



Practice MATTERS

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EDITORIAL TEAM

Dr James Lucas
EDITOR-IN-CHIEF



Louisa Waite
EDITOR



CONTRIBUTORS

Hilary Steele, Suzanne Creed, Dr James Lucas, Dr Rachel Birch, Dr Dawn McGuire, Dr Helen Hartley

PRODUCTION

Emma Senior, Paul Moss

MARKETING

Rachel Lynch, Vicky Colthart

Please direct all comments, questions or suggestions about MPS service, policy and operations to:

Victoria House
2-3 Victoria Place
Leeds LS11 5AE
United Kingdom

chief.executive@medicalprotection.org

In the interests of confidentiality please do not include information in any email that would allow a patient to be identified.

Medicolegal advice

Tel +44 113 241 0200
Fax +44 113 241 0500
querydoc@medicalprotection.org

Membership enquiries

Tel 1800 509 441
Fax +44 113 241 0500
member.help@medicalprotection.org

medicalprotection.org

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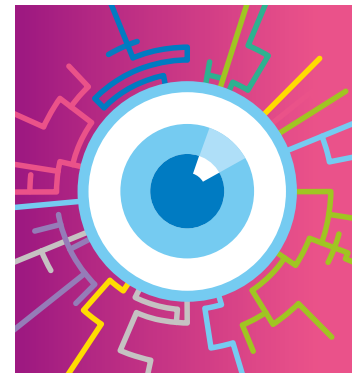
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WELCOME

Dr James Lucas
Editor-in-Chief



Welcome to the latest edition of *Practice Matters*. This September saw another successful general practice conference in Dublin – ‘Understanding Patients, Tailoring Care’. The programme was jam-packed and there were a number of enlightening talks and workshops from experts covering topics from ‘Never Events’ in general practice to managing burnout. Delegates also had an opportunity to network and learn how colleagues are managing the many challenges of general practice. If you haven’t had an opportunity to attend one of our conferences, please do consider joining us in the future.

Rachel Birch, medicolegal consultant at Medical Protection, and Rebecca Ryan, a partner at Matheson Solicitors, provided a talk on the treatment of patients with impaired mental capacity. Rachel, an experienced GP, presented an out-of-hours scenario involving an elderly patient who appeared to have developed delirium secondary to an infection. The patient lacked capacity and as a result of her behaviour, was at risk of harm. Rachel discussed the framework for assessing capacity and suggested practical tips for managing this difficult situation. Rebecca offered a glimpse of things to come. For example, the eagerly awaited Assisted Decision-Making (Capacity) Act 2015 will support and strengthen decision-making in patients with impaired capacity. The main provisions of the Act are not yet in force and we will be looking at its implications for general practice in future editions of *Practice Matters*.

Two speakers from the conference have provided articles for this issue of *Practice Matters*. Suzanne Creed, clinical risk education manager at Medical Protection ran a workshop on consent in general practice, and shares some of the learning points on pages 9–11. We also have an article on the claims experience in Ireland and the argument for change from Hilary Steele, claims lead at Medical Protection, available on pages 6–8.

On page 12 I explain the implications of a recent Irish High Court judgment in relation to patient confidentiality. This is a significant issue in general practice and a common source of queries for Medical Protection’s expert consultants. In our ‘From the advice line’ feature I share advice related to a query about childhood immunisations and parental consent on page 14. Medical claims adviser, Dawn McGuire, shares examples of injection errors on pages 16–17, which are a common cause of claims at Medical Protection, despite being easily avoided. We also look to the future on page 18 and consider the liability of artificial intelligence.

I hope you enjoy this issue. We are keen to hear what our members think so if you have any feedback or comments please do get in touch.

Dr James Lucas, Editor-in-Chief



UPDATE REGARDING MEDICAL TERMINATION OF PREGNANCY

Following the results of the referendum in May, GPs in Ireland are likely to be approached by patients for advice and treatment to terminate their pregnancies.

Medical Protection considers medical termination of pregnancy would fall within the scope of general medical practice. Provided the doctor is appropriately trained and complies with the law and clinical and Medical Council guidance, Medical Protection is willing to offer indemnity to those GPs who choose to provide this service, and presently, does not expect the price of GP subscriptions to be affected by this development.

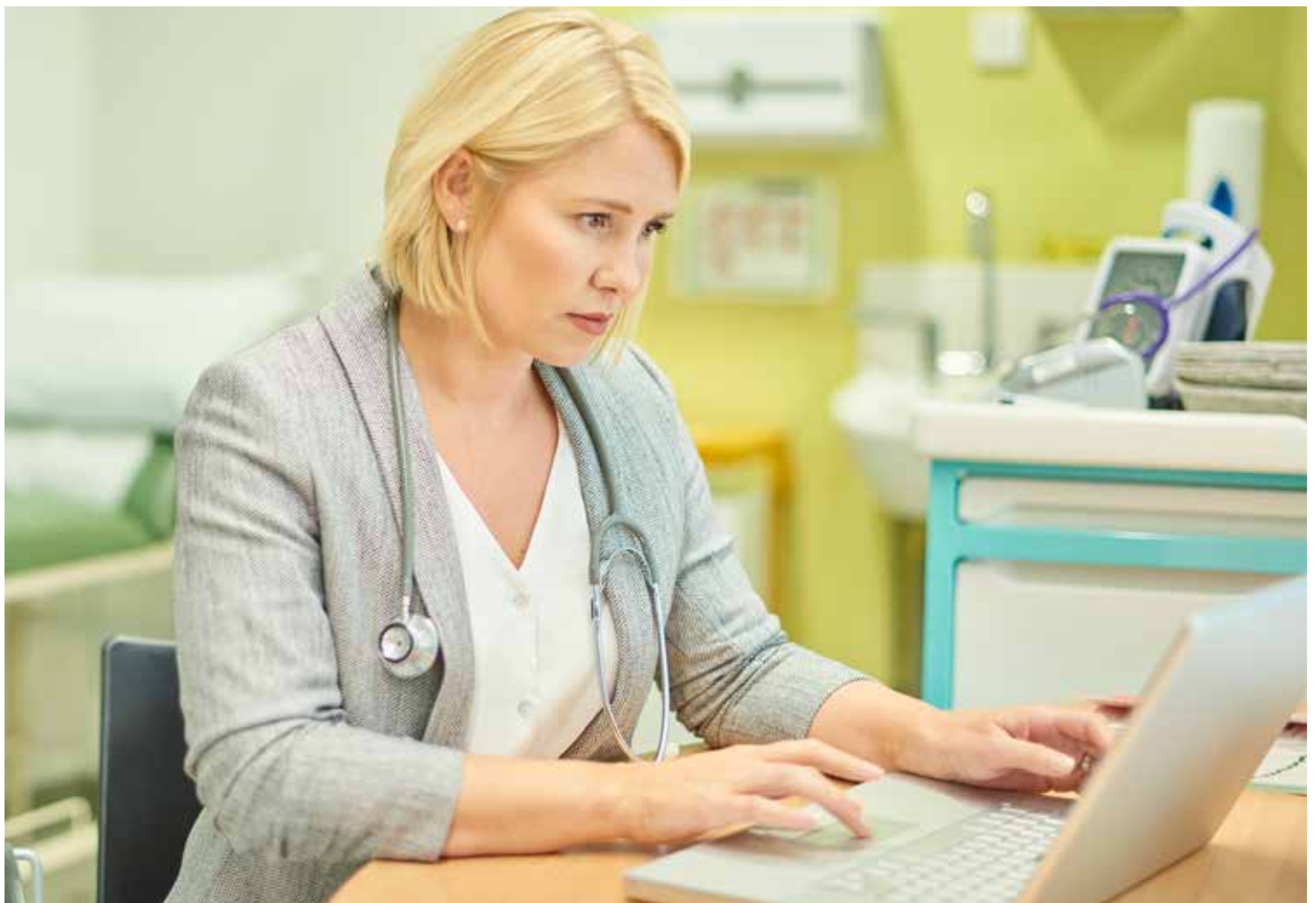
If the proposed legislation is passed, terminations will be legal, without restriction up to 12 weeks – and provided through a GP-led service. Terminations will also be lawful, regardless of gestational age, in cases where there is a condition affecting the fetus that is likely to lead to its death either before, or within 28 days of birth; or where there is an immediate risk to the life, or of serious harm to the health, of the pregnant woman.

