Avoiding Problems
Managing the Risks in General Practice in Ireland

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Important – please note

Due to the dynamic nature of medical law we suggest that you access our website at www.medicalprotection.org/ireland for the most up-to-date information. January 2015

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Review date January 2017

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This booklet is published as a resource for MPS members in Ireland. It is intended as general guidance only. MPS members are always welcome to telephone our medicolegal advice line – 1800 509 441 – for more specific practical advice and support with medicolegal issues that may arise.

MPS is the world’s leading protection organisation for doctors, dentists and healthcare professionals. We protect and support the professional interests of more than 290,000 members around the world. Our benefits include access to indemnity, expert advice and peace of mind. Highly qualified advisers are on hand to talk through a question or concern at any time.

Our in-house experts assist with the wide range of legal and ethical problems that arise from professional practice. This includes clinical negligence claims, complaints, medical and dental council inquiries, legal and ethical dilemmas, disciplinary procedures, inquests and fatal accident inquiries.

Our philosophy is to support safe practice in medicine and dentistry by helping to avert problems in the first place. We do this by promoting risk management through our workshops, E-learning, clinical risk assessments, publications, conferences, lectures and presentations.

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Introduction

At the turn of the last century, the Italian economist Pareto observed that 90% of the wealth of his country was owned by 10% of the population. “Pareto analysis” applied to industrial environments has shown that 80% of errors arise from only about 20% of causes. This concept can also be applied to medical mishaps – most incidents leading to medicolegal problems fall into one of the following categories:

- Failure to appreciate legal and professional responsibilities
- Problems in clinical management
- Medication errors
- Administrative errors
- Failure of communication, including inadequate medical records.
Understanding your legal responsibilities

At MPS we see numerous cases where doctors have unwittingly fallen foul of the law. This is often because they are unaware of the relevant statutes regulating their area of practice or because they have not fully understood the principles underlying considerations such as consent or confidentiality.

The best way to avoid running into similar problems yourself is to develop a good working knowledge of (and comply with) the legal framework that governs the practice of medicine. There are three main sources:

- **Statutes** – These are Acts of the Oireachtas and associated regulations (statutory instruments) laying down clear requirements that must be adhered to. Some, such as the Mental Health Act, cover particular aspects of practice, but there are many others which, although not specific to medicine, nevertheless have a considerable impact on medical practice (for example, the Data Protection Act).

- **Case law** – Principles derived from the interpretation of individual court cases on relevant areas such as consent, confidentiality and clinical negligence. These principles apply to all areas of clinical practice and represent a constantly evolving area of law (what we call “common law”).

- **Codes of conduct and statements of professional responsibility issued by the Medical Council** – All practitioners must comply with the standards of practice and responsibilities that are a condition of their continued registration.

This section of the booklet concentrates on the essential features of three aspects of practice: consent to treatment; confidentiality; and competence.

**Box 1: Examples of important statutes affecting medical practice**

- Child Care Act 1991
- Children Act 1997
- Constitution of Ireland
- Control of Clinical Trials Act 1987
- Freedom of Information Act 1997
- Lunacy Regulations (Ireland) Act 1871
- Medical Practitioners Act 2007
- Mental Health Act 2001
- Non-Fatal Offences Against the Person Act 1997
- Sexual Offences Act 2006
- Status of Children Act 1987
- Coroners Act 1962
- Misuse of Drugs Act 1984
- Sexual Offences Act 2006
- Protection of Life During Pregnancy Act 2013
Consent to treatment

To treat patients without their consent is a violation of their constitutional rights and transgresses a fundamental principle of medical law. The basic rule is simple: no-one has the right to touch anyone else without lawful excuse and if doctors do so it may well undermine patients’ trust. Such behaviour may lead to a clinical negligence claim, a complaint to the Medical Council or criminal proceedings for assault. There are three components to valid consent:

- Capacity
- Information
- Voluntariness

Box 2: Points to remember about consent

- To be valid, consent must be freely given by a patient with capacity making an informed decision.
- Consent is much more than a signature on a form.
- Patients have a right to information about their illnesses, the investigations and treatments proposed. You have a corresponding duty to provide adequate information and warnings, and to answer questions truthfully.
- The amount of detail you provide about risks, alternatives and possible adverse outcomes will depend on the circumstances – eg, degree of urgency – and on the patient’s individual requirements.
- Communicate information in terms that are easily understood by the patient.
- If you are proposing an invasive procedure, you should inform the patient about risks associated with the anaesthetic and risks associated with the procedure itself, especially if they might affect the patient’s decision to proceed.
- Discuss a procedure with a patient only if you are sufficiently knowledgeable to answer their questions.
- If you are responsible for delegating the task of obtaining consent, you must be confident that your delegate has the appropriate knowledge and experience.
- Never coerce a patient into a decision – the patient has the right to refuse consent.
- As a matter of good practice, note in the patient’s records the nature of the discussions that have taken place.
- The consent form, signed and dated by the patient and doctor, is part of the clinical notes and should be filed with them.
- If you are in any doubt about obtaining a valid consent, discuss your concerns with a senior colleague or an MPS medicolegal adviser.
A patient may give express or implied consent to a procedure. In many circumstances, implied consent is sufficient – eg, if the patient undresses for an examination – but in cases where the proposed procedure or treatment is complex, invasive or may have significant consequences for the patient, it is important to obtain express written consent. You are also obliged by law (Control of Clinical Trials Act 1987) to obtain the written consent of participants before including them in clinical trials or research.

Be sure to allow the patient enough time to consider your advice and to reach a decision. If a patient feels that the consent has been “rushed”, a negligence claim may ensue, regardless of whether the procedure is carried out competently or not. See para 37.1 – 37.2 of the Medical Council’s Guide to Professional Conduct and Ethics (2009).

