ABSTRACT: Within the regulatory community, there has been increasing interest in the issue of proportionality in regulation— that is, using the right amount and right types of regulatory interventions to achieve the primary mandate of the regulatory community in order to serve and to protect. The Health and Care Professions Council (HCPC) in the United Kingdom, one of the largest health-care regulatory bodies in the world, recently commissioned a study examining the disproportionately large number of complaints against paramedics in the UK and social workers in England. The objective of the study was to examine the nature of, and to better understand the reasons behind, this disproportionality, and to identify options and opportunities from a regulatory perspective that could be taken to address this issue. The study involved a systematic multi-methods research approach involving four key interrelated research elements:

- A systematic literature review
- A Delphi consultation with international experts
- Interviews (n=26) and four focus groups (n=23) with UK experts, including service users and caregivers
- A review of a random sample (n=284) of fitness-to-practice cases over two years across the three stages of the process (initial complaint, Investigating Committee Panel, and final hearing)

Findings from this study highlight the evolving nature of both professions and the influence of a binary model of complaints adjudication that may not be sufficiently nuanced to balance public protection with practitioners’ learning needs. A non-binary option for understanding complaints against practitioners is suggested in this paper, offering a process that involves and engages both employers and practitioners in a more meaningful manner.

Understanding Complaints to Regulators About Paramedics in the UK and Social Workers in England: Findings from a Multi-Method Study

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Background

The primary mandate of regulators is to protect and to serve the public. The mandate is separable into two sub-parts: the mandate “to protect” and the mandate “to serve.” The mandate “to protect” is traditionally connected with safety and prevention of harm, while the mandate “to serve” is connected with quality improvement and practice evolution. For regulators, these mandates may conflict. For example, for the sake of safety and the prevention of harm, regulators may be tempted to over-regulate or foster cultures of surveillance that stifle professional autonomy and judgment, inadvertently impeding practice innovation and evolution. Within the regulatory community, there has been increasing interest in the issue of proportionality in regulation—that is, using the right amount and right types of regulatory interventions to achieve an appropriate balance between the mandates to serve and protect. This “right touch” regulatory philosophy has been proposed by the Professional Standards Authority in the United Kingdom and is increasingly being adopted in other jurisdictions internationally.

A key feature of “right-touch” regulation (sometimes referred to as “fair-and-just” regulation) is the process of understanding a problem’s nature before attempting to implement a solution. Understanding the problem entails self-monitoring on the part of regulators for the purpose of arriving at a better understanding of the unintended consequences associated with regulatory practices, and enhances the regulatory body’s ability to be agile and responsive to evolving societal and profession-specific needs. Self-monitoring involves not only identification of emerging trends within a regulatory body, but also systematic research to better understand the reasons behind these observations. In this paper, we review recent research commissioned by the
Health and Care Professions Council (HCPC) in the United Kingdom, one of the largest health-care regulatory bodies in the world. HCPC is the regulatory body for 16 diverse health and social care professions including social workers (in England only) paramedics, occupational therapists, clinical scientists, physiotherapists and psychologists.9

Context

Each of the 16 professions regulated by the HCPC has one or more “designated titles,” protected in law in the United Kingdom. Similar to other jurisdictions internationally, these designated titles define a scope of practice and specific restricted acts/activities associated with that profession’s practice. HCPC’s governance structure centers on its Council, composed of 12 members. The Council is made up of up six registrants (from any of the 16 professions) and six lay members.9 Supporting the Council in its responsibilities are a small number of statutory and non-statutory committees. Statutory committees include education and training (responsible for advising the Council on matters related to training and registration of professionals), conduct and competence (responsible for defining standards of practice and professional competence), and investigations (responsible for examining and adjudicating complaints).

If a complaint is raised about the performance of a registrant of HCPC, a panel of Investigation Committee members will generally be assembled to determine whether there are grounds for further actions by the regulatory body. For example, a complaint against a social worker may involve allegations about inappropriate assessment and use of authority to limit parental access to a child; for a paramedic, a complaint may involve allegations about inappropriately entering a private residence during a response to an emergency call. Statutory powers afforded to HCPC in dealing with complaints range from conditions placed on practice to suspension or removal of a registrant from the register in accordance with the specific characteristics of the case itself.