The legislation, which the Government will aim to introduce by the beginning of 2019 at the latest, has completed Dail Eireann

(Third Stage), although the final details with regard to the medical termination service are still to be announced. Minister for Health Simon Harris has indicated that it is a priority for the Government to have a medically delivered, safe and regulated service for the termination of pregnancy for all those who require it in the State.

GPs who are planning to provide this service should be aware and comply with evolving clinical and regulatory guidance, particularly with regard to conscientious objection and working within and maintaining competence. The Medical Council has confirmed that it will establish a working group to review the *Guide to Professional Conduct and Ethics for Registered Medical Practitioners*, in light of the referendum result.

We will share further information with you as it becomes available, so please do check the Medical Protection website or if you require specific advice contact **+44 113 241 0200**.



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MEDICAL PROTECTION TACKLES THE RISING COST OF CLINICAL NEGLIGENCE

THE IRISH CLAIMS EXPERIENCE

Hilary Steele, Medical Protection's claims lead for the Republic of Ireland, explains how Medical Protection is tackling the rising cost of clinical negligence and the increasing burden this is placing on both the State and members

DO WE HAVE A COMPENSATION CULTURE?

In Ireland, claims for compensation continue to rise. From 2010 to 2017 GP claims received by Medical Protection increased by 76%. The Health Service Executive paid out €248.88m in 2017 for clinical negligence claims, which was an increase of over 20% on 2016.

This is a global problem, with the medical profession increasingly under the spotlight and plaintiff firms able to build lucrative businesses with little risk and significant financial rewards.

Medical Protection represents members all over the world, and we see disproportionately higher sums of compensation being awarded in Ireland than elsewhere. For example, in a recent case a child, who fell against a radiator and cut his back, leading to a small scar, was awarded €50,000. On appeal the judge noted it was "possibly, if not probably, the smallest scar I have ever seen form the subject of High Court proceedings in more than 35 years of legal practice" and reduced the payment to €25,000. By comparison, compensation for a small facial scar would be £1,360 – £2,810 in Scotland, England and Wales.

The current guidance on valuing compensation claims in Ireland is set out in the Personal Injuries Assessment Board's (PIAB) *Book of Quantum*, which provides suggested compensation for categories of injury. For example, the recommended compensation for a soft tissue injury to the thumb, such as a minor sprain with no loss of function, is up to €21,200. The equivalent UK guideline for such an injury is up to £1,675.

The addition of high legal fees (higher than in any of the other 40 countries in which Medical Protection operates) has unfortunately created the perfect storm for a compensation culture, in which all too often, the patient's legal team end up claiming more in costs than the patient actually receives in compensation.

This is of course an unwelcome trend, but members can be reassured of the expertise and support of our team of solicitors, who amongst them have more than 50 years' experience of managing claims in Ireland, and who remain committed to ensuring that they deliver the best possible outcome on your behalf.

MEDICAL PROTECTION INFLUENCING CHANGE

We face a major issue with patients' solicitors delaying, or indeed refusing, to provide key information needed to investigate a claim. These delays are understandably frustrating for members, particularly when they seem designed to maximise the legal costs rather than to obtain fair compensation for their client.

Pre-action protocols have been successful in the UK, as they allow the resolution of claims without the need for court action. Inherent in any such protocol is the early disclosure of all relevant information required to investigate and resolve a dispute, which in turn reduces unnecessary legal costs. It seems obvious that all possible steps should be taken to achieve resolution before legal proceedings start, as this benefits both the patient and doctor.

We have recently provided detailed recommendations, including the introduction of a pre-action protocol, to a new Expert Group

set up by the Government to improve the current system for the management of clinical negligence claims. This Expert Group is highly welcomed and we are well placed to offer a unique insight into best practice because of our in-depth knowledge and experience of dealing with claims locally and worldwide. In our recommendations we have focused on each stage of the claim process – from pre-litigation all the way through to the conclusion of a trial.

Medical Protection has drafted a voluntary pre-action protocol that has now been signed up to by leading plaintiff firms and the State Claims Agency. This is already starting to change the way in which plaintiff and defence lawyers are engaging, to the benefit of all parties. The legislative framework for a statutory protocol has been in place for many years and we are optimistic that a binding protocol will be brought into force by the Government in the near future.

LIGHT AT THE END OF THE TUNNEL

We are also encouraged by some recent decisions in the Court of Appeal and the High Court which have, in effect, recalibrated awards of compensation downwards. A recent notable decision is in the case of *Kampff v Minister for Public Expenditure and Reform* [2018] IEHC 371.

This case concerned an application for compensation from Garda Kampff, for injuries he suffered to his hand while making an arrest. He sustained bruising but did not require painkillers or physiotherapy. He was on sick leave for five days before making a full recovery. His legal team argued for an award of up to €21,700 as recommended in the *Book of Quantum*. Mr Justice Twomey provided a detailed analysis of how the Irish courts should value pain and suffering. In particular he pointed to the necessity for awards for personal injuries to be proportionate to the cap on general damages of €450,000 for the most catastrophic injuries such as paraplegia.