**Capacity**

Doctors should presume that adults have the capacity to consent to or refuse a proposed treatment unless it can be established that they lack that capacity. Each assessment of an individual’s capacity should relate to a specific decision – a patient may, for example, be incapable of understanding the complex implications of a major procedure like a liver transplant, but still be able to comprehend the risks and benefits of diathermy to remove a wart.
The test of capacity currently applied in the Irish courts is the “C test”, which derives from the English case of Re C. The test is in three parts, all of which have to be fulfilled for a patient to be deemed competent to make the decision they are being asked to consider:

1. Does the patient comprehend and retain treatment information?
2. Does the patient believe that information?
3. Does the patient weigh that information, balancing risks and needs, to arrive at a choice?

Only the courts (or an official empowered by the court) can consent to treatment on behalf of an incapacitated adult. This does not mean, however, that incapacitated adults should be denied necessary medical treatment. Treatment can – and should – be given if the patient’s doctors, in consultation with the patient’s relatives and carers, conclude that it is in the patient’s best interests (see Box 3). The focus should be on what the patient would consider to be in his/her best interests, not what the doctor would want done if he were in the same position. Any intervention should be the minimum necessary to safeguard the patient’s wellbeing.

Box 3: When a patient is incapacitated

“Where an adult patient is deemed to lack capacity to make a healthcare decision, you should take reasonable steps to find out whether any other person has legal authority to make decisions on the patient’s behalf [see editor’s note below]. If so, you should seek that person’s consent to the proposed treatment.

“If no other person has legal authority to make decisions on the patient’s behalf, you will have to decide what action to take. In doing so, you should consider:

- which treatment option would provide the best clinical benefit for the patient,
- the patient’s past and present wishes if they are known,
- whether the patient’s capacity is likely to increase,
- the views of other people close to the patient who may be familiar with the patient’s preferences, beliefs and values, and
- the views of other health professionals involved in the patient’s care.

Medical Council, *Guide to Professional Conduct and Ethics for Registered Medical Practitioners* (2009), paras 34.5-6.

**Editor’s note:** This would only be if the patient has been made a Ward of Court, in which case you must obtain written consent from the case officer assigned to the Ward. If the proposed treatment is particularly intrusive or carries significant risks, the case officer may refer the matter to the court.
Children and young people

Although the age of majority is 18, the law recognises 16 and 17 year olds as having the capacity to consent to medical and dental treatment on their own behalf.

Box 4: Consent on behalf of a minor

For 16 and 17-year-olds, the position with regard to the refusal of medical, surgical and dental treatment by minors is unclear as the legislation is silent on this point. However, in general terms, where minors have refused treatment, or where parents may refuse treatment of their children, the courts can intervene where that refusal may constitute a serious risk to the physical and/or emotional health or welfare of that minor.

Parents – A child’s mother, whether married or unmarried, has automatic legal guardianship of the child.

The child’s father also has guardianship if he is married to the child’s mother, either before or after the birth of the child. A father who is not married to the mother can be appointed as a joint guardian of the child if he and the child’s mother have made a statutory declaration to that effect. Alternatively, he can apply to the courts to be appointed a joint guardian.
Box 4: (continued)

**Legal guardians** – Testamentary (ie, named in a deceased parent’s will) and court-appointed guardians can make healthcare decisions on a child’s behalf.

**Foster carers** – Foster carers can consent to urgent medical treatment for a child. They can also consent to ancillary treatment, such as a general anaesthetic.* For non-urgent treatment, consent should be sought from the child’s natural parents.

Foster carers or relatives who have been caring for a child for five years or more may be granted a court order that authorises them to consent to “any necessary medical or psychiatric examination, treatment or assessment with respect to the child”.**

**HSE** – If a care order has been made for a child under the age of 16, the HSE can consent to elective treatment in the best interests of the child. It is good practice, however, to also consult the child’s parents if possible.

**The courts** – If a child has been made a Ward of Court, the consent of the court is needed before medical treatment can be carried out, except in an emergency.

The District Court can make an emergency care order placing a child in the care of the HSE if there is uncertainty or dispute about the validity of a refusal of treatment on the part of a parent or a minor aged 16 or more.

**Consent to disclosure of personal health information** – “...Where the individual is below [16 years], the general practitioner should exercise professional judgment, on a case by case basis, on whether the entitlement to access should be exercisable by (i) the individual alone, (ii) a parent or guardian alone, or (iii) both jointly. In making a decision, particular regard should be had to the maturity of the young person concerned and his or her best interests. ... In all of this, the general practitioner should have regard to both the established medical ethics position and the role of parents in their duty of care as laid down in case law.”†

* Department of Health and Children Circular, Consent to Medical Treatment for Foster Children, 6 November 1999.

** Child Care (Amendment) Act 2007, section 43A.

† ICGP and GPIT, Managing and Protecting the Privacy of Personal Health Information in Irish General Practice (2003)

Also see A Guide to Data Protection Legislation for Irish General Practice
In law, the consent of the parent or legal guardian is required if a child is under the age of 16. In practice, however, it is reasonable to seek the consent of a minor with the capacity to understand the nature and implications of the proposed treatment or procedure. This should not present a problem if the child and parents are in accord about a decision to consent to treatment. Difficulties can arise, however, if the parents of a minor are in disagreement with clinicians or the patient about what is in the child’s best interests. In the UK, a minor’s legal capacity to consent to medical treatment is considered on the basis of maturity, rather than age. The “Gillick test” states that a minor under 16 years of age may consent to medical treatment, if he/she is mature enough to understand what is involved.* Although the Gillick test has been recommended by the Irish Law Society’s Law Reform Commission, it has not been endorsed in Ireland.

* Gillick v West Norfolk and Wisbech AHA (1985) 2 BMLR 11

If there are two people with parental responsibility, it is usually sufficient for one of them to give consent, but where decisions may have profound, irreversible consequences, both of them should be consulted. The more complex the care and the greater the level of intervention required, the greater the need to include both parents in discussions and secure the consent of both. You should also seek the consent of both parents when you have reason to believe that they may not be in agreement with one another (eg, if they are no longer living together, are in conflict, and have joint custody of the child).

Even when children lack the capacity to give consent, they should still be involved in the decision-making process.

**Advance directives**

An advance directive is a statement made by a competent adult in anticipation of a time in the future when he or she may lack the capacity to make healthcare decisions. Such statements usually take the form of advance refusal of specified treatments, but may also contain information about the patient’s values and beliefs.

