete point made by McCarthy regarding the patient's specific concern about the presence of MDRs in the surgical theatre without her knowledge or consent. Given the extensive harms to the affected women and the magnitude of associated regulatory failures, it is possible that this legitimate concern was overshadowed. Additionally, the case was complicated by the fact that the MDR in question was himself a qualified surgeon, who then became subject to disciplinary proceedings in relation to his professional conduct.[8] McCarthy noted that:

> the hospital director of the Sydney Private Hospital has advised that medical representatives are permitted admittance to the operating theatre at the discretion of the theatre manager in consultation with the surgeon. They are present to provide technical advice to the surgeon.[9]

The underlying question raised by McCarthy regarding patients' rights to information about who will be present at their surgery remains open and warrants further scrutiny.

Distrust may be compounded by the existence of commercial incentives and the fact that MDRs frequently provide education and device support while also working in a sales capacity. This point is illustrated by the findings of an investigation conducted by the International Consortium of Investigative Journalists (ICIJ) and the Australian Broadcasting Commission (ABC).[10] This wideranging investigation had several different findings, the most relevant to the present discussion being that commercial interests influenced clinicians' choices of medical devices through a lucrative 'kickback' scheme associated with expensive devices. This scheme existed in a series of private health facilities, leading directly to inflation of insurance premiums, reduced quality of devices available in the public sector, and subsequently limited choice for those unable to afford private healthcare. The ensuing damning headlines focused on the commercial as opposed to clinical imperatives driving the choice of devices, with headlines such as 'Pacemaker "Sales Reps" Present at Heart Surgeries'[11] or 'Secret Pacemaker Payments Boosting Private Hospital Coffers but Costing the Health System,'[12] and 'Australia's Health Watchdog Accused of "Too Close" Relationship with Industry.'[13] While the claims in the media were challenged by both the device industry and private health sector, the harm was already done. Clinical decision-making was undermined and, in the eyes of the public, the relationship between industry and healthcare potentially compromised dedication to the 'best interests of the patient' in favour of commercial imperatives.

Both of these cases played out on the very public stage of journalistic enquiry. Our two examples show the issues are yet to be addressed as a question of law. Nevertheless, the presence and impact of MDRs have been identified as both concerning and newsworthy. The widespread reporting and public engagement with the issues raised resulted in significant reputational harm to the individuals and institutions involved. However, the harm extends beyond being merely reputational; it undermines the trust that is central to healthcare relationships. To understand the nature of this harm, we must engage with the nature of trust itself.

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[4] Term used by the Therapeutic Goods Administration; see generally https://www.tga.gov.au/hubs/transvaginal-mesh.
[5] McCarthy, "NSW Health," para. 1.
[6] See discussion in Grieger, "Consumer Law"; see also commentary in *Gill v Ethicon Sàrl (No 5)* [2019] FCA 1905 on the challenges of balancing commercial and clinical interests. Significant patient harm arose out of 'a failure to adequately test the appropriateness of the material, appreciate the potential risks or actively engage with interests beyond the commercial.' Fortunately, these examples of widespread harm are rare and highlight systemic problems beyond the relationship between medical device representatives and doctors, but they do serve to demonstrate the significant risk posed by the merging of commercial and clinical imperatives.
[7] At the Commonwealth level, the ongoing safety and clinical aspects of using transvaginal mesh products is reviewed by the Australian Commission on Safety and Quality in Health Care in response to the recommendations of the Senate Community Affairs References Committee's report, *The Number of Women in Australia Who Have Had Transvaginal Mesh Implants and Related Matters*; see https://www.safetyandquality.gov.au/our-work/health-conditions-and-treatments/transvaginal-mesh. For an example of state-level response, see https://www.bettersafercare.vic.gov.au/publications/transvaginal-mesh-the-victorian-response.
[8] The Surgeon was, in fact, struck off.
[9] McCarthy, "NSW Health," para. 10.
[10] International Consortium of Investigative Journalists, "Medical Devices Harm Patients Worldwide."
[11] Scott, "Pacemaker 'Sales Reps.' "
[12] Scott, "Secret Pacemaker Payments."
[13] McCarthy, "Australia's Health Watchdog."