He went on to stress that the High Court must avoid a concertina effect when assessing compensation. Therefore, when awarding compensation for modest and middle ranking injuries, it must make sure that the award is proportionate in relation to the most serious and catastrophic injuries awards.

Judge Twomey also noted that the Court should apply a degree of scepticism and common sense to a plaintiff's claim regarding the effect of the injury and the pain and suffering experienced.



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PRACTICAL STEPS TO AVOID A CLAIM

There are some practical steps that can be taken to help reduce the likelihood of a successful claim.

Clinical records

What is written in the records is likely to trump any alternative version of events. The key points to note following any consultation with a patient are:

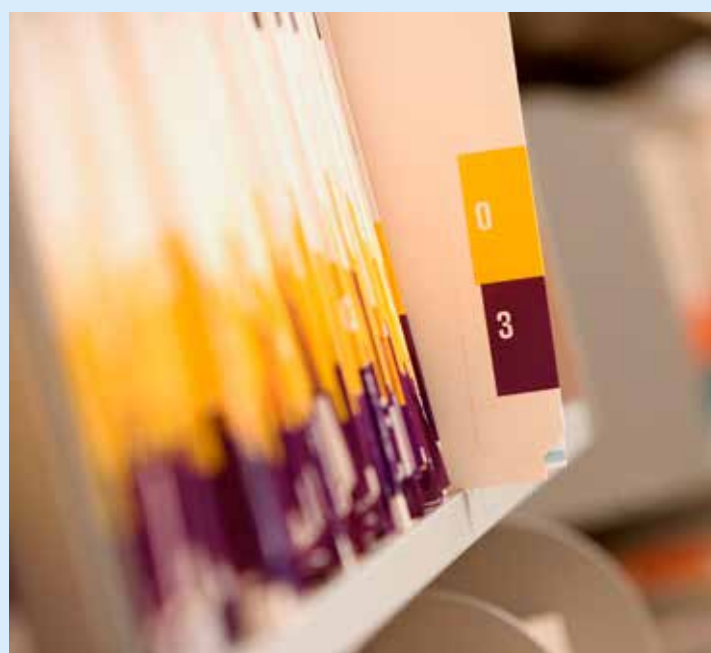
- the presenting complaint
- examination findings, including negative findings
- the diagnosis (including consideration/exclusion of alternative diagnoses)
- a plan of treatment/use of national guidelines
- agreement/consent to the treatment plan
- safety netting.

Many claims involve conflicting versions of events. The patient's recollection of what was discussed may differ significantly to that of the doctor. In these cases, where the patient has suffered an injury, the court will turn to the records as fundamental evidence in reaching a decision. If the records contain a detailed account of the consultation, the court would be unlikely to reject the content of the records as anything other than accurate.

For example, in a case where a patient attends with back pain and is subsequently diagnosed with cauda equina, a record that includes evidence of queries including red flag symptoms; appropriate examination findings, including negative findings; and safety net advice would make it difficult for a patient to succeed in a claim for injury as a result of delayed diagnosis.

Consent

Consent is not just an issue relevant to surgery in hospitals. Increasingly GPs perform a range of minor procedures, making the issue of consent highly relevant in day to day consulting and decision



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making. Minor procedures, such as ear syringing, are often repeated, and at each procedure the patient needs to provide informed consent.

Every day GPs prescribe medication and refer patients to specialists for further investigations. Patients need to be provided with sufficient information, such as alternative options, before they can make an informed choice about the proposed plan of care (and this discussion needs to be documented). In any such discussion the option of doing nothing should be considered.

OUR APPROACH

We fully investigate each claim at the earliest opportunity, using the best expert advice to determine the appropriate strategy and resolve the claim. Our team of specialist lawyers have a reputation for excellence, and are known for being robust and taking an innovative approach. We will defend claims whenever possible and work hard to ensure proportionality of any compensation agreed. We are not afraid to challenge the compensation culture that has developed, leading to often unreasonably high expectations of large awards of compensation for minor injuries.

Support from Medical Protection

Medical Protection has more than 50 years' experience working on Irish claims. In addition to the legal team, Irish members are supported by experienced doctors from a range of backgrounds including general practice, pathology, anaesthetics, general surgery and respiratory medicine. Members will also have a dedicated lawyer and doctor supporting them from the day we open their claim until its conclusion. However, we are not just here to support with the legal and clinical aspects of a claim, but also to provide members with someone to lean on and talk to during what is undoubtedly a very stressful time.

Are we getting it right?

We write to every member in Ireland who receives a claim, asking for feedback on the service they have received and whether there is anything that we could do better. This is just some of the positive feedback from members we have received over the last couple of months:

"Thank you so much for an update and for being in my corner with this challenging situation. I really appreciate it as I've never approached a situation like this and always believe in communication with the patient."

"I am happy to report on this my first experience of potential litigation that Medical Protection have been very supportive and reassuring. It is great to feel not alone. Thank you and your team for their continued support."

"I am very satisfied with my interactions with Medical Protection, and particularly your good self. Initial communication was handled sensitively and this has continued to be the case. Any queries or concerns raised by me have been dealt with appropriately and in a timely fashion. At a stressful juncture such as this, it has been very reassuring to know that you and the team are working on my behalf."

"Many thanks for all your help and assistance. These events are very stressful and I am glad it has been successfully resolved. I would like to acknowledge all your support and help."

If you have feedback on the work that we are doing please do get in touch at Ireland@medicalprotection.org.



Thank you so much for an update and for being in my corner with this challenging situation. I really appreciate it as I've never approached a situation like this and always believe in communication with the patient.



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FIND OUT MORE

To find out more about the work we are doing to tackle the cost of clinical negligence visit:

medicalprotection.org/ireland/about/media-centre/press-releases/press-releases/mps-points-the-way-to-fair-and-timely-resolution-of-clinical-negligence-claims

DILEMMAS OF CONSENT IN GENERAL PRACTICE

Suzanne Creed, clinical risk and education manager at Medical Protection, outlines some of the common risks and dilemmas that staff working in general practice may face relating to patient consent, as well as providing some risk management strategies to mitigate those risks



WHAT DO WE MEAN BY THE TERM CONSENT?

Consent is a fundamental principle of clinical practice. The basic rule is simple: no-one has a right to touch anyone else without lawful reason. If healthcare professionals do so, it may well undermine the patient's trust.