This study stemmed from the observation that there was a disproportionately high number of complaints to the HCPC about two professions: paramedics across the United Kingdom and social workers in England. The mean rate of complaints over a five-year period to regulatory authorities for all 16 professions governed by HCPC was approximately six per 1,000 practitioners, whereas, for paramedics and English social workers, the incidences of complaints were 11 and 12 per 1,000 practitioners respectively.

The objective of this research (which was funded by the HCPC) was to examine the nature of, and to better understand the reasons behind, this disproportionality, and to identify options and opportunities from a regulatory perspective that could be taken to address this issue. Prior to this study, there had not been systematic research undertaken to identify causes of disproportionate numbers of complaints against specific professions.

Research Methods

A multi-method research approach was used, consisting of four key elements: 1) a systematic English-language literature review within the social work and paramedic professions, 2) a Delphi exercise with international experts, 3) qualitative research involving interviews and focus groups with UK-based professionals and service users, and 4) analysis of a structured random sample of cases from the HCPC’s fitness to practice process. This multi-method approach was used to triangulate, confirm and validate findings from diverse stakeholder perspectives, and to provide a more robust portrait of the reasons behind complaints in each of the two professions studied.

Findings

Literature Reviews

Within the profession of paramedicine, there is scant literature available reviewing prevalence and nature of complaints; only two small studies were identified.10 In part this is due to the emerging nature of the paramedic profession itself: In some jurisdictions, paramedics are an unregulated paraprofessional field; within the UK, paramedics have only been regulated since 2000. In Canada and the United States, regulation of paramedicine is infrequent and generally viewed as an employer responsibility.11 While the literature review did not
yield helpful data regarding complaints, it did provide a rich source of information regarding the evolving nature of paramedic practice, and this in turn helped support subsequent phases of the research, especially interviews, focus groups, and complaints-case analyses. This literature highlighted the rapid expansion in scope and autonomy of the profession over the past decade with a commensurate increase in volume and range of services provided. The literature review highlighted that paramedics across diverse jurisdictions no longer simply provide patient transport services but instead must deliver a complex mix of emergency and non-emergency responses to highly variable, highly volatile and often life-threatening situations. In particular, the growing demands on paramedics to supply psychosocial support, conflict management, or to intervene in quasi-legal situations (for example, attending at an injury involving domestic abuse) highlights the changing nature of that profession’s focus.

The literature review also highlighted a significant evolution in societal expectations for paramedics. Members of the public consistently highlight rapid response time as a key quality indicator of individual paramedic’s performance—though this factor, in particular, is highly dependent upon organizational constraints that may be beyond the control of the individual paramedic. When there is insufficient or poor communication within paramedic teams or between management, strained intra-professional relationships and a lack of trust may develop. As a result, service quality may suffer. Several studies noted that paramedic work culture demonstrates a tendency towards under-reporting of errors and a blame-focused environment, in part due to the nature of paramedic employment. Most paramedics are managed as employees within organizations rather than as autonomous professionals. Further, this employment and blame culture exacerbates difficulties experienced by paramedics in managing the complex ethical, conflict and interpersonal communication challenges that are as much a part of the paramedic environment as technical skills such as resuscitation and suturing. Indeed, some of literature noted that the paramedic profession—historically rooted in provision of emergency medical care—was rapidly evolving into a psychosocial care profession, an evolution that is not easily accommodated by those trained and experienced in a different paradigm of the profession. As a result, there was evidence to suggest that a disproportionately large number of paramedics suffer from or are at risk of experiencing job-related burnout.

Similar to the literature in the field of paramedicine, the review of the relevant social work literature did not produce a strong evidence base related to complaints about social workers, but instead helped to identify key issues about the evolution of the profession itself that informed subsequent phases of this research. The literature highlighted the complexity of the role and the contradictions inherent in the field—for example, the paradox of caring for and yet exerting control over individuals, which is a common feature of social work practice. The literature also highlighted the impact of society’s ambivalence towards the role and professional autonomy of social workers in England. Unlike other health and care professionals whose work may be better understood by the general public, the public’s understanding of what social workers actually do is less clear, and this may result in less respect being afforded to their professional responsibilities.