The Nature and Objects of Trust

In spite of its widely assumed self-evident meaning, the concept of trust is more difficult to define than might at first be apparent. In philosophical terms, it is a contested concept: there is no agreed theory of trust able to capture all of its salient aspects. Despite this complexity, there are points of convergence.[14] Interpersonal trust usually refers to a relationship between two people—for example, a patient (P) and a doctor (D) in which P trusts D to Φ, where Φ is a specific task.[15] This understanding corresponds to the conceptualisation referred to in the trust literature as a 'three-place' trust structure, and it is the most appropriate way in which to think of trust in the contexts relevant for us here.[16] The truster P must hold certain beliefs about the trustee D, such as that D is competent to perform the task and can be relied on by P to do so. These beliefs are the cognitive aspect of trust. As well as belief in the trustee's competence, trust also requires an affective aspect; the truster must hold certain optimistic attitudes towards the trustee, regarding the trustee's goodwill towards them. In healthcare, trustee goodwill is specified in terms of the patient's interests: to say that a patient trusts their doctor is to say that they trust that their doctor will act in their best interests. For some scholars, such as Pellegrino,[17] trust is the defining feature of the doctor–patient relationship and, as such, valued in and for itself.

Other relevant features of trust include that trusting makes the truster vulnerable. In virtue of trusting them, the truster grants discretionary powers to the trustee. These discretionary powers are commonly linked to the possession of specialised knowledge or skills by the trustee, such as those held by skilled tradespersons or healthcare professionals. In trusting, the truster believes that the trustee will use those discretionary powers to help rather than harm; for example, the patient trusts that the pharmaceutical knowledge held by her physician will be used to heal rather than poison her. However, lacking the knowledge and/or skills to monitor or independently evaluate the trustee's actions, the truster cedes control and thereby makes herself vulnerable to the trustee. Patients seek healthcare because they lack the requisite knowledge and skills to manage all of their own healthcare needs. This epistemic imbalance—and its related vulnerability—may be exacerbated by any occurrent pain, suffering or anxiety associated with illness. In addition, seeking healthcare requires disclosure of health information that can be of a deeply private nature, disclosure of which may harm the patient.

There is a subform of interpersonal trust, which we can refer to as *distributed* trust. *Distributed* trust arises when a patient's interpersonal trust in their healthcare practitioner extends beyond the parameters of their immediate relationship to include other personnel with whom the healthcare practitioner is, in turn, in a trusting professional relationship—for example, a pathologist or radiologist. In some cases, patients will not have immediate interpersonal relationships with such healthcare workers. Yet, knowing of their role, and of their physician's trust in them, the patient's direct trust in their physician is extended or distributed to those further persons.

We propose that MDRs be conceived of as appropriate objects of distributed interpersonal trust. This will enable an account of the regulatory mechanisms needed for a trust-supportive model of medical device management in clinical settings.[18] In the surgical context, a patient has interpersonal trust in their healthcare professionals, including the surgeon and their assigned nurse. An MDR may be present in theatre to support that surgeon or nurse. The patient will not have any direct interpersonal relationship with the MDR, and likely will never meet them. As such, they have no direct relationship and no cognitive and affective trust in the MDR. Yet, perhaps having been informed of their presence and role during surgery, and trusting in the surgeon's or nurse's own interpersonal trust in the MDR's knowledge and competence, the patient can be said to have distributed their trust beyond their healthcare professionals to the MDR. However, under the existing model, a patient is rarely informed of the role or even presence of the MDR, and their presence is neither widely known of by the general public, in the way that the presence of theatre nurses is. In the absence of such knowledge, there is no foundation for distributed trust.