Consent is the giving of permission or agreement for an intervention, receipt or use of a service, or participation in research following a process of communication about the proposed intervention.¹ Every clinical interaction involving a capacitous patient within general practice rests upon a foundation of consent.

Consequences of inadequate consent

Within general practice failure to obtain adequate consent could result in a clinical negligence claim, a complaint to the Medical Council or even civil or criminal proceedings for assault.

Types of consent

Patients can signify their consent in a variety of ways, for example in writing, verbally face-to-face and, in certain circumstances, by implication, for instance holding out their arm when requesting to take their blood pressure.

The Medical Council reinforces the importance of gaining consent stating: "You must make sure that patients have given their consent before you provide any medical investigation, examination or treatment."² Conversely, it is also important to remember that every adult with capacity is entitled to refuse medical treatment. Clinicians should respect a patient's decision to refuse treatment, even if they disagree with that decision.

Signed consent forms

Signed consent is not a legal requirement in Ireland (with rare exceptions, for example, some treatments under the Mental

Health Act 2001). The presence of a signed consent form does not in itself prove valid consent for treatment was obtained. It simply documents that some discussion about the procedure or investigation has taken place. Consent forms are evidence of a process, not the process itself.

Firstly, for consent to be valid the patient must have the capacity to make the decision in hand. The patient must have sufficient knowledge and information on which to base a decision. The quality and clarity of the information given is the paramount consideration. The information provided should include:

- aim of procedure/treatment
- risks and benefits
- alternatives – which could include doing nothing, if appropriate
- what the procedure entails.

There should be no coercion, in other words consent must be voluntary. Patients should, wherever possible, be given time to consider their options and an opportunity to ask any questions before deciding to proceed with a proposed treatment.

PATIENT INVOLVEMENT

Provision of information is key to obtaining valid consent. Unless patients have sufficient information, they are not in a position to decide what is best for them. Discussion of all the issues surrounding a proposed investigation or treatment is an integral part of the patient's clinical care. These discussions may take place over several consultations, all forming part of the consent process.³

In Medical Protection's experience, a significant proportion of clinical negligence claims include allegations of failure to obtain valid consent. Consent rarely forms a whole claim, but it is often a significant part. In the context of a claim, the information and advice provided to the patient would be thoroughly analysed to ensure that the patient was given all the information in order to make an informed decision. It is therefore critical that all

information provided and discussed with the patient in relation to the consent process is clearly documented on the patient's medical record as evidence that these discussions took place.

Very often we consider consent for treatment as consent for a specific procedure, for example, a surgical operation or an invasive test. It is important to highlight that consent for treatment would also include pharmacological and other therapies such as initiating a new medication or issuing a repeat prescription.

Data from 2015 shows that we prescribe 73.5 million items a year in Ireland, a task that GPs and nurse prescribers will perform on several occasions in any given day.⁴ When prescribing a new medication or reissuing a repeat prescription, issues relating to the consent process, for example risk/benefits of the medication, should be highlighted to the patient as well as documented in the patient's record.

In particular, when using high risk medications such as methotrexate, lithium and sodium valproate, it is important to document the discussions held around the consent process including advice regarding blood monitoring and follow-up appointments. Many clinicians also highlight this important information as a footnote in the 'special instructions' section of the prescription.

A patient information leaflet is a valuable adjunct to counselling prior to any treatment, but must never be seen as a replacement for adequate discussion between doctor and patient. It is best practice to ensure copies of any patient leaflet are included in the patient's medical record.

Practices should consider developing procedure-specific consent forms for the procedures they regularly undertake at the practice, such as minor surgery and childhood immunisations, which should incorporate the advice outlined above.

Medical Protection would strongly advise you obtain written consent in the following circumstances:

- There are significant risks or side effects associated with the proposed treatment or procedure.
- The patient's lifestyle, employment or personal relationships could be adversely affected by the outcome of the treatment or procedure.
- The treatment or procedure is being undertaken as part of a research programme.
- The main purpose of the proposed treatment or procedure is not the patient's clinical care for example cosmetic surgery.



RIGHTS OF UNMARRIED FATHERS IN PROVIDING CONSENT

Recent landmark legislation has increased the rights of unmarried fathers in Irish society.⁶

Consequently an unmarried father will automatically be a guardian if he has lived with the child's mother for 12 consecutive months after 18 January 2016, including at least 3 months with the mother and child after the child's birth.

Practices should be aware of these legislative changes and the implications for obtaining parental consent, in particular in relation to childhood immunisations. Where parents are married, the child's mother and father are automatically the legal guardians.

An unmarried father can become a joint guardian if both parents sign a statutory declaration agreeing to this, or he can apply to the court to be made a joint guardian. In this case, the decision of whether to make the father a joint guardian is made in the best interests of the child.

CONSENT AND CLINICAL PHOTOGRAPHY

Patient images are used for many purposes in clinical practice. It is important to recognise that they form part of patients' medical records as a valuable adjunct to clinical care, and are often shared with other members of the primary care team or colleagues in secondary care for discussion purposes. They also provide valuable evidence in the event of a claim or a complaint.

In all cases it is not only advisable, but necessary, that appropriate consent be obtained and clearly documented in the patient's file.

The use of clinical photography is not without risk and this is particularly the case when using mobile phones to take clinical photographs. It is not appropriate to use personal cameras or the camera facility on personal mobile phones for clinical purposes. This has potential to breach patient confidentiality as patient identifiable information may be inadvertently stored on a personal device or backed up in cloud storage.

Technological advances, in particular mobile applications, have allowed for a number of developments to assist clinicians in clinical photography. Although Medical Protection cannot endorse any particular application, Snap GP is an example of a clinical photography app. This app allows for the patient's name and signature to be embedded into the image itself. The image is transferred securely from phone to clinical record via an encrypted connection. Once the transfer has taken place images are removed from the phone and transfer device.⁷

Some clinicians use a dedicated digital camera, which is used solely for taking clinical photographs. Such photos should then be immediately attached to the patient file and subsequently deleted from the camera.

CONSENT TO TEXT MESSAGES

Text messaging is a cost effective and convenient way to communicate with patients. Text messaging has benefitted many practices by saving GPs time and reducing missed appointments through text reminders.

However, it is important not to assume that just because the practice holds the patient's mobile telephone number on the patient's record, that they have provided consent for text messages to be sent.

Practices should only send text messages to patients when specific consent has been recorded. Patients who consent should be advised of the importance of informing the surgery of any changes to their contact details and it is advisable that the clinicians periodically check patients' mobile numbers.