A further theme in the literature related to the nature of employment within social work: Many social workers are employees within corporatized settings and, given the contentious nature of social work itself, employers may choose to refer concerns to a regulatory body as a professional practice issue rather than manage them internally as employment issues. In this way, employers are better able to maintain public trust and credibility, thereby protecting themselves from blame, and instead, address misconduct or incompetence issues as individual practitioner deficits rather than employer or system-level problems. This tendency towards a blame culture produces a defensive practice orientation, preventing honest relationships and conversations among service users, social workers, and employers...
regulatory level.\textsuperscript{21} In this literature, social workers highlight the impact of organizational factors on their professional practice, which may be influencing their ability to demonstrate competence in complex situations.\textsuperscript{22} Performance management cultures focused on penalizing errors of omission or commission, rather than supportive supervision and quality improvement coaching, tend to dominate social work employment.\textsuperscript{19,22} Further, economic austerity and public service cutbacks have been cited as a reason for cultural shifts in organizations away from mentoring and towards blaming.\textsuperscript{23}

Though their professional practices differ significantly, the literature reviews in paramedicine and social work surfaced similar trends concerning complaints: both are rapidly evolving professions managing environmental complexity and working within organizations that de-emphasize professional autonomy and work within a blame (rather than quality improvement) culture. Both professions struggle with changing societal expectations of their roles based on performance indicators that may be beyond the individual practitioner’s control.

**Delphi Exercise**

The Delphi exercise for this study was undertaken with 14 international experts from regulation, social work, and paramedicine, and provided an opportunity to triangulate findings from the literature review and signpost specific areas for further exploration within the other parts of this study. The Delphi method used for this research involved iterative rounds of focused questions posed to the experts; their answers were then aggregated and sent back to the participants so they could reflect upon their initial responses in the next round of questions. Through this method, experts have the opportunity to engage in peer benchmarking and self-reflection, in the hope of refining and focusing their responses. Experts for this study were recruited through a snowballing key-informant nomination process and were recruited from diverse jurisdictions internationally.

At the completion of the three-stage process, several key themes emerged of relevance to both paramedics and social workers.

First, the Delphi participants reaffirmed the importance of changing public attitudes and expectations towards health and care professionals and, in particular, the growing psychosocial complexity of the work itself: In particular, the increasing prevalence of conflict (verbal and physical) within these fields was identified as a significant source of stress and reason for complaints.

Second, the Delphi participants noted heightened awareness on the part of patients and clients of their “rights” to complain against professionals. As regulators have worked to promote awareness of their role in society to the general public, this has potentially resulted in more individuals becoming aware of the regulatory routes of recourse available to them should disagreement with a professional’s decisions or actions arise. Further, as a culture of accountability, litigation and awareness has grown, and as processes for reporting complaints to regulators have been streamlined through technology, Delphi participants highlighted the logical conclusion of increasing numbers of complaints. On the organizational level, the Delphi participants noted that both paramedics and social workers function as front-line and/or first-line care providers. As such, they are particularly vulnerable to poor management, austerity-linked budgetary cuts, and other cost-cutting/cost-saving measures that may increase workloads, decrease opportunities for professional development, or result in poor/inadequate professional supervision, which in turn could compromise quality of care and service provided.

Finally, the Delphi group noted individual practitioner-level issues that warrant further exploration, including selection, training, supervision and professional development of individuals. For example, paramedics may be unaware of or underestimate the importance of soft-skills (such as conflict management and negotiation, or awareness of relevant legislation governing domestic abuse) in day-to-day practice; in some cases, individuals who select paramedicine as a field of study and a career may believe they are opting for a hands-on technical field rather than a complex psychosocial field. Clearer guidance on the actual realities of each profession, and guidance around ethical responsibilities of individual registrants, were highlighted by the Delphi participants as important areas for further exploration.
Interviews and focus groups

For this study, interviews with 27 participants with expertise in paramedicine, social work and/or regulation were undertaken, along with four structured focus groups (two with service users and two with practitioners in those fields). Participants for this phase of the research were recruited through a snowballing key-informant nomination process.

This qualitative research validated major themes identified in the literature review and Delphi process, and resulted in articulation of four core themes: 1) impact of public perceptions and expectations, 2) challenges of day-to-day professional practice, 3) organizational, cultural, and political climate affecting their work, and 4) the evolving nature of the professions themselves, towards greater psychosocial complexity and ambiguity.

Across the interviews and focus groups, a convergence of opinion occurred (without facilitator or interviewer intervention) regarding actions that could contribute to more effective and appropriate use of the regulatory complaints process, mainly related to communication, collaboration and awareness-building.