Just as trust offers benefits to the truster, it also exposes them to risks. If their trust is misplaced due to untrustworthiness of the trustee, things can go badly wrong. Breaches of trust in healthcare range from practitioner incompetence leading directly to harm to patients (e.g., the botched surgeries of Jayant Patel at the Bundaberg Hospital),[19] to favouring commercial rather than

[14] McLeod, "Trust."
[15] Interpersonal trust can be general (e.g., global trust in the thoughts and actions of a revered mentor) rather than linked to specific tasks, but it is the specific form of trust that is relevant in healthcare, so we focus on that here.
[16] As D'Cruz points out, some theorists (such as Faulkner 2017 and Domenicucci and Holton 2017) deny that trust is always a three-place structure, since in some cases trust may be in a person qua person, rather than being task-limited (e.g., 'P trusts D' rather than 'P trusts D to Φ'); see D'Cruz, "Trust and Distrust," 42.
[17] Pellegrino, "Commodification."
[18] This conceptual task will be the subject of future contributions to this field.
[19] Davies, Commission of Inquiry.

patient interests (as uncovered by the ICIJ/ABC investigation into devices, discussed above), and to malign intent involving sexual and emotional abuse of patients. Thus, the stakes of trust are high for patients.

Importantly, trust is not just interpersonal or distributed: it also takes an institutional form. Institutional trust refers to beliefs and attitudes that an individual or community may hold in relation to a social institution, such as a healthcare system, or an individual institution like a particular hospital. In contrast to interpersonal trust, institutional trust is impersonal and non-specific.[20] There is no single individual who represents the institution and to whom the trusters relate; rather, institutions comprise multiple individuals in diverse roles. Some of these roles (e.g., CEO) may be more relevant in generating trust in the institution than less visible roles such as administrative staff; nevertheless, institutional trust does not entail a one-to-one relationship between an individual and an institution, as there is with interpersonal trust. Institutional trust also differs from interpersonal trust in that it is non-specific. Institutions usually have multiple responsibilities and perform multiple tasks, making it difficult to pin down a specific task (Φ) that the truster trusts the institution to perform. In such cases, whether or not a particular institution is seen to be trustworthy depends on factors including its norms and regulations, the legal and political context, its historical relations with particular communities, its financing, its policies and procedures, and its technical capabilities.[21]

In healthcare, several relevant institutions may be trusted (or not) by healthcare users. These include local facilities, such as particular hospitals, as well as the broader institutional context within which individual hospitals operate, such as district health services. In turn, these are governed by political structures such as health departments, which may themselves be objects of institutional trust or distrust. Additional potential objects of institutional trust are the systems that regulate healthcare professionals, including licensing bodies such as medical or nursing boards, which aim to ensure standards of competence.
The interrelationships between trust in individual health professionals and in the institutions within which they practice have been characterised as a 'multidimensional web.'[22] Within this web, trust of an institution may be the initial step for a patient in coming to trust an individual healthcare professional, but as that professional proves trustworthy (or not), this, in turn, bolsters the patient's trust (or distrust) in the institution.

In addition, the wider social context influences initial trust in institutions. For example, initial trust may be low in jurisdictions noted for corruption or corporate profit-seeking in healthcare, and higher where healthcare is publicly funded or perverse financial incentives minimised. Significantly, historical relations between institutions and communities can greatly affect institutional trust. If a truster identifies with a group that has been historically marginalised, underserved or harmed by the institution, they may not require direct experience with the institution to decide whether to trust that their interests would be well-served by the institution. As Meyer et al. note, there is little empirical research investigating the individual- and system-level relationships that affect trust; however, there is prima facie appeal in the notion of a web of trust in which trust of individuals and of institutions are understood as iterative and mutually interdependent.[23] If a patient distrusts a healthcare institution, they are unlikely to trust its employees until they can demonstrate their trustworthiness. In turn, if initial trust in a hospital is followed by untrustworthy behaviour of healthcare professionals within it, that initial trust is likely to decline, accompanied by distrust of its members. The converse is a virtuous cycle of initial trust in an institution that is reinforced and strengthened by trustworthy actions of its members, in turn, feeding back to increase trust in the institution.