A recent ICGP study on text messaging in general practice examines the common risks and advises of the safeguarding required to ensure patients are appropriately consented and that you have the necessary safeguards in place to protect children and young adults and patient confidentiality. In general, text messages should not be sent to children under the age of 16.⁸

Practices should ensure that they have the necessary safeguards in place to ensure that texts messages are not inadvertently sent to a parent's number, thus breaching patient confidentiality. A policy outlining all the risks and necessary safeguarding procedures is also included in the ICGP document.

CONCLUSION

Consent is needed for all clinical examinations, investigations and treatment involving patients who have capacity to make the relevant decisions in everyday general practice. The decision-making process should be a partnership between the clinician and patient.

Failure to obtain appropriate consent may harm patients, could seriously compromise your doctor–patient relationship and could result in a complaint to the Medical Council, a clinical negligence case or even criminal proceedings for assault.



Nick White/Getty Images

It's a busy Tuesday morning at the practice and the phones are ringing incessantly. One of the calls is from a patient who is extremely unhappy about a text message appointment reminder she has received which was meant for her 15-year-old daughter. The text message asked the daughter to call the surgery as she had missed her follow up appointment with the doctor.

The mum is both shocked and annoyed. She was unaware that her daughter had previously seen the doctor. This has caused a problem at home between the daughter and mother and the daughter is also very upset as she felt her consultation with the doctor was private and confidential. The mother has phoned the practice to complain.

Could this happen at your practice? What is your practice's approach to obtaining consent?

REFERENCES

1. HSE, National Consent Policy, 2017. Available from: hse.ie/eng/about/who/qid/other-quality-improvement-programmes/consent/
2. Medical Council, *Guide to Professional Conduct and Ethics for Registered Medical Practitioners*, 8th Edition 2016. Available from: medicalcouncil.ie/News-and-Publications/Reports/Guide-to-Professional-Conduct-and-Ethics-8th-Edition-2016-.pdf
3. Medical Protection, *Consent to Medical Treatment in Ireland: An MPS guide for clinicians*, 2015. Available from: medicalprotection.org/ireland/booklets/consent-to-medical-treatment-in-ireland
4. Houses of the Oireachtas, Joint Committee on Health and Children, *Report on the Cost of Prescription Drugs in Ireland*, 2015. Available from: webarchive.oireachtas.ie/parliament/media/committees/healthandchildren/health2015/jchc-report-on-the-cost-of-prescription-drugs-in-ireland-081015.pdf
5. ICGP, General Data Protection Regulation (GDPR) and GPs, 2018. Available from: icgp.ie/go/in_the_practice/data_protection
6. Children and Family Relationships Act 2015. Available from: irishstatutebook.ie/eli/2015/act/9/section/49/enacted/en/html
7. Snap GP, Patient Imaging App. Available from: snapgp.com/index.html
8. ICGP, Text Messaging in General Practice, 2018. Available from: icgp.ie/go/search?r=library&q=TEXT+MESSAGING+&x=0&y=0

FURTHER INFORMATION

Medical Protection offers a one hour workshop on Consent in General Practice. For further information please contact our education department: email education@medicalprotection.org or call **+44 113 241 0624**.

CONFIDENTIALITY: CASE LAW UPDATE

Medical Protection's expert consultants frequently deal with queries about patient confidentiality. **Dr James Lucas**, medicolegal consultant and editor-in-chief, explains the implications of a recent High Court judgment in Ireland

Confidentiality is central to the trust between patients and healthcare practitioners. If the therapeutic relationship is to be successful, patients must be confident that intimate details about their health and personal relationships go no further than the consultation room. The need for a confidential medical service is recognised as a public good. The duty to maintain patient confidentiality is rooted in medical ethics, in common law and in law relating to contracts. The General Data Protection Regulation (GDPR) also imposes obligations in terms of the lawful processing of personal data.

But the duty is not absolute. Disclosure of confidential medical information may be required by law, for example, when ordered by a judge in the context of civil litigation, criminal or family proceedings. In rare cases, where patient consent has not been obtained, or where a patient has refused consent, disclosure may be justified in the public interest, to protect others (for example, from the risk of death).

In a recent case involving a patient with HIV infection, the courts in Ireland considered, for the first time, the concept of disclosure of a patient's medical information, against his wishes, to prevent serious harm to another person.¹

THE FACTS IN BRIEF

'A' was a 17-year-old male, in the statutory care of the Child and Family Agency (CFA). Described by the Court as an intelligent and capable person, there was evidence he had significant behavioural

issues in the past. The genesis of the case was A's relationship with 'B', a 17-year-old female, in circumstances where A had been diagnosed with HIV infection at birth. B was one of A's closest friends, but A denied that she was his girlfriend and he also denied that they had ever had sexual intercourse. The CFA was of the view that despite A's denials, B was having a sexual relationship with A. The CFA was also of the view that A was not using condoms.

The CFA sought a declaration from the High Court that it was entitled lawfully to disclose the fact of A's HIV condition and status to B in order to afford her the opportunity of availing of such medical and healthcare testing, treatment and counselling as may be indicated, notwithstanding A's refusal to consent to such disclosure.

THE COURT'S ANALYSIS

The Judge considered in detail the circumstances of the relationship between A and B, failure by A to take his antiretroviral drugs, use of condoms by A, expert medical evidence on the risk of B contracting HIV and medical evidence regarding the effect of disclosure on A.

In relation to the factual dispute, the Court had little hesitation in finding that there was a possibility that A was having sexual intercourse with B, but it concluded that the CFA had not proven, on the balance of probabilities, that there was such a relationship. The Court indicated that even if this analysis was incorrect and A was having sexual intercourse with B, A would not put B at risk by



Confidentiality is central to the trust between patients and healthcare practitioners... but the duty is not absolute.

having unprotected sex with her. Hence, the Court concluded that there was no basis for the breach of patient confidentiality.

BROADER ISSUES

It was made clear in the judgment that the key legal issue in this case – whether medical confidentiality could be breached to prevent harm occurring to a third party – arises irrespective of the ages of the individuals involved and would apply equally to adults. Additionally, the fact that it was the CFA seeking to breach patient confidentiality was not significant and the scenario could just as easily involve a doctor who had the same information. The broader issue behind the question in this particular case was encapsulated as follows: in what circumstances can a doctor breach his or her duty of confidentiality because of the risk of harm to a third party?

(i) The legal test

The Court determined that the appropriate test to apply to ascertain whether patient confidentiality should be breached is whether “on the balance of probabilities, the failure to breach patient confidentiality creates a significant risk of death or very serious harm to an innocent third party”.

