12 Outcomes, Documentation, Quality and Training

Outcomes

Adverse outcomes (complications) have been discussed in general in Chapter 3, and in relation to specific procedures in relevant chapters. We pointed out the importance of careful definition and objective assessment. The same provisos are equally important when attempting to assess the 'success' of our procedures. These are the tools of 'outcomes research', which has recently become more fashionable.

Whether a procedure succeeds or fails can be judged only if the intent is stated clearly beforehand. Our traditional list of *indications* are essentially symptoms or brief clinical scenarios, e.g. haematemesis, post-cholecystectomy pain, jaundice or heartburn. We know that endoscopy may be helpful in these circumstances, but cannot use such terms to define success or failure. In the acutely bleeding patient, we may or may not find a bleeding lesion, and may or may not attempt (or succeed) to treat it effectively. End-points need to be defined more carefully. One method, which lends itself to computer documentation and analysis, is to define the elements of the clinical situation separately. We document the presence or absence of a series of clinical *facts*, i.e. symptoms, prior established diagnoses, prior interventions, aetiological factors, risk factors for malignancy and test results. In that context, we define whether the aim of the endoscopy is: (i) to make (or clarify) a diagnosis; (ii) to check on the progress of a known disease (or the results of recent treatment); or (iii) to provide treatment. Complexity is added by the realization that a single endoscopic procedure may be both diagnostic and therapeutic — or only therapeutic if a diagnosis is made. In a patient with haematemesis, our goal will usually be to make a diagnosis, and to apply therapy if this is technically appropriate and feasible.

There is plenty of room for wishful thinking if we do not define our objective precisely and up-front. Even if we do so, defining a 'success rate' is complex, for this depends on many factors, including (hopefully) the expertise of the endoscopist. The *quality* of the indication is also important, and varies across groups of patients and certainly between reported series. For example, a referral centre may expect to have more 'difficult' cases e.g. a larger proportion of difficult stones or patients with Billroth II gastrectomy for ERCP. Definitions of success also depend on the audience. Endoscopists tend to be preoccupied with *technical* success rates (and complications). As clinicians we

should define success as a procedure which is *more effective* than other available alternatives (as judged by carefully controlled research studies). However, there are other arbiters of success, not least the patient. Herein lies the importance of attempting to assess the effect of an intervention on the patient as a whole, which has led to the development of *quality of life indices*. Another measure of success is *value*, or *cost-benefit*. For those who pay the bills, this may appear to be the most important criterion.

One other problem is the *timescale* of outcome measurement, particularly in relation to therapeutic procedures. Stenting for malignant biliary obstruction looks very good during the first few weeks (e.g. compared with surgery), but the advantages diminish as time passes (and stents clog).

These complexities and others emphasize the importance of using established scientific methods in trying to evaluate our procedures.

Documentation

The importance of careful documentation should be self-evident. There should be a 'paper trail' for any patient undergoing endoscopy which covers the whole process from initial referral (on paper or via the telephone), pre-procedure preparation, examination and checklists, the endoscopy report, the nurses' procedure report, documentation of the recovery phase and discharge, and of the final disposition, advice and follow-up recommendations. The trail should also encompass 'delayed' information such as pathology reports and complication data.

Like many other aspects of endoscopy, the degree to which these aspects of documentation are standardized and regulated varies enormously. In some healthcare systems, payment is dependent upon specific documentation criteria — which is a powerful stimulus to compliance. But proper documentation is nothing more than an illustration of quality care. It is certainly excellent defence against speculative lawsuits. The lawyers tell us 'if it is not written down, it was not done'.

Quantity is not the same as *quality*. Some endoscopy reports are so verbose that it is also almost impossible to find the few crucial pieces of clinical information. Thus, structuring of the data is important.

