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NICE guidance on laparoscopic surgery for inguinal hernias: Guidelines are less clinical excellence than hindrance

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Letters

NICE guidance on laparoscopic surgery for inguinal hernias

Guidelines are less clinical excellence than hindrance

Editor—We have two comments on the paper by Bloor et al on the impact of NICE guidance on laparoscopic surgery for inguinal hernias.1

Firstly, the authors say that guidance from the National Institute for Clinical Excellence (NICE) on laparoscopic hernia repair had no impact on practice and that the rate of laparoscopic repair has not changed much. Although the rate of laparoscopic repair has not changed, NICE guidance has an impact on practice as it stopped the normal progression in laparoscopic hernia repair. Without the guidance the number of laparoscopic repairs would be much larger now.

Secondly, surgeons who were already doing laparoscopic repairs have not stopped doing so, and morbidity has not increased, which means that the NICE guidance was not correct. The European Hernia Trials Group found that the incidence of recurrence in laparoscopic and Lichtenstein repairs was similar (2.3% and 2.9%).2 A recent study from Germany, including 8050 patients, showed that recurrence rate for transabdominal preperitoneal hernia repair is only 0.4%.3

Although the difference is minimal, the true cost of laparoscopic hernia repair is lower.4

In January 2001 NICE said that open mesh repair should be the preferred procedure for primary inguinal hernias, and the laparoscopic repair should be considered only for recurrent or bilateral hernias.

Preferred and considered by whom? The 23 members of the NICE appraisal panel include pharmacologists, healthcare economists, patient representatives, and one surgeon. Apart from written submission, by the Association of Endoscopic Surgeons of Great Britain and Ireland, oral evidence was taken from just one surgeon,5 NICE has made it clear that the reasons have more to do with control of NHS cost than with clinical excellence.6

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Competing interests: None declared.


Late adapters may never change

Editor—With respect to the impact of NICE guidance on laparoscopic surgery for inguinal hernias by Bloor et al, any change process, regardless of the quality of evidence backing it up, is enthusiastically embraced by only a minority of up to 20%, the “early adapters.” The remainder follow suit at a varying pace, leaving a lump of “late adapters,” who may never change if given the choice. Expecting change after only a year would seem to be naively optimistic.

Furthermore, laparoscopic hernia repair, by the authors’ own admission, is a comparatively uncommon procedure, accounting for less than one in 20 of all operations. Despite a minute increase, the number of laparoscopic hernia repairs carried out after the introduction of the guidelines is still low.

The surgeons responsible may be postulated to consist of two groups: the middle to late adapters and those who have made a clinical judgment that, given the circumstances, laparoscopic repair is the treatment of choice for specific patients.

Short of a total ban on the procedure, I can think of no measure by which a notable change in practice could have been achieved in a very short timescale in this particular case. If this is what Bloor et al meant by more active dissemination and implementation procedures, they should have said so.

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NICE evaluation has data shortage and short analysis period

Editor—The article by Bloor et al on the impact of NICE guidance for inguinal hernia repair opens an essential debate. To be confident in the results, however, it would have been useful to know the procedure and diagnosis codes used by the authors in their analysis. This would allow local trusts to undertake a similar analysis to test the impact locally.

Furthermore, how confident are the authors in the data provided within the hospital episode database? If data coding and auditing is poor then using this as a data source for clinical governance purposes may be compromised.

Quite rightly, the authors say the guidance from the National Institute for Clinical Excellence (NICE) needs active dissemination throughout the NHS. By measuring an effect at 12 months after the guidance was issued, however, they assume that guidance should be disseminated and implemented and that the effects of implementation will be shown throughout the NHS within a year.

This may not be long enough. Because of the effects of seasonality, trusts would require at least one year’s data before they could have faith in using the data for monitoring purposes. Future analysis should therefore be based on a minimum period of two years after the guidance has been introduced to allow for local implementation of guidelines. This would then allow trusts to evaluate not only the impact of NICE guidance but also how effective their internal dissemination and clinical governance procedures are in changing clinicians’ practice.

