Global healthcare update

March 2021

Kennedys

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Foreword

Welcome to our global healthcare update for 2021.

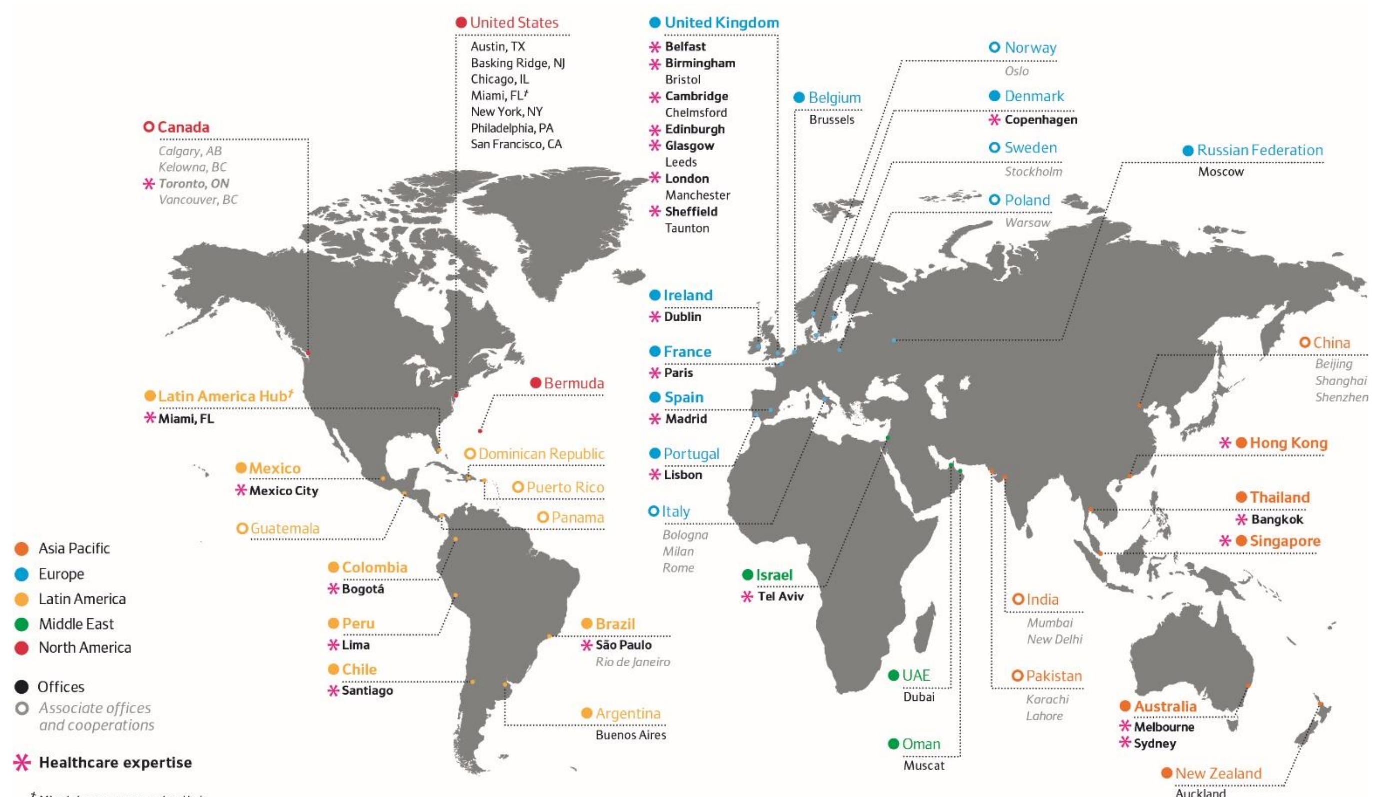
The COVID-19 pandemic has created an unprecedented challenge for healthcare professionals globally. It has brought with it a renewed focus and belief in better use of technology.

In this global update Kennedys' medical malpractice specialists from 16 jurisdictions across the globe discuss the operational and digital response of healthcare organisations and providers, to the pandemic. It is clear the pandemic has accelerated the shift towards remote delivery of healthcare, via ‘telemedicine’, often by way of ‘teleconsultations’. With countries at various stages of that journey, we consider the risks and opportunities that this transition presents and how it may alter the claims landscape.

We also assess the current and potential future impact of COVID-19, as well as considering other key developments for the year ahead.

I hope you enjoy reading this global update and welcome your feedback.

Christopher Malla
Global Head of Healthcare



Asia Pacific
Australia

> **The health system is now facing both short and long term pressures, including the need to fill the workforce gap, build resilience in the workforce, focus on sustaining clinical effectiveness and maintaining a commitment to quality patient outcomes.**

The operational and digital response to COVID-19

- Prior to the COVID-19 pandemic our health system faced challenges in terms of maintaining sufficient numbers of experienced health professionals and carers to meet the needs of an ageing population and increased risk of chronic disease. However, the health system is now facing both short and long term pressures, including the need to fill the workforce gap, build resilience in the workforce, focus on sustaining clinical effectiveness and maintaining a commitment to quality patient outcomes.
- The onset of COVID-19 intensified these pressures on the healthcare system, and accordingly the Federal and State Governments implemented policies including:
  - **Redirection of resources** – lower priority services, such as elective surgery, were put on hold whilst attention was provided to the management and treatment of COVID-19.
  - **Increasing supply** – increasing the supply of a suitably qualified workforce was critical to being able to meet healthcare demands. Practitioners and healthcare staff were redeployed from private settings to the public health system to support COVID-19 efforts. The Australian Health Practitioner Regulation Agency (AHPRA) established a pandemic response sub-register to fast-track the return of retired practitioners to the workforce.
  - **Alternative modes of providing healthcare services** – one of the most significant operational changes to healthcare has been the significant update in telehealth consultations. Telehealth services has continued to grow and expand since its introduction in March 2020, to include general practitioners, specialists, nurse practitioners, midwives, psychologists and other allied health services.
- On 27 July 2020, AHPRA released guidelines for practitioners to assist with the use of telehealth. The guidelines provide that: “All registered health practitioners can use telehealth as long as telehealth is safe and clinically appropriate for the health service being provided and suitable for the patient or client”.[i]
- The guidance adds that the expectations of practitioners utilising telehealth to provide patient consultations/services, are the same as when delivering services face-to-face. The delivery of telehealth and face-to-face services are to be practiced in accordance with the relevant National Board “regulatory standards, codes and guidelines”[ii].
- Alongside telehealth, healthcare providers can also prescribe medicines remotely and have them home delivered to patients by their pharmacist. There has also been a significant increase in public funding of telehealth particularly in the area of mental health.
- The increase in virtual modes of healthcare delivery has not only provided patients with alternative means of access to healthcare but has also assisted in protecting clinicians and patients from potential exposure to COVID-19. It has also enabled the provision of additional clinical advice and information to regional areas and reprioritising the high demands of specialities such as, interventionists, infectious disease physicians and respiratory physicians.
- It is too early to predict the impact of COVID-19 on the Australian medical malpractice claims landscape but we consider there is likely to be an increase in claims regarding delays or misdiagnosis. Historically our industry has seen an increase in claims during periods of economic downturn and all Australian medical defence organisations have reported increased claims numbers in the last 12 months.
- With patients opting for telehealth consultations and not presenting for face-to-face consultations, there has been a reduction in routine health screens, including breast cancer screening, pap smears, and cardiac monitoring. As we have not previously faced the same or similar circumstances presented by the pandemic, the law in Australia will ultimately be evolving.