Participants in this phase of the research articulated their perception of the fractured structure of these professions: In particular, they noted opportunities to align the work of employers, regulators and practitioners in a more systematic manner. The lived experiences they reported highlighted a prevailing sentiment that complaints to regulators serve as a default route of least resistance when service recipients (or employers) are dealing with a difficult situation. Participants felt that the public perception that there is no “cost” to the individual to file a complaint with regulatory authorities may lead to unnecessary or inappropriate use of this channel when other more efficient routes (e.g., organization-based quality improvement) may be more appropriate. A lack of awareness of the legalistic nature of regulatory intervention with a complaint may lead some individuals to misapprehend the statutory requirements of regulators who receive and then must investigate and follow-up on complaints, and the costs and consequences that result for all parties. While transparent, accessible and simple complaints systems are essential for regulators, these attributes may also result in complaints being the default route of choice in managing any practitioner-related issue, big or small. Participants felt that clearer communication and guidance to the public, employers, practitioners, and colleagues around appropriate use of regulatory channels was identified as an important quality improvement opportunity for regulators.

More formalized collaboration within professions and with professional associations was also identified as an opportunity: Currently, regulators may be seen as operating somewhat outside a profession and potentially antagonistic to the best interests of professionals themselves. The legalistic nature of complaints adjudication and the potentially adversarial approach taken when complaints are investigated may give the appearance that regulators are “against” practitioners when it comes to protecting the public, rather than serving both the public and practitioners in supporting effective organizations, systems and practitioner development. Greater engagement by regulators with employers and with practitioners to provide support, to issue guidance, and to alert professional communities when emerging trends may surface were all identified by participants as valuable collaborative tools for regulators. In particular, profession-wide approaches to alternative, constructive ways of handling and resolving disagreements—before they escalate to the level of a complaint—were identified as a crucial contribution that regulators could make to serve and protect both the public and practitioners.

Case Analysis

A unique feature of this research was the in-depth case analysis exploring the nature of complaints about paramedics across the UK, and social workers in England, through an examination of a random 10% sample of 284 cases (52 paramedics and 232 social workers, structured to be representative of each of the discrete stages of regulators’ investigation process). This analysis provided a unique description of characteristics and circumstances of cases that both did not meet the threshold for further investigation (resulting in no action or response by the regulatory body), as well as those that led to further regulatory response or action. The case analysis identified a higher number of older, male practitioners in the overall sample relative to their numbers on the registers in both professions.
In the paramedic sample frame, 85% were employed by the National Health Service (NHS) of the United Kingdom, and 67% worked in acute care settings. The sample indicated a disproportionately high number of self-referrals from paramedics (46%) compared with an average of 10% for social workers, and 6% across the other 14 HCPC regulated professions. In the social worker sample frame, 67% were employed by local authorities, and 69% worked in children’s services. Of complaints about social workers, 56% were from members of the public (compared with 10% for paramedics and an average of 12% for all other HCPC regulated professions during the same period). Of complaints about social workers from the public, 48% arose from child residence and contract disputes.

Few of the cases in either profession examined were characterized by regulatory authorities as deliberate acts of malice, negligence or professional incompetence. There appeared instead to be a disproportionate number of complaints to the regulatory body that did not meet the threshold for further investigation, which eventually led to regulatory action and a final disciplinary hearing. Given the relatively small number of these cases in the study sample frame, it is difficult to identify any profession-wide trends or reasons; instead, individual practitioners’ unique personal circumstances and situations (e.g., addictions or mental health issues) were in most cases identified by regulators as the major contributing factor.

The case analysis reinforced the findings that had emerged from other branches of the study concerning the increasing psychosocial complexity of the paramedic and social work practices and its impact on complaints. The regulatory investigation and adjudication process is highly proceduralized and methodical, using investigative processes and evidence-informed systems to make decisions about practitioners’ fitness to practice. At each decision point in the process, regulators must balance diverse sources of evidence and information.

Each decision point, however, is binary. Investigations proceed, or they are halted; practitioners are found competent or incompetent; members are either fit to practice, or they are unfit to practice. Current regulatory practices only allow for “either/or” distinctions to be made, with no possibility of an intermediate state such as “competent in these circumstances but not in others,” or “generally competent but made one honest error.”