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Beyond single and dual diagnosis in general practice

Editorial—Multiple authorship poses difficulties

Editor—In their editorial Wright et al refer to the increasing links between poverty and poor health. They introduce a new term to describe these health problems, “multiple morbidities.” This is a biomedical construction if ever I heard one, a public health obfuscation. I do not disagree, but the editorial’s multiple authorship fails to drive home the key points in a fragmented article. The irony (and I am sure it is not lost on the authors) is that multiple authorship has inadvertently subverted the clarity of the work.

The issue is not that primary care lacks specialist credentials or that secondary care has become too specialised but that communication across the interfaces continues to be absurdly primitive. Part of this is a reflection of inadequate staffing, poor management, and an antediluvian records system; some is a question of attitude, especially among inexperienced, simply ignorant, or poorly led secondary care teams. Increased undergraduate training in primary care, already under way, has begun to redress the knowledge gap. Further endeavours to include compulsory six month postgraduate training are to be welcomed. Most of all we need more healthcare staff and up to date unified record systems that will deliver speedy and effective communication across all interfaces.

If these caveats are acted on Wright et al need to have no fear. We can safely return to the 19th century care model in which the community based doctor would involve a number of technicians with whom we can explore the multiple morbidities of our patients.

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Patients who do not comply with polypharmacy may be safer

Editor—I concur with Wright et al’s unease about polypharmacy. Consultants with narrower special interests simply bolt on their particular care package if the patient is referred in their direction.

Dare I suggest that general practitioners are specialists in “multiple morbidities,” which may often include persistent unexplained physical symptoms and some degree of somatisation. Could it be incumbent on us as general practitioners to edit the Leviathan of the modern prescription without recourse to our bewildered hospital colleagues?

Are we ready to admit that the dangers of polypharmacy usually outweigh the small absolute benefits of each drug? Half our patients will not manage to comply in any case. Perhaps they are the safer.

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Methotrexate and bone marrow suppression

Drug errors may be implicated in death

Editor—Two points arise from the lesson of the week by Sosin et al on methotrexate toxicity.

Firstly, bone marrow toxicity with methotrexate is a late complication of treatment. Only one of the cases described (case 2) had been treated for less than 12 months, and the authors suggest he had been taking methotrexate daily rather than weekly as would have been recommended. This is consistent with what we showed in our observational study, in which the median delay to neutropenia with methotrexate was 16.9 months, in contrast to other disease modifying anti-rheumatic drugs such as sulphasalazine, with which the median delay was 2.1 months.

This has important implications for monitoring protocols as current guidelines specify more frequent monitoring early in treatment. Whereas with drugs such as sulphasalazine toxicity may reflect hypersensitivity, with methotrexate accumulation seems a more likely cause.

Secondly, there is a further potential source of serious drug errors with methotrexate other than the weekly dosing regimen. The drug comes in 2.5 mg and 10 mg tablets, which look identical in colour, size, and shape. The 2.5 mg tablet is preferred in secondary care, as this allows ready dose titration. However, patients taking 10 mg or 20 mg weekly may be dispensed the 10 mg tablet from community pharmacies. Unless the different tablet dose is highlighted, patients are at risk of a fourfold overdose. Drug errors with the 10 mg tablet have been implicated in at least one death.

This is partially a matter for patients’ education—we regularly emphasise the importance of checking the tablet dose to our patients—and partially a matter for the manufacturers and the National Patient Safety Agency (www.npsa.org.uk). The 10 mg tablet is to change shape soon, but while stocks of the old shape remain in circulation the potential for this error remains.

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Standard collaborative care will be made more difficult

Editor—The paper by Sosin et al on low dose methotrexate and bone marrow suppression reminds us that even very safe drugs need to be monitored with a reasonable degree of care. Case 2 is almost certainly due to overdosage because of daily dosing rather than weekly dosing. Case 1 seems to be due to the drug alone, and in case 3 the patient was exposed to trimethoprim as well as the methotrexate. The patient was not pancytopenic at the time of the death when she developed pneumonia.