- Experts may need to consider the reasonableness/efficacy of a practitioner undertaking a consultation by telehealth and this may include consideration of the individual state health guidelines in place at the time and a weighing up of the risks to patient and doctor.
- There have already been reports of serious failures in public care in regional areas of New South Wales where remote telehealth services sought to replace direct doctor contact particularly in an emergency setting.

Key developments for the year ahead

Regulatory complaints

- Our anecdotal experience of an increase in regulatory complaints has been supported by AHPRA which has reported[iii] that there was a 7.2% increase in the number of notifications made against medical practitioners to AHPRA in the last year (5,745 versus 5,359). The most common types of notifications were complaints about clinical care which accounted for 54.2%.[iv] Medication and communication were the next most common types of complaints.
- Complaints in relation to the provision of mental health consultations by telehealth (including privacy breach claims) and the lack of available resourcing during the pandemic has featured in notifications. Complaints relating to professional boundary transgressions/breaches by medical practitioners are increasingly being tested in AHPRA and the Health Care Complaints Commission before progressing to civil proceedings and are an area of growth in claims.

Courts

- In some jurisdictions in Australia, the courts are continuing to hold directions hearings, applications and trials by audio visual link (AVL). There has, however, been some differences in approaches. Court timetables in Victoria have been affected by the delay in court availability (particularly jury trials) and the legacy of this is likely to continue for at least the next two years as resources are drawn from the civil courts into the criminal courts to address the backlog of cases. This impacts on timetabling for civil matters and court dates and resolution of matters is likely to be delayed, with expedited matters still being given priority.
- With jury trials for medical malpractice matters still being a peculiarity of the Victorian system, Victoria courts have been requesting defendants forego their right to a jury in order to have a matter heard.
- New South Wales has been very fortunate to have had a shorter lockdown period than Victoria. Jury trials are no longer used for medical malpractice claims in New South Wales. Its courts have adopted a pragmatic 'business as usual' approach. While most hearings are being conducted by AVL or a combination of AVL and in person attendances, very limited leeway in respect of timetabling has been permitted to factor in the impact of COVID-19.
- The parties are expected to swiftly progress litigated matters at much the same pace as in pre-pandemic times. Inquests have also proceeded via AVL and in person appearances in New South Wales.

Contacts: Anjali Woodford, Cindy Tucker and Raylee Hartwell

Hong Kong

The operational and digital response to COVID-19

- The Hospital Authority announced the activation of Emergency Response Level in public hospitals on 25 January 2020 as the first wave of COVID-19 hit Hong Kong. Special measures, like postponement of elective/non-emergency clinical appointments, were implemented to focus resources on tackling the pandemic.
- In light of this and social-distancing measures, the city saw a rise in demand for telemedicine. Approximately one month prior to the COVID-19 outbreak, the Medical Council of Hong Kong (the Medical Council) had expressly acknowledged the use of telemedicine in Hong Kong, by drawing up the Ethical Guidelines on Practice of Telemedicine (the Guidelines) in December 2019.
- The Guidelines set out good practice in the delivery of telemedicine to patients situated in Hong Kong, which medical practitioners should comply with. As anticipated, the Guidelines reinforce the overarching principle that medical practitioners practising telemedicine are held to the same standard of care applicable to in-person medical consultations, though the former may come with greater limitations. The following points are important, as contravention may render a medical practitioner liable to disciplinary proceedings by the Medical Council:-
  - Remote consultations are more applicable to patients who have had an existing patient-doctor relationship that is built on trust and mutual respect. The parties must be able to reliably identify each other so as to utilise telemedicine services.
  - To obtain informed consent, doctors are required to fully explain the telemedicine interaction to the patient in a clear and understandable manner, including its limitations, privacy concerns (such as security issues specific to electronic communications, the possibility of technological failure including confidentiality breaches), prescribing policies and other suitable alternatives available.
  - Doctors must be satisfied that the patient is suitable for telemedicine by considering the patient's full medical history. If a physical examination is likely to provide critical information, a face-to-face consultation should be arranged instead.
- Teledentistry, on the other hand, does not appear to have gained traction in Hong Kong amidst this pandemic.

Key developments for the year ahead

- In the past two years, the Faculty of Medicine of two prestigious universities in Hong Kong have each collaborated with listed companies/ overseas world-leading institutions in research and development of projects - including an artificial intelligence based optical coherence tomography retinal disease screening system and magnetic-guided endoscope[v]. It is also encouraging to note that in May 2020, the Chinese University of Hong Kong remarkably led the world's first successful clinical trial on robotic colorectal Endoscopic Submucosal Dissection using a redesigned endoscopic robot and system.[vi]
- The value of novel medical/robotic technology appears to also be recognised by the courts in Hong Kong. The Court of First Instance in *Lai Chi Wai v Tong Hung Kwok and Tsui Siu Fai* [2020] HKCFI 628 set a precedent for allowing a novel head of claim in personal injury claims.
- The then 28-year-old plaintiff, a world champion rock climber, was involved in a road traffic accident with the defendants which left him totally paraplegic. The Court attributed 75% liability to the defendants and 25% contributory negligence on the part of the plaintiff, for omitting to quickly glance to his right to notice the first defendant approaching him at a high speed.
- On the issue of quantum, the plaintiff claimed for the cost of an exoskeleton which was unprecedented in the common law jurisdictions. The defendants disputed this head of claim on the basis that the technology was still under development and the cost for the device was disproportionate (noting the provision made for a powered wheelchair with stand-up feature).
- The Court found the plaintiff to be a suitable and determined exoskeleton user who would make effective use of the equipment for at least the following 25 years of his life, awarding the initial cost of an exoskeleton (around HK$993,800 in 2020) with four replacements, subject to the deduction for contributory negligence.

- This is the first and only case in Hong Kong allowing this head of damage. Though the outcome of each case will turn on its own facts, this case certainly opens up the possibility for similar heads of loss to be sought in medical malpractice claims involving catastrophic injuries.

Contacts: Christine Tsang, Sandy Cho and Ricky Wu

Thailand

The operational and digital response to COVID-19

- In recent years we have seen a number of major hospitals in Thailand move to develop mobile applications or official online chat application accounts (e.g. a line that aims to facilitate customers' access to their health information).
- These new pathways allow patients to consult with doctors remotely, i.e. via a phone/ teleconsultation, either to discuss their medical issue, make appointments or pay medical bills.