At present there is no legislation covering advance directives in Ireland and there is very little relevant Irish case law to clarify their legal status, but the Medical Council provides the following guidance on the ethical position:

“An advance treatment plan has the same ethical status as a decision by a patient at the actual time of an illness and should be respected on condition that:

- the decision was an informed choice, according to the principles of informed consent ..., 
- the decision covers the situation that has arisen, and 
- the patient has not changed their mind.”
If there is any doubt about the validity or applicability of an advance decision, “you should make treatment decisions based on the patient’s best interests. In making such a decision, you should consult with any person with legal authority to make decisions on behalf of the patient and the patient’s family if possible.”

End of life decisions

When patients are seriously ill and lack the capacity to make medical decisions on their own behalf, clinicians may be obliged to make treatment decisions in the patient’s best interests. This might include choosing not to intervene if a treatment or procedure would be burdensome and with little benefit to the patient. The Medical Council advises:

“There is no obligation on you to start or continue a treatment, or artificial nutrition and hydration, that is futile or disproportionately burdensome, even if such treatment may prolong life. You should carefully consider when to start and when to stop attempts to prolong life, while ensuring that patients receive appropriate pain management and relief from distress.”

However, decisions to discontinue a life-prolonging treatment or intervention (such as artificial nutrition and hydration) should be carefully discussed within the healthcare team and with the patient’s family. The substance of your deliberations should be documented in the patient’s notes, and if there is any doubt about the right course of action, the decision should be referred to the law courts (see Box 5).

Box 5: End of life decisions

In 1996, the Supreme Court heard the case* of a 45-year-old woman who had been in a near persistent vegetative state for 23 years and was being fed via a gastrostomy tube. Her mother, with the support of the rest of her family, applied to the High Court for permission to have the feeding tube removed and to allow life-threatening infections to take their course without antibiotic intervention. The High Court judge consented to this on behalf of the Ward, but the institution in which the Ward was living and the Attorney General appealed against the decision.

Four out of the five justices hearing the case upheld the High Court ruling. In their deliberations, they considered whether artificial nutrition and hydration constitutes medical intervention and whether its withdrawal would be in the Ward’s best interests. The four justices who upheld the decision concluded that tube feeding does amount to medical intervention because it is intrusive and that withdrawing such intervention would be in the Ward’s best interests. They took the view that withdrawing artificial means of sustenance would not be tantamount to terminating her life; it would be allowing nature to take its course.

* In the Matter of a Ward of Court (withholding of medical treatment) [1996] 2 IR 73
Emergencies

Legal action against doctors providing treatment without consent in an emergency is extremely rare. In genuine emergencies, do not hesitate to provide immediately necessary treatment unless there are clear indications that the patient would object to the treatment.

**Box 6: The eight rules of Data Protection**

1. Obtain and process information fairly.
2. Keep it only for one or more specified, explicit and lawful purposes.
3. Use and disclose it only in ways compatible with these purposes.
4. Keep it safe and secure.
5. Keep it accurate, complete and up to date.
6. Ensure that it is adequate, relevant and not excessive.
7. Retain it for no longer than is necessary for the specified purpose or purposes.
8. Give a copy of his/her personal data to an individual, on request.
Confidentiality

Confidentiality is central to the trust patients place in their doctors. It is an important legal and ethical principle – doctors must abide by the principles of the 1988 and 2003 Data Protection Acts (see Box 6) and by the Medical Council’s guidance.

General advice

Avoid problems by:

- Ensuring that your registration as a data controller is renewed annually (see Appendix 2 for contact details).
- Obtaining the patient’s consent (and recording it) before disclosing information to a third party. Make sure that the recipient of the information understands that it is given in confidence.
- Being able to justify disclosure without the patient’s consent as being in the public’s interests.
- Letting patients know (directly or through leaflets and posters) that information about them may be shared with other healthcare professionals. Make it clear that they have the right to withhold consent if they wish.
- Making sure that staff who are not bound by a professional obligation to preserve confidentiality are similarly bound by contract, and that they are fully aware that they have a legal obligation over and above their contractual commitments to maintain confidentiality.
- Training staff on information security and patient confidentiality. Most breaches of confidentiality are inadvertent and stem from staff not knowing what constitutes a breach of confidence.
- Introducing a protocol for checking patients’ identities when telephoning them with test results, etc, and a standard message for leaving on an answering machine that won’t compromise a patient’s confidentiality.
- Taking care (and making sure that your staff take care) not to discuss patients where others can overhear – reception areas are an obvious place where confidentiality can be breached unwittingly.
- Placing fax machines in secure areas and checking that information you send by fax will be received in a secure place – telephone first to warn of its impending arrival and ask the recipient to let you know if they don’t receive it.
- Using encryption software when sending emails containing patient information, and warning the patient that you are transmitting information about them by this means.
Box 7: Are you a data controller?

“A data controller can be either an individual doctor or the practice, depending on how the practice operates. If access to a patient’s record is granted to all GPs in a practice because the patient understands that when they attend they could be referred to any of the GPs, then it is likely from a registration perspective that the registration would be made in the name of the practice, assuming that the practice is a distinct legal entity.

“If, in a practice scenario, the GPs were sharing admin services and accommodation facilities only (but from a treatment perspective one GP could not access the files of other GPs) then each GP would likely be a separate data controller in respect of the information within their control and each would have to register separately with this Office.”

Advice received from the Data Commissioner’s Office (18 January 2011)

Confidentiality and medical records

- Keep medical records in a secure place – do not leave them lying around in publicly accessible areas.
- Restrict access to patient records on a “need to know” basis – not all staff need access to the whole record.
- Dispose of records securely by shredding or incinerating them.
- Do not use information contained in the medical records for purposes other than patient care, unless consent has been obtained or the data anonymised.
- For research or audit, anonymise information about patients in such a way that they cannot be identified. If this isn’t possible, obtain the patient’s consent.

Computerised and electronic records

There are many advantages to holding information in electronic form, not least of which is the greatly reduced storage space that is needed. Computer records can be easier to track and access and, if they are password accessible, it is also easier to restrict access to specific personnel.