The notion of institutional trust is relevant to, but does not capture, the distributed trust that a patient extends in cases involving MDRs (though institutional trust may also be in play). As discussed, distributed trust comes about through different mechanisms from those involved in institutional trust. It may be characterised as a form of 'behavioural' trust, rather than 'cognitive' or 'affective' interpersonal trust.[24] As Lahno notes, cognitive trust implies certain mental states in the truster, including expectations of the trustee's goodwill; affective trust involves and is based on emotional bonds between the truster and the trustee, and involves what Karen Jones refers to as 'an affective optimistic attitude.'[25] By contrast, behavioural trust does not imply either cognitive or affective trust bonds. In behavioural trust, we act in a trusting way in relation to certain others, without needing to have the affective bonds or full set of beliefs that usually attend cognitive and affective trust in specific persons.

While it will often be the case that the kind of attitude that a surgical patient has will be more appropriately characterised as institutional trust, we suggest that in some cases, institutional and distributed interpersonal trust can come apart. That is, it may

[20] Nickel, "Trust in Medicine."
[21] Nickel, "Trust in Medicine"; Rădoi, "Understanding Institutional Trust."
[22] Meyer, "Trust in the Health System," 182.
[23] Meyer, "Trust in the Health System."
[24] Lahno, "Three Aspects of Interpersonal Trust," 32–38, cited in Potter, "Interpersonal Trust," 243–255.
[25] Jones, "Trust as an Affective Attitude," cited in Potter, "Interpersonal Trust."

be possible for a patient to have full interpersonal trust in their surgeon, for example, and distributed trust in the practitioner's selected MDR, in the absence of institutional trust. The key point is that where distributed trust arises, the trust is transferred or extended *via initial trust in the surgeon*, not via trust in the institution or regulatory framework. Where distributed trust is breached, an appropriate patient response addressed to their practitioner would be, 'But I trusted *you* to choose a trustworthy MDR to assist you!' rather than, 'But I trusted this hospital to authorise access to only trustworthy MDRs!'

MDRs and Potential Trust Breaches

Having outlined the nature and objects of trust and its foundational role in healthcare, and argued that MDRs are plausibly objects of distributed interpersonal trust, we now briefly canvas the potential breaches to trust caused by the presence of MDRs in operating theatres. First, deception, relating to lack of information about, and lack of informed consent to, the presence of MDRs during surgery is a potential source of interpersonal and institutional distrust. The presence of MDRs during surgery is typical in certain specialties, including orthopaedics. In North American surveys of patients undergoing joint replacement, patients reported that they were not standardly informed about the presence of MDRs prior to surgery, just as patients are not usually told which specific scrub nurses and other theatre staff will be present.[26] But unlike hospital-employed theatre staff, who are licensed and regulated healthcare professionals, there are no standards governing MDRs and, in particular, there is no obligation on their part to prioritise the best interests of the patient. As patients usually remain unaware that an MDR was present during their operation, the impact on trust only becomes apparent in unusual circumstances, such as that of the patient in the mesh case mentioned above. However, the harms can extend beyond the individual patient involved, especially when, as was the situation in the examples outlined above, the role of the MDR is deemed to be 'newsworthy.' It is in the 'court of public opinion' that significant institutional harms can occur.

A second potential impact on patient trust arises in relation to competence. Patients trust that their surgeon, for example, will be competent to perform the operation in question, albeit with the usual supports of theatre and anaesthetic staff. Yet, the novelty and complexity of many surgical devices means that surgeons cannot always use these safely, and must rely on the MDR to be able to competently and efficiently perform the surgery.[27] Given the central role of competence in trusting, this is a significant potential breach. It is possible that some patients would see the MDR as a necessary technician, with no implications for their trust in the surgeon's competence. However, equally, knowing that their surgeon was guided in essential parts of the procedure by an MDR, and that the procedure could not be performed in the MDR's absence, could cause a patient to legitimately doubt their surgeon's competence and, hence, distrust both them as an individual and the relevant institutions, including licensing bodies.