> **"The pandemic has led to a steep increase in the implementation and use of such digital tools and technology by healthcare providers and patients."**

- However, this raises the necessity for a legislative framework that will need to catch up and keep pace with this rapid technological development within healthcare. This 'new normal' in relation to the delivery of medical services could create more risks for healthcare providers and medical practitioners, from the Thai legal perspective.
- One concern for healthcare providers and medical practitioners from the use of remote technology (such as teleconsultations) is the risk of potential liability where the absence of a physical examination and possibility that a doctor may be misinformed by a patient with respect to their symptoms, could result in a misdiagnosis.
- The Supreme Court of Thailand has emphasized the importance of the physical examination:

> **"... an examination and diagnosis of the medical practitioner especially the physical examination is an essential procedure to diagnose the patient's symptoms, state of disease or pathology leading to appropriate treatments."** [vii]

- The Court ruling that the defendant who diagnosed and prescribed medical treatment via telephone without examining the patient was negligent, causing harm to the patient.
- It is notable that according to the notification of the Medication Council of Thailand No. 54/2563, whilst teleconsultations are permitted, the medical provider is still required to comply with standard medical practice and should a claim arise the burden will rest with the provider/ practitioner to establish that they acted in accordance with those standards and were not negligent. The medical provider/medical practitioner must also ensure the remote system/platform that is used is secure pursuant to the laws governing electronic transactions and personal data protection.
- Not every misdiagnosis will be considered medical malpractice. The Supreme Court also recently held that the circumstances and reasons, which led to a misdiagnosis, must be taken into consideration.[viii]
- Furthermore, the conversation between the medical practitioner and the patient via the online/remote application may be crucial evidence to establish whether or not there is medical malpractice.
- According to the National Health Act B.E. 2550, the healthcare provider must notify a patient and relay sufficient health information to them in order for the patient to decide if they would consent to or refuse any medical treatments.
- For a consultation/appointment that takes place in person, Thai courts will usually place reliance on what has been noted in the medical records. In medical malpractice claims in Thailand, claimants often challenge the accuracy of the notes of any conversation(s) between them and the medical practitioner, often asserting that

they are inaccurate and unreliable as they are unilaterally documented by the healthcare provider.

- For those held via online applications, the functionality may enable consultations to be recorded, with the conversation between medical practitioner and patient then integrated within the patient's medical records. The patient's informed consent to record the consultation, would of course need to be obtained in advance. The healthcare provider must also ensure that all information held electronically through such a system is kept strictly confidential pursuant to relevant laws governing personal data protection.

- To mitigate against the risk of medical malpractice claims arising from the use of teleconsultations and similar technology, healthcare providers and medical practitioners should seek as much information as possible from the patient regarding their health conditions and symptoms. Further, where necessary to ensure the medical practitioner has all of the information required to treat the patient or refer them to an appropriate specialist, a physical examination should also then be arranged.

Contacts: Tassanu Chutikanon and Ian Johnston

Europe
Denmark

The operational and digital response to COVID-19

- The Danish healthcare sector has been significantly affected by the COVID-19 pandemic, although seemingly not to the same extent as in many other countries. Many scheduled surgeries have been delayed until hospitals have the capacity to perform them, with resources concentrated on treating the high number of patients hospitalized as a result of COVID-19.
- Furthermore, there has been a change in how citizens attend an appointment with a general practitioner or a hospital appointment. Medical clinics and hospitals must take several precautions to limit the spread of the virus, including patients being required to wear a facemask when entering either a clinic or hospital, social distancing in waiting rooms, and in-person consultations are prohibited for patients with COVID-19 symptoms.
- It is also not possible to book an in-person consultation if there is a risk that the individual has been in contact with someone who has tested positive for COVID-19. The prohibition for consultations with patients that have symptoms of COVID-19 does not apply to hospitals in circumstances that are deemed to be an emergency.
- Remote consultations are being utilised for appointments by both general practitioners and hospitals – particularly by hospitals for follow-up checks or outpatient treatment. That said, our understanding is that general practitioners are examining a similar number of patients in clinics, to that which they would have done prior to the pandemic.
- However, given the precautions that prevent in-person consultations in certain circumstances, there is a risk that for some patients, diagnosis and treatment will then be delayed, in turn presenting an increased risk of injury and loss.
- With regard to medical malpractice claims, in Denmark, instead of going directly to the courts, we have "Patienterstatningen", which is a board that deals with healthcare and medical malpractice claims. In Denmark, patients must use Patienterstatningen and the appeal board "Ankenævnet for Patienterstatningen", before they can take their claims to court. The initial decision on liability usually being made six to nine months following submission of the claim. Following that, the outcome of any appeal (should one be made) will usually take nine to twelve months. Patienterstatningen also handles claims from those who have been infected with COVID-19 and have contracted the virus in hospital.
- In October 2020, the family of a man, who died after contracting the virus at a hospital, was awarded compensation. The hospital had, however, not neglected the guidelines in regard to prohibiting the spread of COVID-19. Patienterstatningen awarded compensation in accordance with the requirements of legislation which provides the right to compensation, without the existence of negligence, in circumstances where the individual sustains rare and severe injuries whilst being treated for something less serious.
- Currently, this is the first claimant to receive compensation for such a claim, but it is anticipated that similar claims will arise, where there is likely to be entitlement to compensation under the same legislation. The extent to which such claims will arise remains to be seen, it not being not possible to accurately assess at this point.

Key developments for the year ahead

- We anticipate that as a result of the pandemic there is potential for claims relating to delayed treatment of non-COVID-19 conditions/illnesses, postponed surgery, misdiagnosis or delayed diagnosis.

Contact: Thomas Arleth

England

> “At the centre of any accelerated and successful digital revolution in healthcare must be the patient.”

Digital health and social care transformation

- What a difference a year makes. The appetite by both patient and clinician, over the course of the pandemic, for the provision of healthcare via digital means has significantly increased. Both in terms of delivery of care and also in terms of monitoring.
- The development, and promotion, of digital healthcare has been dramatically accelerated. NHS England plans to create a new transformation directorate, which will incorporate NHSX. Taking digital to the heart of the NHS. NHSX having started on “the largest digital health and social care transformation programme in the world.”[ix] The aim of which being to provide the technology required to deliver better care across the UK.
- The COVID-19 pandemic has brought with it a renewed focus and belief in better use of technology. Transformation achieved, at a rapid pace, during the pandemic has brought about digital and operational improvement. Continued acceleration of this digital transformation, whilst appreciating change can be uncomfortable, will benefit patients and staff. The ultimate aim is to empower patients, assist them in gaining access to information and improve their health and care provision.
- The Department of Health and Social Care and NHS England have already been working with NHSX so as to develop and support the strategy for a digital future in the NHS. For example, digital urgent and emergency care, such as via NHS 111 online, plus elective care via e-referrals and use of apps, such as the NHS App, to empower patients.
- Opportunities via artificial intelligence, better integrated local care and digital pharmacy provision are all further examples of paths being explored. The desire being to reduce the burden on a stretched NHS workforce and deliver better, and safer, care for patients in the UK.
- There are of course always risks with development and change. The adoption of such technology brings with it cyber security risks, which those working on digital transformation are alive to. A further risk is the digital divide. Those developing the technology are acutely aware of the need not to isolate and endanger patients. Many of the solutions to this rest in tackling economic difficulties. These include costs of products, level of income and funding. In addition, education of users and the ability of infrastructure to support such services also need addressing.
- It strikes us that at the centre of any accelerated and successful digital revolution in healthcare must be the patient. Change is all about people and if the best in digital care and monitoring is to be delivered to the UK population, then there must be buy-in from those that receive the care. Collaborating with users, testing and co-creation all being important.
- To achieve this, expectations need managing and those less digitally able, looked after. Via the training of staff and the benefits being seen by staff, we believe we are already starting to see a shift in understanding and culture, embracing new technology.
- It is the personalised approach, reducing delays to individuals and reflecting a shared purpose of bettering the health of that patient, which we suspect will engender change. Accountability to the patient and giving the patient a sense of ownership will, we believe, secure the future for digital healthcare provision.