Compared to paper records, on the other hand, the effects of unauthorised access to computer records are potentially of a greater magnitude. Moreover, as systems increasingly become networked, the opportunities for security breaches are expanding.
What you can do to minimise the risk of security breaches

- Position computer screens and printers where they can’t be seen by unauthorised people.
- Impress on staff that they must not disclose their password for any reason.
- Change passwords regularly.
- Do not set up a single username/password for use by all locums (or anyone else). Everyone who logs onto the system should do so using an individual username and password.
- Introduce practices such as always locking workstations before leaving them unattended, and set your screensaver to come on after a few minutes of inactivity (make it password protected).
- Use software that restricts access to authorised users and generates audit logs.
- Back up files regularly and keep back-ups in a secure off-site environment.
- Regularly review the effectiveness of your security measures.
- Install a good firewall and a regularly updated virus checker.

Box 8: Questions to ask yourself

- What would your practice do if it had a data breach incident?
- Have you a policy in place that specifies what a data breach is? (It is not just lost USB keys/disks/laptops. It may include any loss of control over personal data entrusted to organisations, including inappropriate access to personal data on your systems or the sending of personal data to the wrong individuals).
- How would you know that your practice had suffered a data breach? Do staff at all levels understand the implications of losing personal data?
- Has your organisation specified whom staff should tell if they have lost control of personal data?
- Does your policy make clear who is responsible for dealing with an incident?
- Does your policy meet the requirements of the Data Protection Commissioner’s approved Personal Data Security Breach Code of Practice?

Data Protection Commissioner, *Breach Notification Guidance* [www.dataprotection.ie](http://www.dataprotection.ie)
Problems in clinical management

Negligence is a legal concept. It does not mean neglect or wilful misconduct, but a failure to attain a reasonable standard of care. Any doctor can make an error of judgment. Some are legally defensible, others are not; what is important is whether the management can be defended by a responsible body of professional opinion.

In cases of negligence, the only remedy available in law is financial compensation: damages are paid to restore claimants to the position they would have been in had the negligent act not occurred. Before damages are payable, however, the claimant must prove all three of the following:

- They were owed a duty of care.
- There was a breach of that duty of care.
- Damage was suffered as a result.

Clinical practice

The test for establishing negligence in a patient’s diagnosis or treatment derives from the *Dunne* case, in which Finlay CJ set out the principles that courts have since applied when assessing the standard of care the patient received. The first of his principles captures the essentials of all the rest:

“...The true test for establishing negligence in diagnosis or treatment on the part of a medical practitioner is whether he has been proved to be guilty of such failure as no medical practitioner of equal specialist or general status and skill would be guilty of if acting with ordinary care,” adding the caveat that “a medical practitioner charged with negligence ... followed a practice which was general, and which was approved of by his colleagues of similar specialisation and skill, ... cannot escape liability if ... such practice has inherent defects which ought to be obvious to any person giving the matter due consideration.”

In other words, a doctor should not be considered guilty of medical negligence if other doctors of equal experience in the same specialty would have followed the same practice; such a practice must, however, be rational and reasonable.

Adopt accepted practice

Accepted practice is easy to define in some areas – prescribing in accordance with the recommendations of the Irish Medicines Formulary is an obvious example. Increasingly, proper practice has to be based on evidence (ie, determined by systematic methods based on literature review, critical appraisal, multidisciplinary consultation and grading of recommendations by strength of evidence). Evidence-based and up-to-date information concerning practical aspects of a wide range of conditions can be found on the internet (see Appendix 1).
Accepted methods of investigation and treatment are often described by clinical guidelines. Such evidence-based guidelines improve the quality of clinical decisions, help replace outdated practices, provide a focus for audit of clinical practice, and provide benchmarks for clinical governance.

Of course, guidelines are guidance, not instructions or commands. They should be regarded as aids to, not substitutes for, clinical judgment and must be interpreted sensibly and applied with discretion. If you decide not to follow the guidelines and your judgment is called into question, you will have to demonstrate why you were justified in not complying with the guidelines. Conversely, if you follow respectable clinical guidelines and base your decisions on evidence, you will be in a very strong position if a claim is made against you.

**Act within your limitations**

Although you are not expected to be infallible, the law expects that, as a doctor, you exercise a reasonable standard of skill and care at all times.

- Never undertake a task that is beyond your competence – when in doubt, seek help from a more experienced colleague.
- Ensure you have sufficient help and equipment available for any procedure you undertake, and for the management of all foreseeable complications.

**Box 9: Refer if necessary**

“If you do not have the professional or language skills, or the necessary facilities to provide appropriate medical care to a patient, you must refer the patient to a colleague who can meet those requirements.”

Keep up to date

Make Continuing Professional Development (CPD) an integral part of your working life. This not only means keeping up to date with new treatments and technologies, but also requires self-reflection and the expansion and honing of your skills, understanding and knowledge-base.

CPD is now a mandatory requirement of registration. All registered medical practitioners are now required by the Medical Council to be registered with a Competence Assurance Scheme and to acquire at least 50 CPD credits each year.

Box 10: Defining poor performance

“Poor professional performance, in relation to a medical practitioner, means a failure by the practitioner to meet the standards of competence (whether in knowledge and skill or the application of knowledge and skill or both) that can reasonably be expected of medical practitioners practising medicine of the kind practised by the practitioner.”

Medical Council, Guide to Professional Conduct and Ethics for Registered Medical Practitioners (2009), para 2.2

Take responsibility for your health

If you have an illness, disability or infection that may put your patients at risk, you must seek medical advice and, if necessary, stop or reduce your practice. The safety of your patients should be your prime concern.

Check equipment

Be fully conversant with any equipment you use – ensure that it has been properly serviced and is in working order before beginning any procedure.

Delegate appropriately

When delegating duties to others, be sure that they are competent to undertake the task and are fully aware of all relevant information concerning the patient. Make sure that they are able to call on competent back-up if it is needed.

Keep comprehensive up-to-date records

The medical record is an essential component of patient care. A good medical record will contain all the information one clinician needs to take over where another left off – or, to put it another way, to allow a clinician to reconstruct a consultation or patient contact without relying on memory. It should, therefore, provide all the
information a newcomer to the care team would need to know about a patient and their treatment plan.