In considering whether the disclosure threshold had been crossed in this particular case, regard was to be had to the balancing of interests, namely between the interest of A whose privacy was at stake, the interest of B who was potentially at risk of harm, and the public interest in ensuring that the public at large has the confidence to disclose the most private details about their health and private lives to doctors.

(ii) HIV infection

The Court determined that the contracting of HIV, although a significant condition, is no longer a terminal one, but rather a chronic and lifelong condition that can be managed. Accordingly, HIV infection is not a ‘very serious harm’ to justify a breach of patient confidentiality. In addition, there is not, in the view of the Court, a ‘significant risk’ of that harm (because the risk of contracting HIV through sexual intercourse is extremely low and can be further reduced through the use of condoms).

(iii) Societal issues

The Court observed that the proceedings in this case were supported by well-intentioned doctors who had the interests of B at heart. However, if the Court granted an order giving medical professionals the right to breach patient confidentiality where a patient has a sexually transmissible disease, that right would necessarily carry with it a responsibility for medical professionals in the future. It would mean that medical professionals could decide, in cases of sexually transmissible disease, whether a sexual partner of the patient needed to be notified of the harm to which he or

she was exposed. With this responsibility could come liability for those medical professionals who failed to breach patient confidentiality, where that failure leads to harm to a third party.

The Court held that there was a public interest in patients remaining open and frank with their doctors. If the order in this case had been granted, it would operate as a disincentive to those with sexually transmissible diseases from seeking medical advice. Such persons would perceive that there would be a risk that their doctor would disclose this fact to their alleged sexual partners (if the patient refused to do so). The Court concluded that this would be detrimental to society as a whole since it could lead to patients with communicable diseases failing to seek medical advice, which could result in those diseases not being treated and becoming more prevalent in the community.

CONCLUSIONS

Where there is a significant risk of death to a member or members of the public, a healthcare professional would not only be entitled to breach confidentiality, but it seems clear that he or she would have a duty to act to try to prevent innocent deaths. Where the risk falls short of the risk of death but still involves a significant risk of very serious harm, the public interest in protecting others takes precedence over the interest of a patient in keeping medical information confidential. It also takes precedence over the public expectation that doctors keep patients’ medical information confidential. However, in the case of A and B, the test had not been met and it would not therefore be lawful to breach A’s confidentiality.

The judgment underscores the importance of patient confidentiality, which must be observed save in the most exceptional of circumstances.

TIPS FOR PRACTICE

1. Disclosures in the public interest can be ethically challenging. Adopt a low threshold for consulting your medical defence organisation.
2. Ensure that a clear record explaining the decision is made in the patient’s records (including in those cases where there is a decision to maintain confidentiality).
3. When disclosing information in the public interest, you should normally inform the patient about the disclosure.
4. Any disclosures that are made should be to an appropriate person or body, and include only the information needed to meet the purpose.²

REFERENCES

1. The Child and Family Agency v A.A. & Anor [2018] IEHC 112.
2. Medical Council. Paragraph 31.3. Guide to Professional Conduct & Ethics for Registered Medical Practitioners. 8th Edition, 2016.

FROM THE ADVICE LINE

Dr James Lucas, medicolegal consultant at Medical Protection, shares a recent case where a member sought advice regarding consent for childhood immunisation



Mrs D, a practice manager, telephoned Medical Protection's medicolegal advice line to discuss a difficult situation. The parents of AF, a 5-month-old girl, were in the process of divorce. AF's father wrote a letter to the practice, explaining that he had recently changed his views about childhood immunisation, owing to reports about long term complications which he had read on the internet. He indicated that the practice did not have his consent to administer any more vaccines to AF.

Mrs D contacted AF's mother, who said that she was a strong advocate of the childhood immunisation programme. AF's mother explained to Mrs D that she planned to bring her daughter to the practice as per the immunisation programme and she expected the practice to administer the appropriate vaccinations, notwithstanding her estranged husband's objections, in the best interests of AF and in accordance with her rights as a mother.

Mrs D was unclear how to proceed in circumstances where the parents were in disagreement about immunisation.

EXPERT ADVICE

Mrs D spoke to Dr C, an expert medicolegal consultant with a background in general practice.

Dr C explained that AF's mother and father were the legal guardians of the child. This meant that both had a right to be involved in decisions affecting the welfare of the child including decisions about health. Where the patient is under 16 years, a parent(s) or legal guardian(s) will usually be asked to give consent for medical treatment on the patient's behalf.

Dr C referred to the Health Service Executive (HSE) National Consent Policy, which explains that the consent of one parent will normally provide sufficient authority in respect of any health or social care intervention in relation to a child.¹ However, there are exceptions to this general rule, including those circumstances where a parent/legal guardian refuses medical treatment on behalf of a child. Dr C advised that the National Consent Policy makes specific reference to the type of situation described by Mrs D, as in where the parents disagree between themselves about the provision of healthcare to their child.

In these cases, the parents should be advised that they have a responsibility to discuss the matter and reach an agreement between themselves as quickly as possible, with the assistance of the HSE advocacy services and a third party mediator if required. If agreement is not possible then the service should generally not



If agreement is not possible then the service should generally not be provided unless it is necessary to safeguard the child's best interests. Legal advice should be sought as to whether an application to court is required.

be provided unless it is deemed by the healthcare professional to be necessary to safeguard the child's best interests. In such circumstances, legal advice should be sought as to whether an application to court is required.

Dr C advised Mrs D to consider, as a preliminary step, inviting AF's father to meet the clinical team at the practice, in order to talk through his concerns about childhood immunisation.

With Mrs D's agreement, Dr C opened a case file in anticipation of her requiring further advice and support with the dilemma. Mrs D wrote to Medical Protection the following week to explain that AF's father had met with a GP and practice nurse, and, having been advised of the benefits and risks of immunisation, had consented to the administration of vaccines to the child.

REFERENCES

1. National Consent Advisory Group, National Consent Policy. Health Service Executive. 2017, Version 1.2.

CHILDREN AND YOUNG PEOPLE: REDUCE THE RISK

Dr Rachel Birch, medicolegal consultant at Medical Protection, provides practical tips to ensure you have systems in place to treat children and young people safely

Medical Protection's Education team have undertaken around 1,400 Clinical Risk Self Assessment (CRSA) visits to practices in the UK and Ireland. They have helped practice staff to identify potential risks to patients and find safe solutions.

The following advice – which is relevant to children and young people – has been gathered from these CRSAs and aims to help you learn from the experience of others, so that you can take steps to ensure that your practice is as child-friendly as possible. This advice is by no means exhaustive, but you may wish to use it as the basis for discussion within a staff training session.