> “Opportunities via artificial intelligence, better integrated local care and digital pharmacy provision are all further examples of paths being explored.”

Key developments for the year ahead

The effect of COVID-19

- The focus over 2021/22 will continue to be on the response to COVID-19, whilst supporting the delivery of other public health services.
- As patient outcomes are reflected on, we anticipate a rise in COVID-19 related claims.

Whether these be claims by healthcare employees or claims by patients. Alleged failures in care both with regard to COVID-19 and other, non-COVID-19, conditions consequent on resource allocation being the obvious areas of claim that we are beginning to see.

- NHS Resolution responded quickly to put in place a new scheme to support their Members - the Clinical Negligence Scheme for Coronavirus. This provides additional clinical negligence indemnity cover for those working in the response to COVID-19, in the event that existing arrangements provided by NHS Resolution do not cover the particular activity.

“The focus over 2021/22 will continue to be on the response to COVID-19, whilst supporting the delivery of other public health services.”

Care under the Mental Health Act

- The Coronavirus Act 2020 included temporary changes to the Mental Health Act 1983. The main safeguards are still in place with the intention being to protect people and the rights of patients.
- In January 2021, following an earlier independent review of the Mental Health Act 1983, the UK Government launched a consultation on proposals to improve mental health services and the experience of those subject to the provisions of the Act.

Moving forward the key principles are to give treatment in the least restrictive way and help people to be as independent as possible.

Liberty protection safeguards

- Implementation of a new system of state authorisation for people who are deprived of their liberty – introducing new liberty protection safeguards (LPS) - has been postponed until April 2022, with certain provisions relating to new roles and training due to come into force before then. The new system, replacing the existing deprivation of liberty safeguards will see responsibility shift away from local authorities in many instances to hospitals, Clinical Commissioning Groups (CCGs) or the private sector.
- Postponement has enabled CCGs and NHS Trusts to focus on the COVID-19 pandemic as opposed to having to get to grips with the significant responsibilities that LPS bring with them.

Stable and affordable state GP indemnity

- Since April 2019 NHS Resolution have been successfully operating the state indemnity scheme for general practice in England - the Clinical Negligence Scheme for General Practice. This Scheme covers clinical negligence liabilities arising in general practice in relation to incidents that occurred on or after 1 April 2019.

- The Existing Liabilities Scheme for General Practice (ELSGP) has now also been established, providing clinical negligence indemnity cover for current and former NHS GP members of

medical defence organisations, where terms have been agreed and liabilities were incurred before 1 April 2019. This will, as NHS Resolution confirm, result in a better and more consistent approach to reducing claims and improving patient safety.

Continued Improvement in maternity services via HSIB and ENS

- The Healthcare Safety Investigation Branch (HSIB), which runs concurrently with the Early Notification Scheme (ENS) at NHS Resolution, continues to pursue safer maternity care by identifying common themes and influencing systemic change. Whilst there have been changes to the approach taken, so as to minimise the impact on NHS maternity services during the pandemic, NHS Trusts with maternity services in England are still referring incidents to HSIB, which are being investigated.

Future accommodation costs

- The case of *Swift v Carpenter* [2020] re-examined how the calculation of damages for future accommodation costs should be undertaken. However, in cases of short life expectancy of say less than five to ten years there remains scope for argument over whether a different approach is justified than that set out by the Court of Appeal in *Swift*. Arguments concerning applicability of rental costs in the circumstances of a short life expectancy are likely to be seen.

Continued application of minus 0.25% Personal Injury Discount Rate

- The rate governing the calculation of claims for future losses was last changed on 5 August 2019. With the Civil Liability Act 2018 requiring that the rate is reviewed at least every five years, we do not anticipate a review this year. Application of the minus 0.25% Personal Injury Discount Rate will continue into 2022.

High justification required to depart from Costs Budgets

- A high level of justification will still be required if a paying party is to successfully persuade a Court to depart from an approved Costs Budget. *Utting v City College Norwich* [2020] re-enforced the position that once a Budget is set, then Solicitors should be confident, providing the Budget has been adhered to, that costs will be recovered.

- Interesting times lie ahead. A mix of political, judicial and economic factors will all shape the above. Much to focus on for all parties, as we all strive, ultimately, for justice to be served and for better, and safer, patient care. A focus on what really matters.

Contact: Ed Glasgow

France

> **“100,000 teleconsultations per week are now taking place, compared to 10,000 before the pandemic.”**

The operational and digital response to COVID-19

- The pandemic has considerably accelerated the application of teleconsultations in healthcare. According to French health care authority (*Assurance maladie*) figures, 5.5 million teleconsultations were carried out between March and April 2020, equating to 27% of all consultations performed during this period. [x]

- It is possible that there may have been a decrease in these figures when lockdown restrictions have been lifted since June 2020, however, it is apparent that teleconsultation is becoming a more common practice with records indicating that 100,000 teleconsultations per week are now taking place, compared to 10,000 before the pandemic.[xi]

- Legislation introduced on 9 and 19 March 2020 has also brought greater flexibility in the use of telemedicine as people affected or potentially infected by COVID-19 could benefit from teleconsultation even without referring to their own doctor beforehand (which was the standard procedure). This greater flexibility directly impacts on the number of patients using teleconsultation.

- Despite teleconsultations presenting difficulties in making a diagnosis in some circumstances - where an in-person examination may assist - there is no distinct medical liability regime in place for this means of delivering healthcare. Prior to the pandemic 'e-health' (healthcare services provided electronically) was already a rapidly expanding market, bringing with it the emergence of new risks in relation to professional liability of medical practitioners and healthcare institutions.
- Medical practitioners utilising teleconsultations must ensure they continue to meet their professional obligations, ensuring vigilance in relation to patient confidentiality and data privacy, and that informed consent to proceed by way of a teleconsultation is obtained.
- They must use appropriate software and above all store data securely. To comply with the General Data Protection Regulation 2016/679, medical practitioners must ensure that patient health information is transmitted in a confidential manner and stored on an approved or certified health data host.
- To assist medical professionals in their choice of a digital tool, the French Government has referenced the platforms available and has rated their level of security. This list is drawn up on the basis of a self-declaration by the different platforms, which are consequently responsible for any inaccuracy in their declaration. It is therefore highly recommended that medical professionals consult this list and choose the most secure platform possible. With cyber-attacks becoming increasingly prevalent, this security is essential.

> **Prior to the pandemic 'e-health' was already a rapidly expanding market, bringing with it the emergence of new risks in relation to professional liability of medical practitioners and healthcare institutions.**

Key developments for the year ahead

- The French government has introduced a vaccination campaign organized in to three different phases. Two principal criteria were taken into account to classify the population: the existence of an individual risk factor for developing a severe form of the virus and the increased exposure to it.
- Vaccination is not mandatory, however it is highly recommended. The vaccination campaign raises the question of vaccine liability in France - for example, potential liability in relation to a defective vaccine; the duty to obtain informed consent; and the method of its administration.