If may be difficult to keep a comprehensive record of patients’ medical histories if they’re liable to “shop around”, consulting a number of different GPs. If you are seeing a patient after a long gap since the last consultation, it is worth asking them if they’ve had any significant illnesses in the intervening months. Educating patients about the importance of continuity of care – maybe in the form of a practice leaflet – is also advisable, especially for patients with chronic conditions or unresolved troublesome symptoms.

If you need to alter the notes at a later date, make it clear that you are introducing a retrospective correction. Any alteration to paper records should be clearly dated and signed. Do not obliterate the original entry – just run a line through it. Never try to rewrite notes at a later date. Do not delete entries in computer records, but add annotations to them if necessary (and date and initial them if the software doesn’t do it automatically).

Do not write derogatory statements or criticisms about patients, colleagues or others; be as objective and factual as you can in making your notes. If you record any history provided by someone other than the patient, make sure you include the source – eg, “Has been ‘confused lately’ (daughter)”. Remember, patients have a legal right of access to their records, which can also be scrutinised by the courts. See MPS’s booklet, Medical Records in Ireland.

Box 11: Medical notes

Depending on the circumstances, the medical record should include the following:

- Sufficient information at the top of each page to identify the patient.
- Results of physical examinations, including relevant history.
- Clinical findings.
- Diagnosis or provisional diagnosis.
- Treatment given or ordered.
- Complications such as drug side-effects.
- Results of investigations and action taken.
- Signed consent forms and notes on key elements of discussions with patient to obtain consent.
- Advice given to patient.
- Referrals and provision made for follow-up.
- Details of the substance of all consultations and telephone conversations.
Medication errors

Box 12: Medical Council guidance

“...You must ensure as far as possible that any treatment, medication or therapy prescribed for a patient is safe, evidence-based and in the patient’s best interests. You should be particularly careful when prescribing multiple medications in case the combination might cause side effects. You should also take particular care when prescribing for patients who may have an impaired ability to metabolise the medication prescribed. You should weigh up the potential benefits with the risks of drug adverse effects and interactions when deciding what to prescribe. This also applies to the exercise of the prescribing of generic drugs. A patient’s treatment regime should be reviewed periodically.”


Although, strictly speaking, medication errors should come under the heading of clinical management, they account for such a high level of complaints, claims and patient safety incidents that they deserve separate mention. The four most common errors are:

- Wrong dosage
- Inappropriate medication
- Failure to monitor treatment for side-effects and toxicity
- Communication failure between the doctor and patient.
Underlying these are myriad causes (see Box 13). Most of the errors can be avoided by simple checking procedures and clear, open communication.

**Box 13: Some causes of medication errors**

- Badly transcribed instructions
- Illegible prescriptions
- Miscalculation of dosage
- Confusion between similar-sounding drug names or similar-looking packages
- Clicking on the wrong drug in a drop-down menu
- Prescribing contraindicated drugs
- Not checking for potential drug interactions
- Not reviewing repeat prescriptions
- Failure to follow up/monitor
- Failure to act on laboratory results.

**When writing prescriptions**

- Be sure that the treatment is indicated.
- Check that the intended drug is not contraindicated and that the patient does not have a history of adverse reactions to it. Ensure that it will not interact with the patient’s other medication and warn the patient about any potential interactions with over-the-counter remedies.
- If issuing a hand-written prescription, write legibly, taking special care if the drug name could easily be confused with another – use capital letters and give the generic rather than trade name.
- If you use a computer for your prescribing, be aware of the risk of selecting the wrong drug from a drop-down menu (eg, penicillamine instead of penicillin).
- Write clear and unambiguous instructions for dosage, frequency and route of administration.
- Note the prescription and any other relevant information (eg, warnings given to the patient) in the medical record.
- Ensure that the patient is aware of what is being prescribed, and why.
Checking procedures

- Be particularly careful when choosing the dose for a drug you are not familiar with.
- If a pharmacist questions a drug order or prescription, check it carefully – many problems are prevented by helpful interaction between colleagues.
- Always read the label on the bottle or vial before administering a drug or other substance, such as water for injection.
- Establish the identity of the patient and double-check the prescription before administering medication.

Communication

- If you are prescribing medication to be administered by other members of the healthcare team, issue clear and unambiguous instructions – answer fully any queries they may have.
- Make sure that your patients understand how to take the medication you prescribe, and that you warn them of any possible serious side-effects or effects that would make driving or operating machinery dangerous.
- If medications are administered on the premises (eg, vaccines or steroid injections) document it (name, time, dose) in the appropriate place in the medical records.
Systems

Even if you already have systems in place, it is worth subjecting them to regular review to see if they’re working as planned or can be improved. This is also an opportunity to remind staff how important it is to follow the procedures laid down. Important aspects to consider are:

- Reviewing repeat prescriptions
- Printing and signing repeat prescriptions (see the case report below)
- Monitoring toxicity levels (eg, thyroxine)
- Flagging up drug allergies
- Alerting relevant members of the practice (eg, the practice nurse) to prescription changes
- Carrying out a significant event audit when medication errors come to light.

See MPS’s factsheet on Repeat Prescribing.

Box 14: Case report

Receptionist changing a prescription has profound repercussions

A four-month-old baby girl died in the UK following an error in issuing a repeat prescription for Frusemide at her local general practice surgery.

She had been taking Frusemide since she was four weeks old, but the strength of solution had recently been changed because she was having trouble swallowing it in 5ml doses.

When her mother rang the surgery to ask for a repeat prescription, the receptionist seemed to be confused by the two prescriptions on the system and apparently changed the dosage on screen before printing off the prescription and adding it to the pile of repeat prescriptions for signing.

A doctor, unaware that changes had been made to the prescription, signed it on the assumption that it was a normal repeat prescription. The prescription he signed, however, was for a 10x strength, 5ml to be taken twice a day. A solution at that strength should, however, have been taken in 0.5ml doses.