My concern about this paper relates to box 1, in which it is stated that non-steroidal anti-inflammatory drugs may cause bone marrow suppression when combined with methotrexate, and to the statement in the paper itself that patients and health professionals must be aware of the importance of avoiding interacting drugs.

In rheumatological practice it is normal to prescribe methotrexate with non-steroidal anti-inflammatory drugs, a combination that has been found to be both safe and effective. Methotrexate is not in itself an analgesic, and most patients require additional pain relief, of which the most effective method is undoubtedly non-steroidal drugs. Sosin et al do not mention aspirin specifically, which probably is more dangerous than the other non-steroidal drugs (and is often not regarded as a non-steroidal in normal usage) because of its specific effect on renal tubules, where methotrexate is excreted.

Methotrexate has attracted an undeserved reputation as a dangerous drug, mainly because of its use in oncology, where it is used in much higher doses than are used in rheumatology and without the benefit of dosing with folic acid. Linking together non-steroidal drugs and methotrexate in the way that has been done in this paper will increase anxiety among general practitioners and make standard collaborative care more difficult.

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Competing interests: None declared.

Authors’ reply

Editor—We agree with Grove that bone marrow toxicity is not usually an early complication of methotrexate treatment and that current guidelines recommend more rigorous monitoring of the blood count in the early stages of treatment. Therefore all healthcare professionals who come into
contact with patients taking methotrexate must be aware of this complication so that it may be recognised early, providing the best chance of a successful outcome.

We also agree with the second point raised by Grove, that a change in the shape of the 10 mg methotrexate tablet is long overdue and, we hope, will help considerably to avoid dose error.

Clarke comments that non-steroidal anti-inflammatory drugs are highly effective analgesics and are routinely used in combination with methotrexate in rheumatological practice. Our paper was primarily aimed at non-rheumatologists who may come into contact with such patients for other reasons, such as the patient in case 3, who was exposed to an interacting drug (trimethoprim).

We agree with Clarke that methotrexate is, when used correctly, a safe and very effective drug. As mentioned in our paper, evidence is coming to light that methotrexate may be used in rheumatoid arthritis. We hope that by making non-specialists aware of the rare but serious side effect of bone marrow suppression we can encourage the safe use of this highly effective drug.

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Medical community may be partly responsible for cancer misery

Enrort—The article by Murray et al prompts me to highlight a less quoted cause of misery of patients with advanced cancer.1

The World Health Organization estimated that in 2020, 20 million new cases of cancer will be diagnosed each year and 75% of these will occur in nations that between them have only 5% of resources. India, with only 20 dedicated cancer centres and 13 hospices, has around 3 million patients with cancer at any one time, of whom 80% are incurable.2 In India one in 10 deaths is related to cancer, and only 3% of the people who need palliative care receive it.3

Many patients become victims of alternative medicine practitioners,4 and those few who escape are required to visit government hospitals that are overcrowded and under-funded.

Patients with advanced cancer are made to feel less deserving of medical efforts in non-paying settings. They are welcome in private hospitals, and they commonly undergo unwarranted investigations and interventions. Forceful promotion and incentives are promoting the use of chemotherapy to improve “quality of life” in hopeless cases. This institutionalisation of death, commercialisation of suffering, and prolongation of lucrative illness is becoming rampant. Most patients are not even referred to a palliative care specialist because offering false hope fetches more money than giving solace to the patient and his or her relatives.

The prevalent practice of the “anecdote based medicine” emanates from lack of multidisciplinary cancer centres, continuing medical education, political will, infrastructure, and poor availability of morphine. Palliative care, counselling, home care, rehabilitation, psychotherapy, breaking bad news sensitively, and communication skills are sparsely practised.5 Medical students aim for a lucrative private practice; those opting for studies in prevention and palliation are considered academically unsound.