- In the case of recommended vaccination, direct damage may under certain conditions only give rise to a right to compensation under an amicable settlement procedure. This allows the Conciliation and Compensation Commission to seek to establish liability on the part of the producer of the vaccine, the physician or any other person involved.
- The liability regime for vaccine accidents varies depending on whether the vaccine is mandatory or not. If it is, a specific regime in place since 2002 through the *Kouchner* law, applies. In accordance with this, the French state is directly liable to those injured as a consequence of mandatory vaccination and to compensate them through the ONIAM (National Office for Compensation for Medical Accidents), as an expression of national solidarity.

“ The vaccination campaign raises the question of vaccine liability in France ”

- The extent to which COVID-19 related claims will be brought against healthcare providers remains to be seen.
- The deployment of 5G in 2021 is expected to enable the further advancement and application of telemedicine in France, including the development of tele-surgery, tele-surveillance and tele-consultations in conditions yet to be determined, in terms of the regulatory and legislatory framework and also from a technical standpoint.

Contact: Aurélia Cadain

Ireland

“ During the initial surge of the pandemic in March 2020, Ireland experienced a significant shift in the landscape of its healthcare sector.”

The operational and digital response to COVID-19

- During the initial surge of the pandemic in March 2020, Ireland experienced a significant shift in the landscape of its healthcare sector. Amidst fears that the public healthcare system would be unable to cope with the strain of the pandemic, an agreement was reached which saw the Health Service Executive take over the use of all private healthcare facilities in the state, for a period of three months.
- In the spirit of solidarity, the intention of this agreement was to provide additional beds and facilities for the treatment of both COVID-19 and non COVID-19 patients, and to prevent the public healthcare system becoming overwhelmed. To facilitate this additional capacity, private patients were unable to seek treatment at private hospitals during those three months. In reality however, the private hospitals across the state were largely empty for a period of three months, as the additional facilities were not required.
- With the latest surge of COVID-19 in December 2020 / January 2021, the healthcare sector is again drawing on the excellent relationships in place between the public and private hospitals in the state. A new agreement has been reached with most private hospitals whereby the state would have access to 15-30% of capacity in those private hospitals. However, the continuity of access to private healthcare during the pandemic, is now ensured.
- As was the case globally, Ireland has witnessed a shift to telemedicine and remote consultations where possible during the pandemic, although this is most apparent in the primary care setting. Insurance providers responded swiftly to extend cover to clinicians

for telemedicine services for the duration of the pandemic. Once the pandemic is over, it is likely that cover for telemedicine will be included in policies as a matter of course.

- A number of the principal indemnifiers in Ireland have advised that they have not yet seen an increase in any telemedicine claims.
- Collateral harm claims relating to the pandemic are anticipated to rise sharply in the coming years, with delayed diagnosis claims, particularly for cancer patients, predicted to rise in prevalence.

> **"Once the pandemic is over, it is likely that cover for telemedicine will be included in policies as a matter of course."**

Key developments for the year ahead

- Civil justice reform in Ireland, particularly for clinical negligence claims, is on the horizon, heralding an efficiency overhaul of the existing system.
- The publication of the *Administration of Civil Justice Review Report*[xii] in October 2020 provided over 90 recommendations to improve the Irish civil justice system. One of the key recommendations was the implementation of pre-action protocols for clinical negligence claims, which were first given a statutory footing in 2015[xiii] but have yet to be put into effect.
- The Review Group highlighted the multitude of benefits of the introduction of pre-action protocols in Ireland, including early inter-party communication, leading to early identification of issues; early and full disclosure of information and medical records; and the potential of the protocols to facilitate more cases resolving at the pre-action stage.
- Implementation of pre-action protocols has also been recommended by the *Expert Group Report to Review the Law of Torts and the Current Systems for the Management of Clinical Negligence Claims*[xiv], chaired by Mr Justice Charles Meenan. The report, published on 17 January 2021, states that: "*The benefits of pre-action protocols and case management are all too obvious*" and include earlier engagement between the parties, which would ensure that claims would only come on for hearing after all issues had been clearly defined.[xv]
- Importantly, the report also recommends sanctions for failure to comply with the pre-action protocol requirements. Judge Meenan's report also recommends the creation of a dedicated clinical negligence list and case management procedures for clinical claims. All of which are steps that we anticipate would greatly assist the progression of cases and improve efficiency.
- As a first step, it is hoped that the necessary Regulations to introduce the pre-action protocols will be finalised this year.
- The Personal Injuries Guidelines Committee - set up pursuant to the Judicial Council Act 2019 - is set to overhaul the current Book of Quantum, including the provision of more detailed heads of damage and a re-assessment of the level of recommended awards. The final guidelines are due for publication in July 2021.

> **"Civil justice reform in Ireland, particularly for clinical negligence claims, is on the horizon, heralding an efficiency overhaul of the existing system."**

Contact: Joanne O'Sullivan

Portugal

> **The use of telemedicine is in its infancy and for several reasons it is quite some way from being a complete solution to addressing the difficulties experienced in Portugal.**

The operational and digital response to COVID-19

- As in many other countries, hospitals in Portugal have of necessity prioritised the provision of emergency treatment and ongoing care to those with COVID-19. With this reallocation of resources, telemedicine, has provided an alternative means of accessing healthcare services.
- However, the use of telemedicine is in its infancy and for several reasons it is quite some way from being a complete solution to addressing the difficulties experienced in Portugal. For example, with an ageing population, there are many who do not have access to or do not feel comfortable with using remote means to engage with healthcare services.
- Despite these limitations, use of remote consultation has been gradually increasing in Portugal, with analysis published by Portugal's government showing that there were a total of 44,534 remote consultations in 2020, compared with a total of 29,778 in 2019.[xvi]
- Although there is growing optimism for the role that telemedicine can provide in the delivery of healthcare, it requires additional investment from the government to ensure the platforms used are secure in relation to handling and displaying sensitive patient data, in order to provide protection to patients, medical practitioners and healthcare providers.

Contact tracing apps

- When facing a pandemic the Health Ministry may issue exceptional public health emergency measures. Consequently, the application TRACE COVID was developed, as a support tool to follow up on patients in self-care or an ambulatory regime and to monitor the compliance of measures applied to patients with (or those suspected of suffering with) COVID-19.
- An app aimed at breaking the chain of infection: the STAYAWAY COVID, has also been developed, enabling a user to be notified if they have been near another user who has subsequently tested positive for COVID-19. As with other apps, this data processing is to be limited to warning the user of potential exposure risk and may not be used as a control tool to monitor lockdown or social distancing rules.
- Further, it is its exceptional and transitory nature that allows and provides justification for the national health authority to be the data processor and to control the public health situation through such means.

- The use of data and technological solutions during the pandemic has been an essential means to reduce and limit infection. It perhaps also raises some interesting questions about the role of such technology once we emerge from the pandemic. It is clear that data privacy and protection must continue to be imperative.

Key developments for the year ahead

Court claims and trial dates

- The most recent lockdown measures introduced by the government on 28 January 2021 included the suspension of all legal deadlines and limitation periods in all civil claims, as well as the obligation to reschedule or cancel all court dates.
- A similar restriction of court activity was implemented during the first full-scale lockdown, almost a year ago, which has hindered the normal flow of claims and these new restrictions will continue to impact on the lifecycle of claims for some time yet.