1. CHILD PROTECTION

- Ensure that you have an up-to-date and regularly reviewed child protection policy and a nominated clinical child protection lead.
- Familiarise yourself with the Children First guidance.¹ Tusla have developed a free online child protection training module to complement this guidance.² The Health Service Executive (HSE) has also clarified the roles and responsibilities of staff.³
- Arrange for all your staff to have up-to-date child protection training.^{2,4}
- Clearly display posters in consultation rooms and the reception area, with easy-to-find details of who should be contacted if there are child protection concerns.
- Ensure that all new staff have the appropriate pre-employment vetting checks, where indicated.

2. APPOINTMENTS

- Allow young persons under 16 to see a clinician without the presence of an adult if requested.
- Consider displaying a poster to let young people know that they may request to be seen alone. Unwillingly attending with an adult could potentially prevent a young person from asking for help.
- Consider offering teenage-friendly times for consultations, for example, over school lunch breaks. Young people are more likely to access help if it is convenient to them.
- Practice privacy notices, detailing how patients' personal data is used, should be provided in a format that can be understood by children and young people.⁵
- Children under 16 can consent to medical treatment if they understand what is being proposed. Clinicians should encourage the young person to involve their parents in such decisions, however if the young person refuses, then the Medical Council outlines a list of factors to consider before proceeding with treatment.⁶
- You should ensure there are no child protection concerns, that the young person's views are stable and reflect their core values and beliefs, and that their decision is not affected by physical or mental ill-health. Having considered these factors, and if a young person demonstrates the maturity and intelligence to fully understand the nature of the treatment, the options, the risks

involved and the benefits, and you feel it is in their best interests, then their wish not to involve their parents should be respected.

3. CONFIDENTIALITY

- Young people who have the capacity to understand the implications of their health and treatment have a right to expect confidential healthcare.
- Ensure that you have systems in place to protect their confidentiality. For example, a 14-year-old may not want his parents to know that he saw the doctor to discuss mild symptoms of anxiety; a 15-year-old may not want her mother to pick up her prescription for her acne cream.
- Develop clear protocols for test results and prescription requests to ensure that results or prescriptions are not given to parents without the consent of the young person.
- Because parents have legal rights to access medical records of their children until they are 18, the Medical Council advises that you should tell children and young people that you cannot give an absolute guarantee of confidentiality. This is a complex area of law. If a parent or guardian requests access to the medical record of a child who is capable of understanding their rights to privacy and data protection, and the young person refuses consent to disclose the information, you should seek medicolegal advice.
- Consider excluding children under 16 years old from your text messaging service, as there is a risk that their parent's mobile number could be linked to their record.

4. HEALTH AND SAFETY

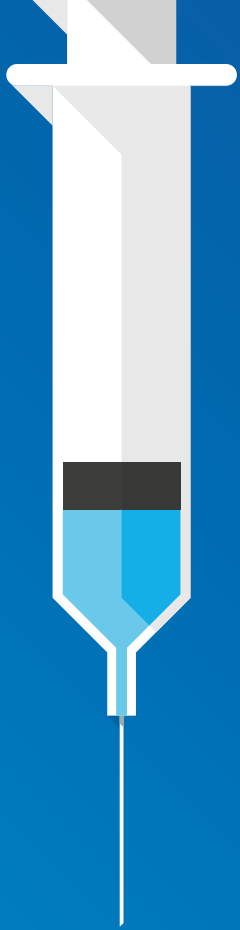
- Ensure that sharps bins are not located on the floor or within easy reach of children. These large bright yellow boxes may attract the attention of small children, who may perceive that they are part of the practice's toy collection.
- Consider a dedicated children's waiting area – with toys – as this may encourage children to be more relaxed and potentially easier to examine once they are in the clinician's room.
- Organise a regular cleaning rota for any toys that the practice provides for young patients. It is accepted that soft toys are more likely to be a risk of infection than hard toys, therefore consider only providing hard toys in waiting areas.⁷
- Conduct a regular safety check of toys and discard any that are broken.

FURTHER ADVICE

CRSA for General Practices improves the quality of patient care and reduces your exposure to unnecessary risk. This unique consultancy programme has been designed especially for primary care and involves the whole practice team. For more information visit: www.medicalprotection.org

REFERENCES

1. Department of Children and Youth Affairs. *Children First: National Guidance for the Protection and Welfare of Children*. 2017. Available from: dcya.gov.ie/documents/publications/20171002ChildrenFirst2017.pdf
2. Tusla. *Children First E-Learning Programme*. Available from: tusla.ie/children-first/children-first-e-learning-programme/
3. HSE Children First National Office. *Putting children first: roles and responsibilities of HSE staff under Children First*. 2017. Available from: hse.ie/eng/services/list/2/PrimaryCare/childrenfirst/resources/staffrolesandresponsibilities.pdf
4. Health Service Executive. *Children First Training*. Available from: hse.ie/eng/services/list/2/PrimaryCare/childrenfirst/training.html
5. Irish College of General Practitioners. *Processing of Patient Personal Data: Guideline for General Practitioners*. V1.2, 2018. Available from: icgp.ie/go/in_the_practice/data_protection
6. Medical Council. *Guide to Professional Conduct and Ethics for Registered Medical Practitioners*. 8th edition, 2016. Available from: issuu.com/mcirl/docs/guide_to_professional_conduct_and_e?e=12642421/35694606
7. Merriman E et al. Toys are a Potential Source of Cross-infection in General Practitioners' Waiting Rooms. *British Journal of General Practice* 2002;52(475): 138–40.



INJECTION ERRORS

A common cause of claims at Medical Protection is injection errors. While generally they are relatively low in value, they frequently cause anxiety to patients and clinicians, and are easily avoided. **Dr Dawn McGuire**, medical claims adviser at Medical Protection, looks at some typical cases

CASE STUDY 1: WRONG INJECTION

Ms F attended an appointment for a three monthly vitamin B12 injection. When the appointment was booked, the receptionist had entered the reason as 'Depo injection'. Nurse C proceeded to administer Depo-Provera, a contraceptive injection. She did not confirm with Ms F her reason for attendance that day and she did not check the patient's prescription history either.

Nurse C only realised after the injection was administered that vitamin B12 had been recently prescribed to Ms F, and her fears were confirmed when she clarified with Ms F the reason for her attendance. Ms F complained about Nurse C and the practice apologised. A significant event analysis was conducted by the practice for everyone's learning.

However, Ms F instructed a solicitor to pursue a claim against Nurse C. Ms F alleged anxiety and mental distress as she was trying to conceive. Her solicitors obtained a condition and prognosis report from a consultant psychiatrist who diagnosed Ms F with adjustment disorder requiring a course of cognitive behavioural therapy.