Source: Daily Mail 17 March 2010
Prescribing for children

While all the foregoing advice on avoiding medication errors applies to both children and adults, special care is needed when prescribing, preparing and administering drugs to children. Drugs that are relatively innocuous in adults may have adverse effects in children. Variations in height, weight and body mass can make them more susceptible; or they may quickly accumulate toxic levels as a result of slower metabolism and excretion. In many cases referred to MPS, errors occurred because the doctor failed to check the appropriateness of the drug and its route of administration in children or infants, or to prescribe the correct dose.

Advice for safer paediatric prescribing

- Limit the drugs you use to a well-tried few and familiarise yourself with their dosages, indications, contraindications, interactions and side-effects.
- Refer to a paediatric formulary when appropriate.
- If you are prescribing in very small amounts of less than 1 milligram, prescribe in micrograms (written out – not abbreviated) to avoid confusion over the placing of decimal points.
- When prescribing for a child, it is particularly important to give the parents all relevant information such as:
  - the name of the drug
  - the reason for the prescription
  - how to store and administer the drug safely (if appropriate)
  - common side-effects
  - how to recognise adverse reactions.

Parents must always be warned about side-effects, particularly those that will be distressing to the child. It is also helpful to remind them of the importance of storing drugs in their labelled containers and out of the child’s sight and reach.
Administrative procedures

Errors have a tendency to compound themselves, so it is worth taking the time to ensure that essential tasks are carried out carefully (see Box 15). Many complaints arise from simple mistakes that could have been easily avoided. The most common administrative failures are:

- Failure to pass on important information
- Failure to arrange appointments, investigations or referrals with the appropriate degree of urgency
- Failure to review the results of investigations
- Failure to arrange follow-up and monitoring
- Mislabelling, misfiling and failure to check labels.

Develop appropriate systems

In a busy practice, it is easy to dispense with protocols or overlook a crucial administrative procedure in the interests of speed. If your staff are unaware of the rationale for introducing a protocol, they are less likely to adhere to it. The best way to gain their compliance is to involve them in drawing up the protocols in the first place (that way, you also ensure that they are workable from the staff’s point of view).
Carry out an assessment of routine procedures and protocols to identify potential problems, and develop systems for averting them. Particular risk elements are:

- Telephone use – eg, logging and passing on messages, discussing patient-identifiable information within hearing range of other patients, non-professional staff giving medical advice, documenting telephone advice
- Communicating results of investigations
- Following up missed appointments
- Prescription renewals and reviews
- Maintaining medical records – filing, tracking and security
- Making and following up on referrals
- Keeping relevant people informed about changes in a patient’s condition or circumstances.

**Box 15: Suggestions**

- If a test or a referral is urgent, make sure the request is marked “urgent” and that you make a diary note to check that it has been actioned. Telephone the laboratory or department if necessary.
- If a letter needs to be typed, mailed, faxed or e-mailed urgently, impress the need for speed on the secretarial staff.
- Make sure there is a formal system for recording and passing on telephone messages – scraps of paper and post-it notes are easily ignored or mislaid.
- Arrange a foolproof system for reviewing results of investigations: if a test result is abnormal, deal with it promptly and appropriately.
- Make sure records are filed properly.
- If you tell a patient you will do something – such as sending further information, or making a referral – record it in the case notes, and either do it before seeing your next patient or make a note of it on a “Things to Do Today” list.
- Write or dictate referral letters promptly, and make sure that appropriate individuals receive copies.

**Adverse incident reporting system**

Incident reporting has proved to be a useful tool in preventing error in high-risk industries, such as aviation, nuclear and petro-chemical industries. It has increased investment in the development of proactive and reactive safety systems. If an aviation incident occurs it is reported, investigated and lessons are learnt. Is there an incident reporting system at your practice? Reporting when things go wrong is essential, as it explores the underlying causes of patient safety incidents and allows learning to be obtained from them.
All GP practices should have protocols that encourage staff to report untoward incidents. Staff should feel they can report incidents without the fear of personal reprimand. A positive patient safety culture is one that has open communication, mutual trust, shared perceptions of the importance of safety and confidence in the efficacy of preventative measures.

**Continuity of care**

The concept of the “family doctor” is changing as busy people (especially infrequent attenders) choose to take the first doctor available for an appointment rather than wait to see “their” doctor. In urban areas especially, a growing number of patients “shop around”, either consulting a variety of doctors about a particular condition or consulting a different doctor for each episode of illness. The continuity of care that GPs have traditionally provided is gradually becoming a casualty of our modern world, but patients may be at risk without it. At MPS we frequently see claims arising from communication gaps when patients consult a series of GPs in the course of one illness.

Here are some tips for maintaining continuity of care when multiple doctors are available:

1. Impress on patients, via notices in the waiting room and on the practice’s website, if you have one, why it’s important to see the same doctor regarding an ongoing complaint. Making clear follow-up arrangements and using language like “Come back and see me if it gets worse” will help to reinforce this message.

2. Draw up protocols for reception staff taking appointments. It could be standard practice, for example, for them to ask the patient if they have attended the practice recently about the same problem and, if the answer is “yes”, to suggest that they see the same doctor. Explain to staff why this is important.

3. Write sufficiently comprehensive notes at each consultation so that any one else who sees the patient can understand fully what happened in the consultation, understand the progress of a patient’s condition and be fully aware of what has already been done.

4. Read the most recent entries in a patient’s medical record so that you are aware of any ongoing problems that have not been resolved or that might have a bearing on the consultation.

5. Institute an alert system so that investigations and tests are followed up and, if necessary, acted upon.

6. Make arrangements for a colleague to check your emails and correspondence while you are off sick or on leave.

7. Be especially careful if you are doing out of hours work or home visits, where you might not have access to the patient’s notes, to take a thorough history and ensure either that it is inserted into the patient’s notes or that the patient’s GP gets a copy at the first available opportunity.
Failures of communication

Underpinning good patient care is good communication, and this goes beyond establishing good relations with patients. In today’s team approach to delivering healthcare, communication has to extend to more people and there are therefore more opportunities for it to fail.