Contacts: Luís Paulino and Paulo Almeida

Spain

The operational and digital response to COVID-19

- It has been necessary for healthcare providers in both the public and private sectors, to implement and develop new virtual solutions in order to continue providing services during the pandemic - through telephone and video consultations and the use of apps to facilitate points of contact between patients and providers.
- The impact of the implementation of virtual healthcare on the claims landscape is as yet unknown. We anticipate that practitioners may struggle to obtain full information from a virtual consultation compared to an in person appointment, presenting an increased risk of medical malpractice claims relating to misdiagnosis and late diagnosis.
- In Spain, as elsewhere, resources within the healthcare sector have been necessarily focused on treating those with COVID-19, requiring the reallocation of resources. Whilst essential to address the challenges presented by the pandemic, one concern is that the knock-on effect of this may be an increase in claims arising from patients with non-COVID-19 conditions, disease or illness that have been affected, perhaps through cancellation and/or delay in respect of treatment or surgery, or a delayed diagnosis.

“The impact of the implementation of virtual healthcare on the claims landscape is as yet unknown.”

- At this stage we are yet to see medical malpractice claims arising in relation to COVID-19.
- There are however some instances where criminal proceedings are underway in connection with deaths arising in care homes as a result of COVID-19, for example where residents had not transferred to hospital for treatment.

Key developments for the year ahead

- In Spain there have not been any statutory or regulatory changes of particular note in the last year that have impacted on medical malpractice claims and at this point we do not anticipate any particular changes in this respect in the near future.
- Claimants generally seek lump sum damages in Spain despite the possibility of this being replaced by a lifetime allowance. There is case law emerging whereby some courts are applying a hybrid solution by providing a lump sum with respect to the personal injury aspect but applying lifetime allowance for care costs and other future losses.
- Claims relating to injuries sustained at birth where there are future treatment and third party care and assistance costs, continue to be those where compensation payments are the highest.

Contact: Alfonso de Ramos

Latin America

> **As a result of limited public healthcare resources more people have started to engage the services of the private healthcare sector during the pandemic.**

- The pandemic has made it evident that professional and high quality healthcare is crucial to the development of the societies we all live in.
- Traditionally, Latin America has been reliant on public healthcare systems to provide care for its population, with far more limited use of private healthcare providers. As in so many countries, the pandemic has challenged the healthcare systems of the majority of those within Latin America, particularly in terms of capacity and availability of beds. As a result of limited public healthcare resources more people have started to engage the services of the private healthcare sector during the pandemic, realizing that is better to have a private health plan.
- Awareness of options for private medical insurance products that are available has also increased and development of the private healthcare sector is expected.

Contact: Alex Guillamont

Brazil

> **“ We may see allegations of medical malpractice relating to the lack of capacity in hospitals during the pandemic, shortages in supplies of oxygen to administer to those being treated for COVID-19, and possibly claims for medication errors. ”**

- Some practitioners and hospitals are using forms of telemedicine such as teleconsultation, and this has increased as a result of the pandemic. However, use of telemedicine in Brazil continues to be at an early stage and not used as widely yet as in other parts of Latin America.
- We may see allegations of medical malpractice relating to the lack of capacity in hospitals during the pandemic, shortages in supplies of oxygen to administer to those being treated for COVID-19, and possibly claims for medication errors. At present, there are a limited number of claims emerging. The most common non-medical malpractice claims are against health insurers that refuse to indemnify the insured.

Contact: Fabio Torres

Chile

- In Chile most Clinical Centers, especially those in the private sector, have implemented telemedicine, for basic consultations. This transition however is not without its challenges, particularly in ensuring privacy of patient information. At present we are not seeing medical malpractice claims relating to COVID-19.

Key developments for the year ahead

- In relation to other developments, the Court of Appeal of Antofagasta recently ordered a surgeon to pay compensation of almost USD 1,049,000 for negligence in relation to bariatric surgery, performed in 2012. The claimant presented with serious post-surgery complications that went unnoticed and therefore untreated, and led to the claimant's early retirement. The damages awarded in this case are notable for being high, particularly as the ruling is against the medical practitioner as an individual, rather than against the Clinical Center.

Contact: Gian Lorenzini

Colombia

- Due to the pandemic there has been an increase in telemedicine services provided by both the social security health system (Entidades Promotoras de Salud) and private health insurance providers. Teleconsultations are taking place and are being expressly recommended by health authorities in Colombia in order to avoid further contagion.
- In addition, to reduce attendances at hospitals and clinics for non-COVID-19 related health matters, healthcare providers are undertaking home visits to carry out medical examinations and to take samples.
- To the extent that medical appointments can be carried out remotely, it has been the preferred option and recommendation in Colombia.
- The significant increase in the use of telemedicine/remote delivery of healthcare has helped reduce the risk of infection and has enabled optimisation of the space within hospitals to treat patients with the virus. The technology also provides the opportunity to increase access to healthcare in Colombia for those sectors of the population who live in more remote/rural areas where significant travel is required in order to access hospitals and clinics.
- The main risk that we consider telemedicine /remote consultations present, is that physical examination is often important to reach the correct diagnosis or to determine that the patient should be referred to another specialist. Whilst we have not yet seen malpractice claims for misdiagnosis arising from a remote consultation, it is possible these types of claims will occur as the use of this method of delivering healthcare increases further.
- Whilst we are not currently aware of any COVID-19 related medical malpractice claims, we anticipate a possible trend in healthcare claims related to: (i) COVID-19 testing; (ii) COVID-19 medical attention (both pre-emptive and regarding the medical treatment of the disease); and (iii) vaccination, which to date is still uncertain in Colombia.

Key developments for the year ahead

- Having been anticipated during the second half of 2020, reform of Colombia's social security healthcare system is now expected this year. The Bill (identified as *Proyecto de Ley 010 de 2020*) - providing for systemic reform of the healthcare system on a macro-level - had stalled during debating in Congress and was also delayed as a result of the pandemic. The Bill was subsequently removed to be presented in the first half of 2021. In its current form we do not anticipate the Bill (if enacted) will impact on medical malpractice claims, particularly as medical tort regulation is not addressed within the Bill.
- However, the revised version of the Bill to be presented will hopefully include provisions addressing any learnings from the pandemic and will start its debate proceedings in Colombia's Congress, and there may yet be several changes that could have potential impacts.