In most institutions the 'paper trail' is still indeed a trail of paper. It will be a series of sheets, including freehand writing, checklists (e.g. for risk factors), printed forms (e.g. consent forms) and typed procedure reports and recommendations. Paper records are inefficient, usually in the wrong place and easily lost. It is certainly time to leap from the notepad to the keypad. Desktop (and handheld) computers provide an excellent medium for this documentation. With appropriate network-

ing, all of the information can be available to anyone who wishes to see it it at numerous sites — including at home or a distant office. Endoscopy reports can be faxed directly without going through a paper report, or transmitted electronically to another location (Fig. 12.1).

We have been particularly interested in computer databases for almost 20 years. The equipment is no longer a problem. The power of desk and laptop instruments is now sufficient to deal with all of our data (and images). The problem has been to define the content and structure of endoscopy-related databases and, in particular, to agree on some standards for content and terminology.

The efforts of many individuals and some national endoscopy societies has resulted in a document entitled *Minimum Common Terminology*, recently published jointly by the European, US and Japanese endoscopy societies. This is essentially a method for describing what we may see or do. Version 1.0 is not perfect, but it is a good start.

Commercial endoscopy databases are in evolution; several function effectively already. One practical question is whether the data are entered by secretarial staff alone, or also by nursing and medical staff (directly or via printed checklists). In our units, the patient details and administrative data are entered by a secretary/receptionist; doctors then enter all the medical data, which immediately generates reports for the medical record and referring doctors. A goal is to have each data entry take no longer than dictating a report. However, dictation is only part of the doctor's work if computers are not used; there are delays involved in correcting and signing typed documents. With a little practice and suitable programs, all of the data can be entered in 3–5 min.

There are many advantages of computer databases over other forms of record-keeping. The structure can be defined carefully, with safeguards so that key questions must be answered before the program will proceed or the report record is complete. Only appropriate answers are accepted, and irrelevant keys made non-operative. It is easy to produce and modify automatically word-processed forms, listings and reports — although most systems do allow some free text sections so that the format is not restrictive. Computers can deal with large amounts of data for analysis, but can also be individualized so that relevant points (e.g. drug sensitivities, previous technical problems, sedation requirements) for particular patients are automatically presented for any subsequent visit. Multi-user operation or a network system means that several screens can work simultaneously, and all of the data are instantly available (or can be entered) in different places (e.g. reception/secretary/endoscopy room) without the problems of physical transfer of paper. Computer management is virtually indispensable for any unit offer-

GASTROENTEROLOGY

ERCP REPORT (10/10/__)

Name : Mrs Smith
MRN : 890856
DOB : 04/08/45 Age : 51 yrs
SEX : Female
Attending MD: R. Jones

Mrs Smith presented with pain and jaundice, with a diagnosis of GB stone/disease (574.2).

Prior treatment: No relevant surgery; no endoscopic therapy.

Health status: Mild problem (ASA II). Co-morbidities were not noted. Risk factors for endoscopy were not identified.

Recent diagnostic studies: US scan (abnormal).

Laboratory results: Haematocrit normal, platelets normal, WBC normal, PTT normal, prothrombin ratio normal, albumen normal, AST normal, ALT normal, alkaline phosphatase 196, bilirubin normal, amylase normal, lipase normal.
Results in attacks: LFTs abnormal, amylase normal, lipase normal.

Indication: To clarify diagnosis and to treat. Cholecystectomy is planned.

Procedure: Endoscopy was performed in the X-ray dept as an inpatient/consult, on an urgent (on schedule) basis by Dr. Jones, assisted by Dr. Brown, after fully informed consent was obtained. The patient was sedated and was given prophylactic antibiotics; vital signs and oxygenation were carefully monitored (for details see nurses' report). The procedure started at 15:02 and lasted 31 minutes. It was very well tolerated, and views were excellent.