Within increasingly complex practice contexts seen in paramedicine and social work, in which no idealized right answers are possible or available, it can be challenging to make findings concerning binary outcomes, such as “competent/incompetent.” Also, such complex practice contexts appear inherently to provoke strong emotional responses from patients/service recipients. When—from their perspective—suboptimal or unsatisfactory outcomes result, frustration may emerge, seeking a channel for retribution. The transparency, availability and ease of making a referral through the regulatory complaints process provides such a pathway, which in turn leads to (as was demonstrated through this case analysis) a significantly large number of complaints that do not proceed past preliminary investigation. This outcome, in turn, can amplify complainants’ initial emotional responses, both towards the practitioner that was the subject of the complaint and towards the profession and sometimes the system as a whole (including the regulatory body). This vicious cycle can appear to self-perpetuate, and risks alienating all parties in the system.

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CURRENT REGULATORY PRACTICES ONLY ALLOW FOR ‘EITHER/OR’ DISTINCTIONS TO BE MADE, WITH NO POSSIBILITY OF AN INTERMEDIATE STATE SUCH AS ‘COMPETENT IN THESE CIRCUMSTANCES BUT NOT IN OTHERS’...
To complainants, it may appear as if the profession is “circling the wagons” and protecting itself from outside threats — the veneer of regulation proves to be simply lip-service and many experience their complaint as unaddressed and unresolved. To practitioners who are the subjects of complaints, it may appear as though regulatory authorities are engaging in unnecessary and damaging quasi-litigation; and the taint of even a preliminary investigation on a practitioner’s confidence and reputation can be significant. Further, it casts the regulatory body as the antagonist of the long-suffering professional, who must endure unnecessary (and unfair) inquiries regarding his or her competence.

The binary nature of the current complaints adjudication process may itself be inadvertently contributing to this spiral. As highlighted by the professions of social work and paramedicine, health and care professionals work in complex environments characterized by professional judgment and compromises; there are many circumstances where less-than-ideal solutions may be the only ones realistically available, even if these are unsatisfactory to all parties involved. A binary complaints adjudication system that may be incapable of actually addressing this contemporary reality of practice runs the risk of worsening the situation. There is a need for a rigorous and systematic investigation process, as the sample of cases studied here indicates there were cases of deliberate malfeasance and frank incompetence on the part of practitioners. Such cases are, in many ways, the easiest to manage from a regulatory perspective as they involve clear breaches of ethics, practice standards or competency expectations. However, as highlighted by this study, these cases are the significant minority of those that the regulatory authorities deal with, and the same rigorous and systematic investigation process that is applied to the majority of cases is both time- and resource-intensive and provokes distress among the practitioners who are the subjects of complaints. A menu of alternative approaches to investigation, adjudication, and resolution of complaints — rather than the current one-size-fits-all process — may be an option to consider. Such a menu must balance both the rights of the patients/service recipients and the needs of practitioners: Patients/service recipients should be ensured of transparency, fairness, openness and procedural integrity, and practitioners should be respected and have the complexity of their day-to-day practice acknowledged.

Discussion

A dominant theme of this research has been how current regulatory practices concerning complaints adjudication may not always be best suited for the realities of contemporary practice. As highlighted through this research (particularly the focus groups/interviews and case analyses), alternatives for improving the current system could focus on improved communication by regulators, enhanced collaboration across the employment and regulatory sectors to support a quality improvement (rather than blame) culture, and consideration of more nuanced ways of addressing the real-world complexities associated with day-to-day practice. Despite a disproportionate number of complaints against social workers and paramedics, the case analysis did not find that this led to a disproportionate number of ultimate findings of impairment or incompetence. Instead, this case-analysis indicated that there were a disproportionate number of complaints that did not meet the threshold for further investigations. Despite this, the costs and consequences — for complainants, for practitioners and for regulators — were significant. Worse, findings of this study suggest a form of regulatory iatrogenesis may be part of current systems: Regulatory practices themselves may be inadvertently contributing to a spiral of alienation among practitioners and regulators, and between professions and the public they purport to serve.