Contact: Monica Tocarruncho Mantilla

Mexico

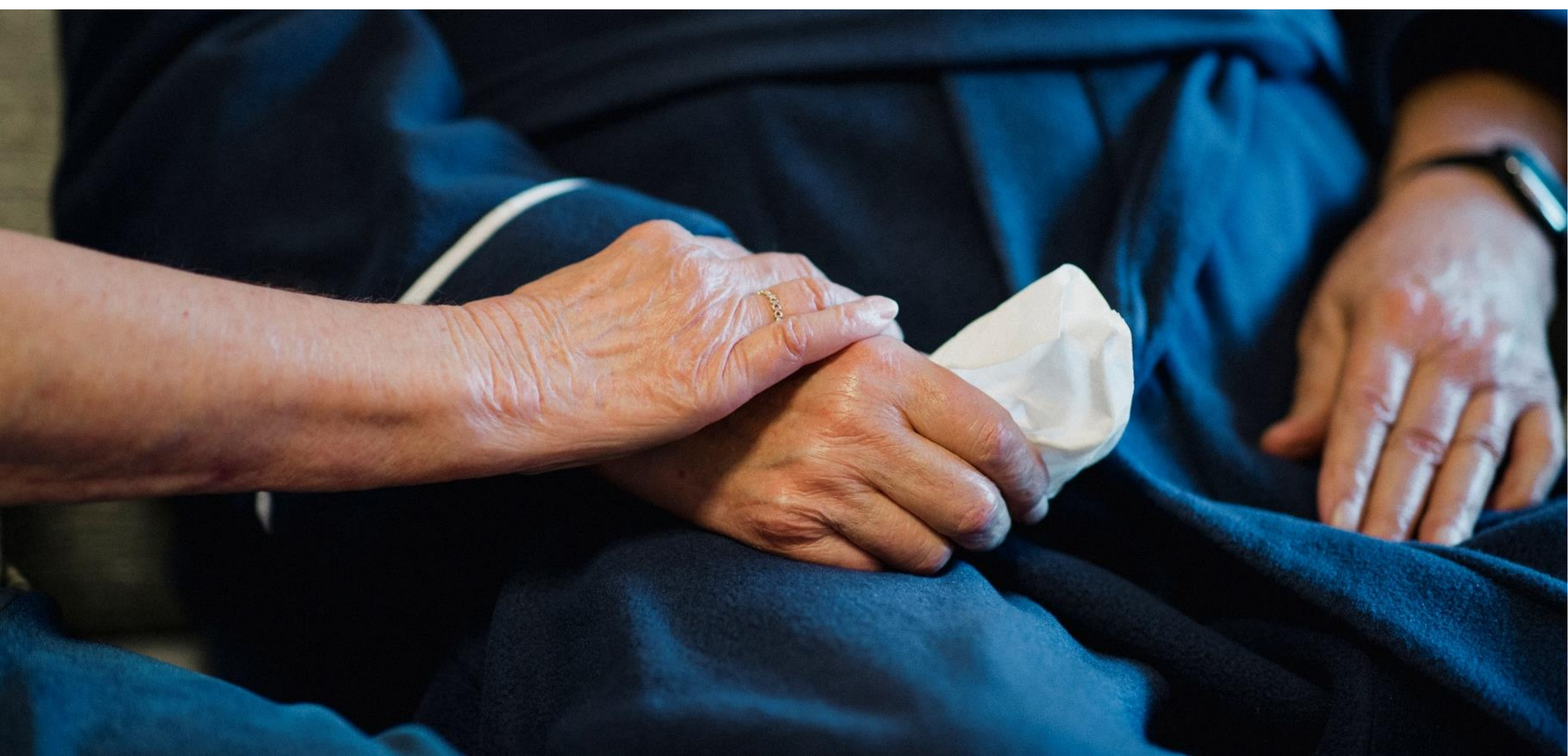
- In Mexico we are not aware of a significant development or shift towards virtual or remote delivery of healthcare as a result of the pandemic.
- To date we are not seeing medical malpractice claims relating to COVID-19, however we anticipate that such claims are likely, but may not materialise for two years or more. It is likely that we will see claims against medical practitioners and hospitals alleging improper or lack of medical attention during the pandemic. Prior to the pandemic there are examples of claims that have been made against hospitals because of negligence. It is possible that similar claims will arise as a result of the pressure on hospital resources throughout the pandemic.

> **“In Mexico we are not aware of a significant development or shift towards virtual or remote delivery of healthcare as a result of the pandemic.”**

Key developments for the year ahead

- There are a number of judicial decisions which provide protection to those affected by medical malpractice and the provision of comprehensive compensation - holding not only doctors but also hospitals responsible: ‘apparent responsibility’. Interpretation of that responsibility by the courts can present risk to healthcare providers and medical practitioners.
- For example, in some circumstances that present particular difficulty for the claimant to establish proof of an error, the court has shifted the burden to the healthcare provider/medical practitioner to demonstrate it acted appropriately. In many cases the scope of responsibility can be extended to the hospital, as well as the individual medical practitioner.
- As a result of change to the principal law in Mexico - the Political Constitution of the United Mexican States - international treaties now take legal precedence. As a consequence there has been a shift in the approach taken by the courts in the level of compensation awarded in medical malpractice claims. In accordance with the approach taken by the Inter-American Court of Human Rights, the Supreme Court of Mexico has formally recognised the principle of ‘full reparation’, and this is now being applied by the lower courts, resulting in higher compensation payments being awarded.
- A further developing trend in Mexico is the increasing cost of medical care, not only linked to but also above inflation and without a limit set by the Government. For this reason, insurance premiums have increased significantly. What is expected in the medium term is that the health system will have serious complications as a consequence of increased life expectancy and long-term or chronic diseases (diabetes, hypertension) are increasing significantly.

Contact: Alberto Torres



Peru

Whilst the use of technology for the remote delivery of healthcare is relatively new in Peru, we anticipate the emergence of new types of claims associated with its use.

- Since 2016 Peru has taken steps to provide a legislative framework for the use of telemedicine, with certain statutes including Law 30421 - Telemedicine General Law, having been enacted. During the pandemic, Legislative Decree 1490 has been issued to strengthen the scope of telemedicine.
- Other provisions have also been issued to set guidelines for telemedicine development as a strategy for the provision of healthcare services. The purpose of the guidelines being to improve the efficiency and quality of telemedicine services, as well as to increase its coverage through the use of information and communication technologies in the national health system.
- In Peru, the pandemic has led to the acceleration of digitalisation of healthcare, resulting in a remarkable increase of telemedicine offerings, at least for outpatient consultation. The Telemedicine National Centre was opened in 2020 in Cercado de Lima and has more than 20 medical specialties (such as, oncology, cardiology, dermatology, pneumology, paediatrics, among others).
- It is anticipated that widespread implementation of telemedicine will have a positive impact given Peru has many rural areas without any or very limited access to healthcare services. Despite the benefits that telemedicine offers, in Peru it also comes with new governmental challenges in providing further internet coverage in those rural areas.
- Whilst the use of technology for the remote delivery of healthcare is relatively new in Peru, we anticipate the emergence of new types of claims associated with its use. Similarly, whilst we are not currently handling COVID-19 related medical malpractice claims, we anticipate claims arising in matters such as delayed diagnosis and treatment of non-COVID-19 related conditions, vaccine related claims, infection whilst in hospital through inadequate preventative measures, among others.

Key developments for the year ahead

- After its launch in 2016 without reaching the expected results, in August 2020, the Susalud Contigo app was updated to become more user friendly, encouraging citizens to submit complaints through it. The app is intended to promote and defend Peruvian citizens' health rights. Through it, users from healthcare centres (public or private) may obtain information regarding their healthcare insurance, map out the closest healthcare facilities with GPS technology, report any alleged medical malpractice and submit complaints regarding their health insurance. We anticipate the app’s update may contribute to an increase in the number of minor medical malpractice claims.
- Other developments include the digitalisation of medical records and personal data in at least 70% of those centres administered by the Peruvian public healthcare provider (ESSALUD), which currently is a work in progress. Despite this, we are not aware of any legal provisions to ensure further steps are taken to help guard against cyber-security breaches and this may lead to sanctions and claims against hospitals.
- In 2018, according to public sources [xvii] 80% (approximately 52,000 claims) of the total number of medical malpractice claims submitted in Peru were either due to (1) difficulties accessing healthcare services or (2) difficulties in obtaining adequate information for health needs.
- We anticipate that during 2021, difficulties accessing healthcare services due to priority given to COVID-19 related matters will still be among the most recurrent claims, together with those related to infections whilst in hospital through inadequate preventative measures.