The nature of the relationship between the practitioner and the MDR may threaten patient trust by creating a financial conflict of interest. MDRs derive their salaries from the medical device companies that employ them to generate sales. In turn, MDRs and their companies enter into complex webs of financial relationships with surgeons and other practitioners, including offers of incentives and rewards to surgeons who use their devices.[28] Such incentives may threaten the practitioner's commitment to the patient's best interests, resulting perhaps in the choice of a suboptimal device for a particular patient, just because it is supplied by the MDR. Here, distributed as well as individual trust may be breached, if the patient trusted that the MDR as well as the surgeon would be bound by their best interests. Conflicts of interest are exacerbated when the surgeon is involved in the device development and marketing themselves, as occurred with the DePuy metal on metal hips.[29]

In summary, trust is multilayered, complex and crucial in the successful provision of healthcare. In some circumstances, trust arises out of a direct relationship (such as the interpersonal trust between a doctor and patient); in others it is distributed to those trusted by the trustee. Of equal importance is institutional trust that rests on the reputation and conduct of healthcare institutions. The complex interplay of relationship, expectations and reliance that constitute trust has been characterised as a 'multidimensional web'[30] threading through the clinical environment. If this web is disturbed by the introduction of an unexpected entity or a failure to respect the truster (i.e., the patient), then the therapeutic relationship can be harmed along with broader institutional harms through loss of reputation. The introduction of a non-clinical person into the clinical environment and decision-making process may erode patients' trust and destabilise the foundations of the healthcare relationship, potentially

[26] See, for example, Lieberman, "Financial Conflicts of Interest"; Camp, "Surgeons' Financial Conflicts of Interest"; Camp, "Financial Relationships"; Yi, "Financial Conflicts of Interest."
[27] Fuchshuber, "Ensuring Safety"; Bedard, "Industry Representatives' Participation in Surgery."
[28] Hockenberry, "Orthopedic Device Makers."
[29] See Johnson, "Joint Issues."
[30] Meyer, "Trust in the Health System," 182.

leading to harm for patients, institutions and wider society. Thus, the erosion of trust can not only harm the individuals involved in the transaction, but also reflect negatively on the relevant professionals—as well as the clinician and the MDRs alike.

The question then arises as to how, in the context of MDRs in theatre, steps can be taken to ensure that this web is maintained and all participants are protected. It is here that we turn our attention to the regulatory environment and ask whether there is an appropriate or effective response at law. Once harm has occurred, the usual response is to seek some form of recompense, often by taking legal action. However, this traditional retrospective response may not provide a meaningful remedy where the relevant harm is best characterised as health system or society wide and intangible—two characteristics that can be attributed to a loss of trust. A more appropriate approach may be a prospective one, the crafting of appropriate guidelines, policies that are both transparent and clear. This 'soft' or 'grey' law approach would, potentially, support a trustworthy inclusion of MDRs in theatre. We do not intend to provide an in-depth legal analysis at this point; rather, we aim to briefly canvas some options and raise potential alternatives, considering whether the *ex ante* (prospective) or *ex poste* (retrospective) regulatory approach is the most appropriate.

The Current Regulatory Landscape

As the role of MDRs in the clinical environment is not directly subject to any independent regulatory oversight, this discussion must, therefore, begin by considering the effects on MDRs of the broader context and features of healthcare regulation more generally. The healthcare sector is a highly regulated industry, subject to and governed by several laws and layers of legislative frameworks, which presents challenges when focusing on a specific, non-clinical participant such as the MDR.

The delivery of healthcare services and products in Australia is subject to both state and Commonwealth law and regulatory interventions.[31] Not only are there different layers of authority, but also there is a diverse mix of regulatory strategies in healthcare settings. Broadly speaking, the current approach is best characterised as 'responsive regulation,'[32] which encourages regulators to deploy a mix of strategies ranging from persuasion to enforcement. At the same time, there is often a preference in the healthcare sector for regulation strategies to be 'risk-based.' That is to say, the regulatory response should follow an analysis of the nature of harms and, in the light of this analysis, be proportionate and focused on identifying the best means of controlling risk.[33] Theories of both 'responsive regulation' and 'risk-based regulation' inform regulation in the health sector through a multifaceted system of 'polycentric' governance. A polycentric regulatory setting describes regulation involving a network of both government and private entities rather than a single dominant and authoritative regulator. There are significant strengths in this polycentric model in the healthcare environment, where multisector technical expertise may be required and values are shared across the regulatory network.[34] However, where we are considering an intangible harm such as decline in interpersonal, distributed or institutional trust related to the role of MDRs, the existing approach may fail to provide adequate protection for the patient.