Synthesizing themes that emerged from this research, a novel model for consideration of complaints
against paramedics and social workers has emerged as a potential option to consider, one that shifts from the traditional binary adjudication process and instead emphasizes partnerships with local employers and professional bodies to lead interventions. This should not challenge the vital role regulation plays in setting standards and ensuring that all professionals continue to meet these standards throughout their professional working lives. There will always be a small number of individuals, as evidenced in the final hearing cases who, with malice or without, cause harm. They must be held to account. There is no evidence to suggest that the current system of regulation does not meet its obligations to the public in this regard. However, the findings of this study suggest that there are many more professionals who, with appropriate local employer-led support and intervention, may never have been referred to the regulatory body in the first place. The responsibility for design of such a system, focused on quality improvement rather than blame, rests with all arms of the professions—employers, regulatory bodies, advocacy groups, educators and regulators—all working collaboratively.

An alternative for consideration that evolved from this research highlights the notion that complaints are rarely binary but instead fall on a continuum. Given that the HCPC is based in the UK, we used a soccer (i.e., football) analogy to suggest a complaints adjudication process involving three levels, analogous to what soccer referees use:

...THE FINDINGS OF THIS STUDY SUGGEST THAT THERE ARE MANY MORE PROFESSIONALS WHO, WITH APPROPRIATE LOCAL EMPLOYER-LED SUPPORT AND INTERVENTION, MAY NEVER HAVE BEEN REFERRED TO THE REGULATORY BODY IN THE FIRST PLACE.

...a yellow, dark yellow, and red card (see Figure 1). A yellow card would be focused on relatively minor issues that warrant conversations with the practitioner but little else. A red card would be significant major disciplinable events that go beyond employment standards and speak to the core of what it means to be a professional in practice. In between there would be a dark yellow card, which would apply to the types of real-world, one-off situations that fit neither the yellow nor red card categories. If

![Figure 1](The Continuum of Impact on Fitness to Practice and the ‘Dark Yellow Card’)

**Yellow Card Infractions**
- Traffic offenses
- Personal disputes
- Off-duty incidents
- Residence and contact disputes
- Conflicts with colleagues
- “Unkempt” appearance
- Inappropriate use of social media
- Disputes with colleagues and service users
- Acting unprofessionally towards service user
- Delayed reporting

**Dark Yellow Card Infractions** (*"one-off" complaints*)
- Aggressive behavior towards colleagues
- Failure to complete patient record form
- Failure to check vehicle
- Failure to undertake clinical checks
- Inadequate assessment and record keeping
- Delayed communication with a family member

**Red Card Infractions**
- Repeated misdiagnosis
- Incorrect treatment
- Conviction/cautions
- Deliberate fraud
- Serial instances of inadequate care/inadequate assessment
- Sexual boundary violations
Conclusions

Understanding the complaints process within a regulatory context is essential for regulators to ensure they are achieving the right balance between serving and protecting the public. This study illustrates a multi-method approach to the issue that blends regulator-specific data with broader profession-specific trends within a context of societal evolution of expectations of professions. Each part of this study contributed meaningful and unique information to the overall analysis; when taken together, the four separate methods within this project provided regulators with unique insights into their practices and a potential model for improvement they could consider in the future. The soccer refereeing card system proposed by findings of this study is offered as a practical way to consider non-binary options for understanding complaints against practitioners...

Acknowledged sincerely by the practitioner, within the context of quality improvement and professional development, such one-off complaints could be best managed at the local level by the employer, with regulatory support. This non-binary approach to complaints may also have the advantage of identifying precursor behaviors earlier in the process. These may be predictive of future behaviors that are more dangerous or serious.

This approach also provides employers with greater evidence to invest in employees in a meaningful way to prevent small problems from becoming larger ones later on. This analogy may have the potential to be used as an educational and practice development tool.

There are, of course, limitations to this research: The focus was on two mid-sized professions with distinct professional scopes of practice. Though they both share some common characteristics concerning rapidly changing societal expectations and practice contexts, it is unclear if this work is generalizable to other professions, or other jurisdictions. The multi-method research methods used here provided opportunities to validate and cross-check findings from one part of the study with data from other parts; while there is internal cohesiveness to this approach within the professions studied, transferability to other professions has not been considered. Given the nature of complaints cases in professions, each case in the case-analysis was considered as a unique data set, using a case-series methodology; as a result, there was no attempt to quantify complaints trends across the data set. In the future and with a larger data set of cases to study, such an analysis may provide additional useful data for consideration by regulators. While the patients’ and clients’ perspectives were part of the data set in this study, the study team itself did not include individuals who were patients/clients themselves or representatives of such groups, and this may have introduced bias into the framing of findings. The approach utilized in this study has value for hypothesis generation and may be a useful starting point for researchers in other fields.

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