Whilst the use of technology for the remote delivery of healthcare is relatively new in Peru, we anticipate the emergence of new types of claims associated with its use.

Contact: Fernando Hurtado de Mendoza

Middle East

Israel

COVID-19 related med-mal claims in Israel

- In March 2020, the public healthcare system as a whole had to go into a state of emergency within a matter of days. Dealing with a mostly unfamiliar virus and the risk of exponential spread of the disease, meant that the system had to make significant organizational changes.
- Resources were diverted from regular medical needs to specific 'COVID-19 related' ones, with a number of hospital wards for example, converted specifically for the treatment of those with COVID-19.
- Whilst under such circumstances, the risk of medical mistakes, and subsequent medical malpractice claims, was significant, to date there have been sporadic claims relating to elderly homes. However, we have not seen the large number of claims that may have been anticipated.
- We anticipate that as time passes and knowledge relating to diagnosis and treatment of the virus grows, scrutiny of health services delivered during the pandemic will increase. It is possible that what would be perceived as acceptable and reasonable medical conduct during the early stages of the pandemic, may be considered as negligence a year later.
- Claims against the state and public health funds for negligently failing to adequately prepare the public healthcare system for the pandemic, resulting in errors in the treatment given or a lack of treatment of COVID-19 patients, are unlikely to receive the courts' sympathy. It is doubtful whether such claims have a real chance of being successfully brought.
- Accepting claims against clinicians, for failing to diagnose and/or treat infected patients is similarly an unlikely outcome at this time. Under the circumstances that existed, where no coherent procedures for the diagnosis and treatment of patients were established, it is hard to envisage the court holding a healthcare professional to have breached their duty (when the scope of 'the duty' was unclear). Issues of causation may also hinder the potential claimant.
- Of course, as time passes and knowledge of the disease grows, one can anticipate that COVID-19 associated claims will be dealt with in the same manner as all other medical malpractice claims. However, at present, unless the circumstances are extreme and the negligence is gross, we do not consider such claims would have sufficient prospects of success.
- The same principals seem to apply to claims associated with non-COVID-19 patients, affected by the redirection of resources and staff to enable greater capacity for the treatment of COVID-19 patients, as well as the shift towards remote delivery of healthcare. We anticipate that one must see severe negligence causing serious damage for a claim to be accepted.

Contact: Yaron Ben-Dan

North America

Canada

> “The allegations are broadly similar across all claims in that there has been a substandard response to COVID-19 by way of internal procedures, policies and practices.”

- In Canada a significant number of long-term care homes are currently defending class action claims arising from the spread of COVID-19.
- The allegations are broadly similar across all claims in that there has been a substandard response to COVID-19 by way of internal procedures, policies and practices. It is argued, long-term care homes have negligently failed to prevent the introduction of COVID-19 into their facilities; and thereafter, have failed to meet the challenge of controlling spread within the homes.
- Two Canadian provinces, Ontario and British Columbia, who have introduced legislation to limit civil liability arising from COVID-19 claims in the interests of preserving the industry at large.

British Columbia

- On 18 March 2020 British Columbia declared a state of emergency pursuant to the Emergency Program Act 1996. Pursuant to the authorities provided within the COVID-19 Related Measures Act (the CRMA), the Solicitor General made Ministerial Orders on 2 and 22 April 2020, which were implemented as formal legislation by the CMRA on 10 July 2020.
- The CRMA provides that a person is required to act in accordance with applicable emergency and public health guidance, or reasonably believe they are acting in accordance with such guidance, in order to be protected from liability. Conduct that constitutes gross negligence is not protected.
- Applicable to hospitals and long-term care homes, the civil liability protection applies to any person engaged in a prescribed act including directors, proprietors, owners of the business/service, employees and volunteers.
- The CMRA has a retrospective scope commencing from 1 January 2020 and will be automatically repealed 10 July 2021.

> **In Canada a significant number of long-term care homes are currently defending class action claims arising from the spread of COVID-19.**

Ontario

- Ontario’s Bill 218 received Royal Assent on 20 November 2020, and enacted Supporting Ontario’s Recovery Act and Municipal Elections Act 2020 (SORA). SORA defeats all causes of action in negligence arising from the transmission of or exposure to COVID-19 as long as the accused party (section 2(1)):

  (a) “acted or made a good faith effort to act” in accordance with public health guidance and any laws pertaining to COVID-19; and

  (b) was not “grossly negligent” in its conduct.
- SORA applies to a range of defendants including hospitals, long-term care homes and retirement homes.
- In light of SORA, in order to maintain an action for civil liability in relation to a claim arising from COVID-19, a plaintiff must now establish that the defendant failed to act or make a “good faith effort” to act in accordance with public health guidance and any laws pertaining to COVID-19, and was grossly negligent.

Negligence or gross negligence

- We consider the definitions in both provinces synonymous despite their subtle difference in language. Both effectively protect the actor insofar as they believe they acted in compliance with the relevant guidance subjectively, and whether or not their conduct was reasonable from an objective standard.

- Both the CMRA and SORA exclude protection for ‘gross negligence’. In the absence of clear legislative intent in either province to define a term, we look to case law.

- The leading authority on the definition of gross negligence remains the Supreme Court of Canada’s 1942 decision in *McCulloch v Murray* [1942] SCR 141 where the Court considered the term in relation to a motor vehicle accident claim under Nova Scotia legislation.

- In totality, the case law suggests that courts have been hesitant to establish a firm definition of gross negligence. The only common thread appears to be that gross negligence will be interpreted in light of the surrounding circumstances and the ordinary standard of care which applies to those circumstances, gross negligence requiring a substantial departure from ordinary negligence.

Impact

- We anticipate judges across the board at any case management stage will strongly encourage mediation and other forms of alternative dispute resolution (ADR), given the higher legal threshold to be met. Furthermore, for those claims where the parties engage in ADR, we expect settlement sums to be significantly reduced and in some cases, claims withdrawn with each party bearing their own costs.

- Accordingly, the cost to long-term care home insurers and their insured’s is likely to be significantly less than the potential exposure anticipated prior to the legislative changes that have been implemented.

Contact: Balraj Sihota, Dolden Wallace Folick LLP, Kennedys’ associate office

Further information

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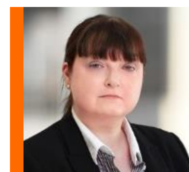

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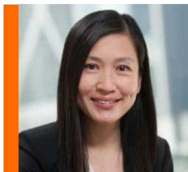

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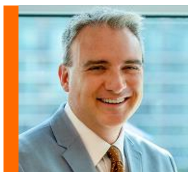

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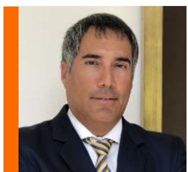

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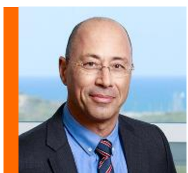

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