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Obesity may confound relation of early pregnancy loss to risk of heart disease

EDITOR—Smith et al observe that adverse events in early life can be related to apparently disparate events later in life.1 For spontaneous pregnancy loss and subsequent ischaemic heart disease, they assume a role for inherited and acquired thrombophilias in the mother as a common aetiological factor. They adjusted for the potential confounding effects of maternal age at the time of first birth, height, socioeconomic deprivaton, essential malnutrition, and complications during the first pregnancy. They were apparently not able to adjust for maternal body weight and thereby in conjunction with height, obesity. Maternal obesity is strongly associated with pregnancy loss, at least in subfertile women,2 and is an independent contributor to risk of ischaemic heart disease. Obesity may therefore be operating as a confounding factor in the association between pregnancy loss and subsequent heart disease.

The influence of obesity may also explain in large part the results of previous studies that have found an association between the total number of pregnancies and maternal risk of ischaemic heart disease. High parity is associated with adult weight gain.2 The confounding effect of obesity is also consistent with the null effect of therapeutic abortion on risk of ischaemic heart disease, as there is no particular reason for obesity to be strongly associated with receiving a termination.

The reported study had the strengths of prospective data collection, but it relied on data that were not collected for the purposes of the present analysis and may not contain details of all relevant confounding factors. Although the observation of Smith et al is important and multiple factors may be making a contribution, including inherited and acquired thrombophilias, we need further analysis on the effects of obesity and additional studies linking reproduction, adult weight gain, and increased risk of disease.

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Fatal dysnatraemia caused by elective colonoscopy

Lesson was unnecessarily alarmist

EDITOR—The lesson given for Ayus et al’s report of fatal dysnatraemia after colonoscopy was that plasma sodium concentration should always be checked after colonoscopy.1 We speculate that this strongly worded advice may have been added by your editorial team, in our opinion entirely without warrant and also against the carefully worded discussion and conclusions of the authors.

The patients described in the report all had reasons for potential electrolyte imbalance (one was taking diuretics, two had end stage renal failure). The primary reason for the communication was that patients with abnormal electrolyte handling, including some elderly patients, who have high volume balanced electrolyte preparation require monitoring of their plasma electrolyte status. Sick or frail patients and those with complications require extra care. Any fatality or serious consequence of medical manipulation deserves careful consideration by the profession.

However, many millions of colonoscopies have been performed around the world without any other such report of fatal electrolyte imbalance. Similar bowel preparation has been safely used for many years for barium studies, and more recently for “virtual colonography” and other procedures. The benefits of colonoscopy are huge, combining unusually accurate diagnosis, the potential for immediate polypectomy, and so the chance of reducing the currently appalling incidence of colorectal cancer.

That such a rare event should be accepted for and given prominence in the
BMJ with an added touch of tabloid sensationalism is surprising. Sick patients require appropriate monitoring, and well people and their medical attendants should expect that colonoscopy (and the bowel preparation before it) should be an atraumatic and very safe experience. We and others are striving to raise standards of colonoscopy performance, training, and availability. For the BMJ to raise unwarranted fears about routine arrangements for elective colonoscopy (emergency colonoscopies are vanishingly rare) is not in the general interest.

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Additional cost for colonoscopy providers may be unnecessary

Editor—Respondents on bmj.com to the article by Ayus et al have already questioned the lesson that serum concentrations of sodium should always be checked after colonoscopy.1 Many millions of colonoscopies have been performed around the world without any other such report of fatal electrolyte imbalance.

Many millions more may be performed in the future. It may be ill advised to make an argument for an across the board increase in procedural costs—checking serum concentrations of sodium should always be checked after colonoscopy. We doubt, however, that asking the patient whether the palpation hurts leads to an invariably higher positive response compared with silent palpation and simple observation for a non-verbal response. We imagine the reverse being the case since "tough guys," in particular, may express pain but deny it on being asked.