Communication between primary care, secondary care and social and voluntary services should be seen not as a chain, but as a communication net, within which any one member may need to communicate with any other (see Figure 1). Good management requires all members of the communication net to be conscious of who is doing what – an adequate standard of continuing medical care can be achieved only if all participants – both medical and nonmedical – understand their roles.

Box 16: Communicating with colleagues

“Doctors working in multidisciplinary teams should ensure that there are clear lines of communication and systems of accountability in place among team members to protect patients.”

Medical Council, Guide to Professional Conduct and Ethics for Registered Medical Practitioners (2009), para 46.1
Keeping people informed in the interests of continuity of care must be balanced against the need to maintain confidentiality, and both these issues should be borne in mind when sharing relevant information about patients. Unless the patient asks you not to, it is entirely appropriate to share information about patients with people involved in their care.

**Recording essential information**

Inadequate medical records are the underlying cause of many failures of communication – the records are the essential tool of communication between members of the multidisciplinary team. Subtle but significant changes may be missed when several different doctors see a patient over many days, unless adequate information is available from previous examinations.

What you include or leave out of the record is a matter of professional judgment, but you should take care to include all information that other members of the team will need to continue care of the patient safely. As months or years may elapse between treatments or illnesses and staff may have changed in the meantime, the records should also serve to reconstruct events at a later date without recourse to memory.

**Box 17: Sharing care with colleagues**

Ensure that colleagues who deputise for you, whether formally or informally, are fully aware of all relevant details of the patients for whom they are responsible.

Practices should establish protocols for the transfer of relevant information between doctors who cover for each other, particularly in co-operatives and when deputising services are used.

If it is in the patient’s best interests and you have their implied or express consent, welfare and voluntary agencies and family carers should be given any relevant information.
For hints on keeping good records, and advice on access to and disclosure of medical records, phone MPS’s Communications Department and ask them to send you a copy of the MPS booklet, Medical Records, or download it from our website.

**Box 18: Case report**

**Poor communication with blinding results**

A diabetic clinic in a teaching hospital diagnosed TB in a diabetic patient with a history of weight loss. He was admitted to hospital and, on discharge, was prescribed three months’ supply of ethambutol, rifampicin, pyrazinamide, isoniazid and pyridoxine.

A month later, he was seen in the diabetic clinic but there was no discussion of his TB treatment. He failed to attend his next appointment.

Three months after starting TB treatment, the patient began to complain of deteriorating vision and his GP made an urgent referral to the eye clinic. The GP had not yet received a discharge letter about the patient’s last hospital admission for the treatment of TB, nor had the diabetic clinic informed him of the diagnosis, so his referral letter to the eye clinic made no mention of the fact that the patient was taking ethambutol.

The patient attended the eye clinic several times over a month, but no history of TB or treatment for TB was obtained – his visual loss being attributed to diabetes. However, his vision continued to deteriorate and by the end of this period he was only capable of counting fingers. A week later, the patient attended the diabetic clinic. Only then was the diagnosis of ethambutol eye toxicity raised.

The patient was seen immediately in the eye clinic where the diagnosis was confirmed and the ethambutol stopped, but by then he had sustained a permanent loss of 90% of his vision.
Communication between specialties

As a doctor, you are not expected to be infallible, but you are expected to put yourself in a position to make a reasonable clinical judgment and manage the patient appropriately thereafter. This includes making an adequate assessment of the patient’s condition, arranging appropriate investigations and, if it is indicated, referring the patient to another practitioner.

Referrals

First of all, be sure the patient understands the reason for the referral and has appropriate expectations. You should also give patients an estimate of when they should expect to get an appointment, and tell them what to do if they haven’t been contacted within the expected time.

When making a referral, indicate the degree of urgency and provide all relevant clinical details (including the history, clinical signs and, when appropriate, physical examination).

Communicating with patients

Patients who are kept informed about their condition and are involved in deciding on the appropriate treatment are more likely to comply with the treatment you suggest, and less likely to complain if things go wrong.

It is particularly important that you tell patients about the possible side-effects of drugs or treatment you are ordering, and that they know what complications to look out for and what to do if they develop.

Warn patients about the risks before carrying out any procedures or prescribing medication. “Informed” consent is dealt with in more detail in the MPS booklet, Consent to Medical Treatment in Ireland, which can be downloaded from our website or ordered through our Communications Department.

If patients are receiving treatment, tell them when to return for review and what symptoms or signs of adverse effects or changes in their condition to report. If possible, give them an indication of when they might expect to see an improvement in their condition, and when to call you if it doesn’t transpire within a certain timescale.

Document any advice you have given the patient. It is useful to document in the record any supporting literature or written information given to the patient.
If things go wrong

Even though we all know that to err is human, few of us can easily accept our own mistakes. This is probably more the case in healthcare than in most other occupations, because errors can have such serious consequences. In a survey of MPS members who had experienced untoward incidents in their practice, almost all of them found that it shook their confidence and eroded their job satisfaction. Complaints from patients tended to be taken as personal attacks, with the doctor feeling angry, hurt and betrayed. Some of these effects lasted for years.

The intensity and duration of the emotional aftermath does not seem to relate closely to the seriousness of the error or the nature of the complaint; the crucial factor is the ability of the individual doctor to put the experience into perspective and seek out practical and emotional support. Lessons can be drawn from this:

- Assess the circumstances realistically – don’t blow an error or a complaint out of all proportion; remind yourself of all the things you do get right and all the patients who are satisfied with your care.
- Talk the matter through with trusted colleagues and friends who can both empathise with you and give you a realistic assessment of the situation.
- Contact MPS for practical assistance in dealing with a complaint or claim and for advice about handling the emotional repercussions.
- Learn from the situation. If you did make a mistake, acknowledge it. Report it as an adverse incident and engage with your colleagues in developing strategies to prevent similar errors occurring in the future.
- If you have been unjustly accused of substandard care, think what may have brought the accusation about – was it a communication problem, for example? How might you have handled it differently?
- If a patient has complained about you, try not to react defensively by avoiding the issue or making counter-threats. Investigate the complaint and be prepared, if you have made a mistake, to give the patient their due – a full face-to-face explanation, a sincere apology and an assurance that you will take steps to avoid a repetition of the problem.
- If, after the complaint has been investigated, it is evident that the complaint has no foundation, you should still see the patient and explain the outcome of the investigation, give a full account of events and try to ascertain whether the complaint has been caused by a misunderstanding that you can put straight.