Turning to the device industry more broadly, despite the absence of an independent regulator imposing controls on the MDRs, the industry itself sits within a multifaceted regulatory framework that includes some oversight of the roles and responsibilities of MDRs and accountabilities for their actions. Regarding the medical device industry, the principal actors are private industry regulators, both local and international.[35] These have been influential in identifying and managing the relevant risks to the industry through the development of industry standards.[36] The work of these organisations has explicitly recognised the

[31] Under the Australian Constitution, the delivery of health services is designated as a state government function, and the federal government is involved mainly through funding arrangements. As a result, each of the state governments is responsible for the regulation of health services in public hospitals; in the community including by general practitioners, community nurses and other community-based health supports; and in screening and immunisation programs. The Commonwealth is primarily responsible for funding and oversight of Medicare, the Pharmaceutical Benefits Scheme, and the Therapeutic Goods Administration. There are also shared responsibility agreements, usually detailed in a national agreement by the Council of Australian Governments, such as the Australian Health Practitioner Regulation Agency. In addition to the jurisdictional responsibilities of government, a further complexity is that Australia operates both public and private health services as a mixed system. Private health services, including private hospitals, operate alongside and are integrated with the public health system, and are subject to private health insurance regulation.

[32] See Ayres, Responsive Regulation; Sparrow, The Regulatory Craft; Grabosky, "Beyond Responsive Regulation."

[33] Freiberg, Regulation in Australia, 458.

[34] See Richards, Technology, Innovation and Healthcare, 28–44.

[35] For example, the International Organization for Standardization is a non-governmental organisation whose membership is made up of elected representatives from national standards organisations in more than 130 countries. Its standards are developed by technical committees of experts from business and industry. See https://www.iso.org/home.html.

[36] In Australia, ISO 13485:2016 has been formally recognised for the purposes of section 41DC of the *Therapeutic Goods Act 1989* (Cth) as a standard for the manufacturer of all kinds of medical devices that require a quality management system for conformity assessment. Quality management systems that comply with the standards specified in a Conformity Assessments Standards Order are treated as complying with

potential growth activity of the medical device sector and acknowledges the requirement for the industry to adhere to coherent health sector regulation to ensure and maintain patient safety. Most importantly, they are best placed to manage the regulatory 'pacing problem,' which refers to clinicians keeping up with the industry. The pacing problem is constructed as a key driver for the presence of MDRs in clinical settings, as they bring up-to-date technical knowledge of the product into the clinicians' workplace.

In relation to individual medical device companies and MDRs in Australia, there is an established system of self-regulation[37] that is best characterised as a responsive model of regulation, through the professional body the Medical Technology Association of Australia (MTAA). The Medical Technology Industry Code (MTIC) was introduced in 2001 to formalise ethical business practices for member companies and promote socially responsible conduct by all companies in this industry sector. Its stated aims are:

> to promote high standards of integrity across the [Medical Technology] Industry so that patients and Healthcare Professionals can have confidence in their dealings with the Industry and its products. The Code provides a framework and mechanisms for setting standards of behaviour, educating Companies in the agreed standards, monitoring Industry activities, and providing self-regulation and disciplinary functions.[38]

The MTIC sets out self-regulatory standards that are compulsory for members of the MTAA and that serve as a voluntary industry code for all medical technology companies. The Code is complemented and supplemented by a range of training and related programs to assist awareness of the ethical responsibilities of industry members. Interestingly, the Code explicitly states that MDRs may be present in clinical healthcare settings and work closely with surgeons in this context.[39]

The Code also acknowledges the wider regulatory framework for ensuring appropriate behaviour by industry,[40] and provides that where there is another therapeutic industry code that is more relevant in the circumstances or requires a higher standard of behaviour, then that code will apply. Despite acknowledging the potential presence of MDRs in operating theatres, as well as training and advising surgeons, the Code fails to provide any clarity regarding expected behaviours in theatre (e.g., the balance between selling and advising) and is silent regarding information to be provided to patients about their presence and role. This represents a significant gap in the current model, and it is here, in this gap, that trust can be eroded due to the potential for a perception of a lack of due care for, and/or respect of, individual patient interests.