Let us be selective in the use of scarce medical resources. We should reserve serum measurement in the context of colonoscopy for the few patients in whom notable electrolyte disturbance as a consequence of preparation for the procedure, or whose clinical condition afterwards, makes a potentially life threatening imbalance likely.

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Competing interests: None declared.


Patients with ligamentous injury need better treatment in Britain

Editor—In his editorial supporting the use of the Ottawa rules, Heyworth suggests that injured ankles be separated into two groups: those with simple ligamentous injury to soft tissue or a small avulsion fracture and those with more serious fractures requiring immobilisation.1 This unfortunately reflects the casual treatment given to patients with ligamentous ankle sprains in British accident and emergency departments.

Up to a third of patients with an ankle sprain may develop disabling problems such as recurrent instability or chronic pain.

Doctors and nurses should be aware that the Ottawa rules are simply guidelines to decide which group of patients should have radiography. Patients with severe ankle sprains—for example, those who cannot bear weight—need more than a compression bandage and advice on ice and elevation: they also need protection in an ankle stirrup or cast, and they should be referred for physiotherapy for stretching, strengthening, balance, and return to sports exercises.2

A more thorough approach to patients with severe ankle sprains should prevent long term problems. This requires a culture change in the country’s accident and emergency departments to recognise that ligament sprains can be more disabling injuries than fractures.

The decreased popularity of the Ottawa rules in the United States and mainland Europe could also possibly be explained by the use of stress radiography, etc, in patients with ankle sprains.

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Authors’ reply

Editor—Fogarty points out a problematic aspect in the interpretation of the palpation items used in the Ottawa ankle rules (and other rules that use information from clinical examination). We agree that an imprecise description of the exact palpation procedure may lead to inconsistencies in the application of the rule.

We doubt, however, that asking the patient whether the palpation hurts leads to an invariably higher positive response compared with silent palpation and simple observation for a non-verbal response. We imagine the reverse being the case since “tough guys,” in particular, may express pain but deny it on being asked.


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Competing interests: None declared.


Evaluating and managing chronic dysphagia

Dysphagia should prompt urgent gastroenterological referral

Editor—Leslie et al reviewed the investigation and management of chronic dysphagia well from an endoscopic and thoracic standpoint,1 but we think that an article directed at a general readership should have emphasised gastroenterological causes more. From a gastrointestinal perspective, dysphagia is an alarm symptom that should prompt urgent referral to exclude cancer.

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Ottawa ankle rules

Sign may not be objective

Editor—In their paper on the accuracy of the Ottawa ankle rules, Bachmann et al consider the wide variation in specificity, citing subtlety of palpation technique as a possible contributing factor.2

They are correct. If you palpate an ankle, or anything else for that matter, and ask the patient, “Is that sore?” you will invariably get a much higher positive response rate than if you palpate silently and simply observe for a non-verbal response.

The moment you rely on a patient to “give you” your clinical sign you are no longer dealing with an objective sign, such as an enlarged liver or a heart murmur. Instead you are dealing with an extension of symptoms, with all the subjectivity that this entails. It is no wonder then that studies that rely on the estimation of bony tenderness are frequently associated with wide variations in specificity.

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Competing interests: None declared.


Government directives have led to the two week wait scheme. The quoted Department of Health figures record 23 000 diagnoses of dysphagia in 2001-2 and 253 oesophageal perforations (all causes). This implies a maximum rate of 0.05%. This makes flexible endoscopy—encompassing mucosal resection, ablation, and dilatation—we have had only three perforations in over 1000 procedures. Upper gastrointestinal endoscopy is a safe and accurate method of investigating oesophageal dysphagia.

Lewis et al discuss the oesophageal conditions that give rise to dysphagia, including cancer, achalasia, and reflex disease, but they do not mention other diseases such as external compression and eosinophilic oesophagitis. Eosinophilic oesophagitis is identified only histologically in oesophageal biopsies which are found to have a high density of eosinophils. We therefore strongly encourage oesophageal biopsy of all patients with dysphagia.