Nurse C and all three GP partners were Medical Protection members.

As this case was deemed indefensible the claim was settled.

Medicolegal insight

Over the last 12 months Medical Protection was notified of ten similar claims in England and Wales alone.

The commonest mistakes involved vitamin B12, used for vitamin B12 deficiency or pernicious anaemia, and Depo-Provera, which are both usually administered every 3 months. Other injections

that were wrongly administered were the flu vaccination, depot-antipsychotic medication and Prostag, which is administered for prostate cancer, endometriosis and uterine fibroids.

Injections can also be administered in the wrong site. The most common error is steroid injections (for example, Kenalog) administered into the deltoid or thigh instead of gluteal muscle. Deep intramuscular injections must be given into the large muscles of the buttock. They should not be administered into the upper arm or the thigh as this can result in unsightly lipid dystrophy.

For these sorts of claims the damages (monies paid to the patient) depend on the side effects experienced. The solicitors' costs are usually higher than the damages paid to the patient.

LEARNING POINTS

- Always check with the patient the reason for their attendance and check their prescription history.
- Remind ancillary staff (nurses and healthcare assistants) who undertake these duties to be vigilant of these common errors.
- It is in the interests of Medical Protection members to ensure that nurses and other employees with high levels of clinical autonomy subscribe to an indemnity or insurance scheme in their own right.

CASE STUDY 2: FLU VACCINATION ADMINISTERED WITH USED NEEDLE

Dr A, a GP registrar, gave two patients their flu vaccinations opportunistically when they attended for their chronic disease management. Dr A re-sheathed the syringes and left them in the packs with the other unused syringes as an aide-memoire to enter the flu vaccination code into the patients' medical records later. He wrote the patients' names on the label of the syringe but forgot to follow up as intended.

At the end of the surgery the health care assistant collected the flu vaccination tray from Dr A's consultation room and placed it back in the refrigerator ready for the next day.

The next morning Dr O saw Mr P for depression and gave him his flu vaccination. After the needle had been inserted into Mr P's arm, Dr O noticed that she was unable to depress the plunger of the syringe to administer the vaccine. It was then that she noticed that two of the syringes in the pack were empty but were labelled with patients' details.

Dr O immediately informed Mr P of the error and apologised. She proceeded to give Mr P the correct flu vaccination. Public health advice was sought and a full serious untoward event investigation was undertaken within the practice. Mr P and the original two patients underwent HIV and hepatitis testing, all of which eventually came back negative. Mr P was advised to receive HIV suppressant medication and hepatitis B vaccination while waiting for the final results.

Eight months after the incident, Dr O received a letter of claim from a solicitors firm, alleging clinical negligence and requesting damages plus legal costs. Medical Protection settled the claim with a contribution from the State, on behalf of Dr A.

Medicolegal insight

In this situation, the pre-filled flu vaccination syringes came in packs of five with needles attached. They are for single use only. Once administered, they must be disposed of in the sharps bin immediately.

During the last flu vaccination season (September – December 2017), Medical Protection was notified of three claims where a used needle was administered. In all three cases the staff who administered the initial flu vaccination had re-sheathed the syringe and left it in the pack with the other unused syringes, leading to the subsequent inadvertent incidents.

Patients typically claimed for severe distress and anxiety as they had to undergo infectious disease screening and vaccinations (HIV and hepatitis B and C) for a period of 6 months. Fortunately, none of the claims so far have resulted in transmission of these blood-borne diseases.

LEARNING POINTS

- Always dispose of used flu vaccinations immediately and remind nursing staff and health care assistants to do the same.
- Adverse incidents should be investigated using 'root cause analysis' or similar methodology and learning disseminated to all staff within the practice.



These case studies are based on issues arising in Medical Protection cases from around the world. Facts have been altered to preserve confidentiality.



ARTIFICIAL INTELLIGENCE: WHO'S LIABLE?

Advancements in medical technology can bring huge benefits for patients and clinicians alike – but new approaches can also mean new risks.

Dr Helen Hartley, head of underwriting policy at Medical Protection, looks at where the liability lies for artificial intelligence

For many, the concept of artificial intelligence conjures images from the darkest recesses of Hollywood imagination: robots running amok and rogue algorithms instigating World War 3.

In medicine, however, its benefits are impossible to ignore – only recently a study in *Nature Medicine* journal reported on an algorithm that can learn to read complex eye scans.¹ When tested, it performed as well as two of the world's leading retina specialists and did not miss a single urgent case.

But what has not been proven is the infallibility of artificial intelligence (AI). When a mistake does occur, where does the liability lie?

ROBOTS IN THE DOCK

Clinicians should ensure any robot or algorithm is used as part of – not in place of – sound clinical judgment and proficiency. Algorithms, including those used by triaging apps, should not be blindly followed without regard to a patient's particular clinical features or circumstances, such as geographical location, which may impact on the probability of certain diagnoses. Medical Protection membership can provide protection with regard to allegations against your clinical judgment.

However, we do not currently offer protection against errors arising from the programming or functioning of an AI programme, app or platform. It is expected that the creators and/or producers of these will seek independent advice regarding their indemnity requirements, which may include the potential for multiple serial claims to arise from errors or service disruption affecting an AI product. Similarly, with regard to the use of any surgical equipment, product liability would

apply in relation to robot malfunction, whether hardware or software.

A Medical Protection member using a robot as part of a surgical procedure would however remain liable for any alleged negligent use of the robot, and as such, would be eligible to request assistance from Medical Protection should an issue arise.

In order to minimise the risk of malfunction or errors, any clinician intending to rely on AI equipment should ensure they are satisfied that it is in good working order, that it has been maintained and serviced according to the manufacturer's instructions, and that product liability indemnity arrangements are in place.

CLINICIANS SHOULD ALSO:

- Adhere to any local checklists before 'on the day' use.
- Only use equipment on which they have received adequate training and instruction.
- Consider the possibility of equipment malfunction, including whether they have the skills to proceed with the procedure regardless, and ensure the potential availability of any additional equipment or resources required in that event.

REFERENCES

1. De Fauw J et al. 'Clinically applicable deep learning for diagnosis and referral in retinal disease', *Nature Medicine* 2018; DOI:10.1038/s41591-018-0107-6.

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Phone **+44 113 241 0200 (UK)** Fax **+44 113 241 0500 (UK)**

Membership enquiries

Phone **1800 509 441** (toll free within Ireland) Fax **+44 113 241 0500 (UK)**

member.help@medicalprotection.org

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Medical Protection

Victoria House
2 Victoria Place
Leeds LS11 5AE
United Kingdom

info@medicalprotection.org

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