Self-Regulation and Trust

Self-regulation has been favoured within the responsive regulation model that applies to the technology and innovation sectors, due to the sector's need to be responsive to fast-developing products and technical change. While private standard-setting bodies may be criticised for being too industry focused, most modern standards are influenced and reviewed by a range of non-state actors that have collective expertise in the risks (including social and ethical risks) posed by new technologies. The 'technical' committees of many standards organisations comprise multiple stakeholders, including representatives from government agencies, consumer groups, NGOs and academics. Private standard-setting bodies often have greater knowledge and expertise of industry practice and are, therefore, likely to be able to formulate more relevant and effective standards. Although voluntary, there is a strong incentive from within industry to comply with private standards. In addition, industry standards often have a trickle-down effect, as they may later be given formal legal status if incorporated into national regulatory regimes.[41]

Similarly, while traditionally criticised as putting the fox in charge of the henhouse,[42] within a complex polycentric model the role of professional membership organisations and even of informal voluntary codes of conduct have proved highly effective

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the relevant parts of the conformity assessment procedures for quality management systems set out in the *Therapeutic Goods (Medical Devices) Regulation 2002* (Cth).

[37] For an overview of the definition of self-regulation, see Freiberg, Regulation in Australia, 108.

[38] Medical Technology Association of Australia. *Medical Technology Industry Code of Practice Edition 12*. Macquarie Park: MTAA, 2022

[39] See Medical Technology Association of Australia, Code of Practice, art. 3.2.

[40] Such as, for example, consumer complaints and/or consumer health bodies, advocacy organisations, healthcare professionals or their professional colleges, government health agencies, or hospital administrators. Many individual companies in the medical technology industry, particularly those with international reach, have their own internal guidelines and codes.

[41] Six, "Trust in Regulatory Regimes," 17.

[42] Arguably, self-regulation by private industry where there may be perceived financial conflict of interest may not be readily identified as a strong regulatory measure to build or repair public trust in the healthcare context. There are notable exceptions to this assumption in the financial and telecommunications industry ombudsmen in Australia, which are both private industry self-regulators that have achieved a high degree of public trust in their regulatory functions.

regulation tools over time in technical industries, like medical devices. Like private standards, these codes may be amended relatively quickly to reflect developments in research and development of new technology. The more established codes may also have multiple purposes and can, among other things, establish risk-management frameworks, generate and gather data, and facilitate information exchange, all of which assists regulators with the 'pacing problem.' Self-regulation within a responsive regulation model is, therefore, an important part of the regulatory enterprise in relation to MDRs and managing risk. Building and maintaining trust is also a key regulatory aim of 'responsive regulation.' The theory posits that ideally 'regulatory agencies devolve responsibility for social control to agents who are in day-to-day relationships of interdependency with those whom they regulate.'[43] Braithwaite and Makkai recommend 'a dynamic regulatory strategy of dialogue and trust as a first choice followed by escalation to more punitive regulation when trust is abused.'[44] However, in this model, trust and cooperation and/or compliance are closely linked, and punitive strategies are not measures that may be used to build or repair trust.