This article gives a good overview of dysphagia from an otorlaryngology perspective, focusing on patients with cricopharyngeal dysphagia. It omits several important oesophageal conditions giving rise to dysphagia, and, although it promotes a multidisciplinary approach, it is lacking in encompassing the investigation and management skills and opinions of other specialties, especially gastroenterology.

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Competing interests: None declared.

Cover up and stay out of sun to prevent skin cancer

Editor—Messages to prevent skin cancer should emphasis the need to cover up and stay out of the sun. They should also emphasise the biology of the condition.

The message that those chosen by Darwinian natural selection to live in Australia have black skins, which protect them against skin cancer, and those chosen by Darwinian natural selection to live in Europe have no such protection when living in Australia, is not commonly given, probably because it would be unpopular. However, it could be a most effective educational tool.

The skin of northern Europeans distributed throughout continents for which it was not chosen by natural selection may not be effectively protected unless fully protected by clothing, the equivalent of black skin.

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Competing interests: None declared.

Text messaging raises medicolegal issues

Editor—Pal’s personal view on communicating with patients by mobile phone text messaging is a novel insight into how doctors are exploiting new technology to benefit patients. It also raises some interesting medicolegal issues.

The Medical Defence Union has received several calls on its medicolegal advice line from members who believe that they can provide a more efficient service to patients by communicating via text messaging and email but have concerns about the legal and ethical considerations.

Our advice is that there is no reason why doctors should not harness new technology to improve care for patients, but that they need to reassure themselves and their patients that the benefits to patients from using text messaging outweigh the drawbacks. They will need to have a system to record the messages themselves, the date and time sent and received, and any action taken. Doctors will also have to take reasonable steps to ensure the proper functioning and maintenance of the mobile phone. Possibly most important of all, they must agree on the vocabulary used to minimise the risk of patients’ misreading or misunderstanding the message.

It is also worth remembering that, with text messaging you may know to whom you are sending a message but you may not know for sure where the message you receive comes from. It is encouraging to see that Pal uses a system of code words and other security features to protect patients’ confidentiality. We advise doctors who are considering communicating in this way to bear in mind the need to ensure confidentiality of patient information.

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Gastroenterological input should have been included

Editor—The clinical review article by Leslie et al on chronic dysphagia gives a clear and succinct overview of managing dysphagia in a multidisciplinary team, specialising in cricopharyngeal dysfunction and oesophageal dysphagia. We advocate strongly the use of a multidisciplinary team in investigating and managing patients with chronic dysphagia, but Lewis et al make little mention of a gastroenterological input. This is a notable omission as a large proportion of dysphagia is related to primary oesophageal or gastrointestinal disease.

Management and investigation of dysphagia are not portrayed adequately. The investigation of choice for dysphagia by gastroenterologists or upper gastrointestinal surgeons is flexible endoscopy. This enables accurate visualisation of abnormalities allowing options for biopsy, histological examination, and therapeutic intervention.

The authors quote a 2.6% perforation rate for endoscopy. This is a dramatic overestimation of current clinical practice. We have had no perforations from 3500 diagnostic endoscopies. During therapeutic endoscopy—encompassing mucosal resection, ablation, and dilatation—we have had only three perforations in over 1000 procedures. Upper gastrointestinal endoscopy is a safe and accurate method of investigating oesophageal dysphagia.

Lewis et al discuss the oesophageal conditions that give rise to dysphagia, including cancer, achalasia, and reflux disease, but they do not mention other diseases such as external compression and eosinophilic oesophagitis. Eosinophilic oesophagitis is identified only histologically in oesophageal biopsies which are found to have a high density of eosinophils. We therefore strongly encourage oesophageal biopsy of all patients with dysphagia.

This article gives a good overview of dysphagia from an otorlaryngology perspective, focusing on patients with cricopharyngeal dysphagia. It omits several important oesophageal conditions giving rise to dysphagia, and, although it promotes a multidisciplinary approach, it is lacking in encompassing the investigation and management skills and opinions of other specialties, especially gastroenterology.

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