Patients expect a great deal from their doctors, not least of which are super-human abilities. This means that you are almost certain to disappoint some of your patients some of the time. All you can hope to do in the circumstances is to try and turn negative experiences into positive learning opportunities, thus refining your skills and building, rather than eroding, your confidence.
Appendix 1

Sources of guidelines, research and evidence-based care

Bandolier
www.ebandolier.com
www.jr2.ox.ac.uk/Bandolier

A monthly journal, based in Oxford but with a global perspective, Bandolier is a trustworthy and well recognised source of evidence based healthcare information.

Centre for Evidence-based Medicine
www.cebm.net

An Oxford-based centre established with the aim of developing, teaching and promoting evidence-based healthcare and providing support and resources to anyone who wants to make use of them. Its website has useful links to specialty-specific EBM sites.

Clinical Evidence
www.clinicalevidence.bmj.com

BMJ Clinical Evidence publishes systematic reviews summarising the current state of knowledge and uncertainty about the prevention and treatment of clinical conditions. Athens users and subscribers can access the reviews online via a PC or PDA. There is also a handbook available for purchase.

Clinical Knowledge Summaries
www.cks.library.nhs.uk

A reliable source of evidence-based information and practical “know how” about the common conditions managed in primary care. CKS is commissioned and paid for by NHS Evidence, a service provided by the National Institute for Health and Clinical Excellence (contact them before using the website).

The Cochrane Collaboration
www.cochrane.org

An international organisation that aims to help people make well-informed decisions about healthcare by preparing, maintaining and promoting the accessibility of systematic reviews of the effects of healthcare interventions.
The General Practice Notebook
www.gpnotebook.co.uk

*The GP Notebook* has an extremely good webpage with links to evidence based medicine arranged by condition/specialty and external links to more EBM sites.

**eGuidelines**
www.eguidelines.co.uk

This site focuses on EBM for primary care. It comprises regular summaries of national and European guidelines and also hosts a useful database (CLIP) of clinical effectiveness initiatives implemented by practices across the UK.

**Health Evidence Bulletins Wales**
www.hebw.cf.ac.uk/index.html

Collection of evidence based guidance for prevention, diagnosis and treatment of medical conditions.

**Lenus**
www.lenus.ie/hse

The Irish Health Repository providing access to journals, research reports and HSE publications.

**National Guideline Clearinghouse**
www.guideline.gov

A comprehensive database hosted by the US government of evidence based clinical guidelines and related documents from around the world. It has a useful facility for comparing guidelines.

**National Institute for Health and Clinical Excellence**
www.nice.org.uk

This is a statutory body in the UK which is charged with improving the quality of clinical services across the NHS by formulating guidelines on numerous conditions, and advising on methods of audit with relation to these guidelines.

**NHS Centre for Reviews and Dissemination (CRD)**
www.york.ac.uk/inst/crd

The Centre for Reviews and Dissemination (CRD) is a department of York University, established in 1994. It carries out high quality systematic reviews that “evaluate the effects of health and social care interventions and the delivery and organisation of healthcare”. It publishes several bulletins which can be downloaded from its website.
Scottish Intercollegiate Guideline Network (SIGN)
www.sign.ac.uk

The Scottish Intercollegiate Guidelines Network (SIGN) was formed in 1993. Its objective is to improve the quality of healthcare for patients in Scotland by reducing variation in practice and outcome, through the development and dissemination of national clinical guidelines containing recommendations for effective practice based on current evidence.

Surgical Clinical Guidelines
www.rcsi.ie/index.jsp?p=321&n=597

A collection of international guidelines added to each month by the Royal College of Surgeons in Ireland. They select the guidelines that have the most relevance to Irish surgical practice.

The Trip Database
www.tripdatabase.com/index.html

Clinical search tool designed to allow health professionals to rapidly identify the highest quality clinical evidence for clinical practice. Registration is free.
Appendix 2: Data Protection

Office of the Data Protection Commissioner
Canal House
Station Road
Portarlington
Co. Laois.

LoCall: 1890 25 22 31
Phone: 00353 57 868 4800
Fax: 00353 57 868 4757
Email: info@dataprotection.ie

You can register as a data controller online at www.dataprotection.ie or by post.

The ICGP has produced several useful guides to different aspects of patient confidentiality and IT security. They can be downloaded from the ICGP’s website at www.icgp.ie. We particularly recommend Managing and Protecting the Privacy of Personal Health Information in Irish General Practice (November 2003), which has been endorsed by the Data Protection Commissioner.
References


2. Ibid, para 42.3

3. Ibid, para 22.2

Other MPS publications

- Avoiding Problems: Managing the Risks in Hospital Practice
- Consent to Medical Treatment in Ireland
- MPS Guide to Medical Records
- MPS Factsheets (various topics)

All these publications can be downloaded from www.medicalprotection.org/ireland

To order hard copies, please write to, telephone or email:

**The Communications Department**

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Granary Wharf House  
Leeds, LS11 5PY  
United Kingdom

Tel:   +44 (0) 113 241 0530  
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Email: publications@mps.org.uk

Further information

For information, publications, general advice and case reports, visit www.medicalprotection.org/ireland

For help with your membership, email member.help@mps.org.uk

For medicolegal advice, email querydoc@mps.org.uk

Please do not use email to send us any of the following:

- Legally sensitive documents or information confidential to you, your patients or your legal advisers.
- Do not send us information that would allow a patient to be identified, by name or by context.
- Any membership details – such as your membership number – which may be used to defraud either you or MPS.
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E querydoc@mps.org.uk

Membership enquiries
T 1800 509 441
F +44 (0) 113 243 0500
E member.help@mps.org.uk

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

Chief Executive
Medical Protection Society
33 Cavendish Square,
London W1G 0PS, United Kingdom

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

Calls to Membership Services may be recorded for monitoring and training purposes.

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