Regulatory Processes and Building Trust: Potential Solutions

Regulatory scholars Six and Van Ees have built on the responsive regulation model to propose regulatory processes of trust building and repair at individual and organisational levels. They emphasise:

> the importance of looking at the micro-level process so as to understand the mechanisms for successful trust building in regulatory relations and also how the dynamics of distrust work and can be remedied. Trust building processes are more successful if expectations are explicitly shared and needs and interests are exchanged and acknowledged.[45]

Identifying 'micro-level processes' and relationships requires identifying and acknowledging the different types of trust involved in the MDR context (interpersonal, between patient and surgeon and between surgeon and MDR; distributed, between patient and MDR; institutional, between patient and institution, surgeon and institution, MDR and institution, and public and institution). The process of identifying these trust relationships draws all partners—that is, health professionals, healthcare institutions and patients—into the regulatory aim of building trust.

Six and Van Ees recommend two broad 'clusters' of recommendations for developing processes to build trust in regulation, the first of which is to focus on transparency to all partners. They note 'when trouble occurs, it is important that [all regulatory actors] have the interpersonal and communicative competencies to address the trouble in a nonthreatening inquisitive way, so that the trouble may more likely be resolved.'[46] Second, they state that because 'trouble events' are (almost) inevitable in regulatory relations, it is important that relations between organisations are maintained at different levels and that within each organisation there is good internal, vertical communication about the developments in the relationship. This is so that 'when trouble occurs at the operational level and immediate resolution is not possible, then it may be resolved at a higher management level.'[47]

Regarding the regulation of MDRs, this approach suggests regulation should be focused on analysing and supporting the key relationships between MDRs, health professionals, healthcare institutions and patients to promote transparency and communication at all levels. Informing patients about the role of MDRs (and specifying who should do this) is particularly critical, given the current lack of awareness of and opacity surrounding their direct and indirect involvement in patient care. Basic measures such as ensuring the MTAA Code provides greater clarity about MDRs' responsibilities to patients and that hospital policies are transparent and explicit about their protocols for the presence of MDRs in clinical contexts are examples of this approach. Broadly speaking, these recommendations may be located within the regulatory theory of 'informational regulation,' which has been the most dominant form of regulatory method in the past 10 years internationally.[48]

In the context of the regulation of MDRs, this method of regulation would also target the generation and dissemination of information about their activities and promote transparency between MDRs, health professionals, healthcare institutions and patients.

[43] Freiberg, Regulation in Australia, 56.
[44] Braithwaite, "Trust and Compliance," 1. However, they do also underplay the importance of processes of trust building and repair in this model.
[45] Six, "When the Going Gets Tough," 75; see also Six, "Trust in Regulatory Regimes," 16.
[46] Six, "When the Going Gets Tough," 67.
[47] Six, "When the Going Gets Tough," 68.
[48] See Freiberg, Regulation in Australia, 331–361.

Conclusion

We have explained that transparency and communication are crucial to the establishment and maintenance of trust in healthcare. The responsive regulation approach to healthcare continues to support the application of appropriate multilayered and diverse regulatory tools. As we have seen, the existing regulation of healthcare is complex and multifaceted (or polycentric) including traditional regulatory instruments (legislation), broad industry-based codes of conduct and, in some circumstances, local policy directives and guidelines. However, despite all these measures, the activities of MDRs in clinical environments remain largely unregulated. We have argued that it is this gap that threatens patients' individual, distributed and institutional trust in the healthcare system. We have also explained that this gap is not, however, impossible to fill.

We have argued that self-regulation of MDRs plays a significant role in a responsive regulatory model in healthcare. We have also noted that trust in healthcare relationships can be harmed through a lack of information, and that retaining and building trust requires open communication. The response to the concern about the trust relationship between MDRs and patients does not involve a significant cultural shift beyond that of moving from one of silence to one of transparency. The current model of health regulation and professionalism of healthcare providers includes a positive obligation for communication, where a similar obligation can be placed within the existing codes, guidelines and policies in relation to the activities of MDRs. In particular, industry codes can be amended to include an expectation of disclosure of the presence and role of MDRs in surgery. Local healthcare policies can reflect this positive obligation and only permit the inclusion of identified and potentially approved MDRs. A holistic approach grounded in principles of open disclosure is consistent with broader health regulation and would respect the patient, uphold standards of professional integrity and foster a stronger relationship of trust in healthcare.

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