Radiological findings

Oesophagus : normal
Stomach : normal
Pylorus : normal
Duodenal bulb : normal
Post bulbar : normal
Main papilla : normal
Minor papilla : not sought

Endoscopic survey

Bile duct : Stone (common duct)
distal duct size was 7mm, drainage was not checked
there was 1 stone, max diameter 5mm
Gall bladder : did not fill
Pancreatic : main orifice filled; minor orifice not attempted
Duct : normal

Special diagnostic techniques: Biopsies were not taken; cytology was not taken; cultures were not taken.

Endoscopic treatments: Biliary stone extraction was performed with success. (43264) Stones were removed by basket. Balloon dilator to 8mm.

Complications: None immediate.

Comments: PT WITH KNOWN STONE DISEASE, EPISODIC BILIARY PAIN, ADMIT FROM SURGERY CLINIC WITH JAUNDICE, NO F/C/S. SINGLE STONE REMOVED, UNABLE TO FILL CYSTIC DUCT. REC. CHOLECYSTECTOMY AS SOON AS POSSIBLE.

Diagnosis after Endoscopy: GB stone/disease (574.2).

Follow-up plan: Clinic review within one month.

Signed .....

report to attending MD, patient file. (printed: 10/11/__)
Copy to Dr. Local (fax: 904 8763)

Fig. 12.1 Computer-generated endoscopy report.

ing proper follow-up and surveillance services, not only because of the need to spot non-attenders and follow correct schedules, but because the sheer volume of correspondence becomes overwhelming without the ability to print batches of letters automatically, correctly addressed and dated.

With these advantages come some constraints—the need for immediate technical help, regular data backup and a fool-proof security system.

Image documentation

Photographic slides and cine and video recording have been part of endoscopy since its beginning. These records were mainly used for teaching, and their physical mass often defied attempts at efficient storage and retrieval.

The fact that all of our information is now digital opens wonderful new possibilities. Colour prints can be produced immediately at the touch of a button for inclusion in the patient record and report. We are rapidly moving towards comprehensive 'image management' so that vast amounts of image data can be captured, stored and retrieved electronically. Automatic storage of full motion videos will follow.

Digital storage opens up the possibility of image analysis and enhancement (possibly for enhanced diagnosis), and also *image transmission*. This allows the sharing of images (and related data) at distant sites through telephone lines. Endoscopy (and its related images from radiology and histology) lends itself to 'telemedicine'. We can already supervise and advise our trainees from a distance (through TV links) in our units. Soon we will be giving advice and teleconsultations across the country on a routine basis.

Data analysis

Computerization of data collection and storage provides tremendous opportunities for analysing our activities (Figs 12.2 and 12.3). Essentially these are of two types: housekeeping and research.

1 *Housekeeping* means keeping track of who is doing what and why (including costs). We can monitor patients who need to come back, e.g. for stent exchange or polyp follow-up. With appropriate input, this becomes an important management tool, e.g. providing data about procedure room and equipment usage, turn-around times and staff requirements.

2 *Research* is enormously enhanced by computerization. Provided the right questions are asked prospectively, we can look at important correlations and outcomes. Standardization of databases will allow sharing of data from multiple institutions.

Run date: 11/03/96 | Statistics of procedures with Exam date 01/01/96 – 30/06/96
Run time: 14:20:08
Run by: | Doctor:

	Diag-nostic	Thera-peutic	Sub-total	Rel. value	Emergency		Public	Out-patient	In-patient	
					In hr	Out hr			GI	Consult
UPPER	372	141	513	654	74	37	92	273	109	131
COLON	189	75	264	603	32	14	35	147	48	69
FLEX	128	15	143	79	8	3	13	99	20	24
ERCP	98	257	355	1,836	39	14	45	200	103	52
TOTAL	787	488	1,275	3,172	153	68	185	719	280	276

Fig. 12.2 Computer-generated report of endoscopy activities.

Quality improvement

Knowing accurately what we are doing (using housekeeping data) is the essential basis for improvement. We measure the process, institute new policies and measure the result. 'Quality assurance' or 'audit' used to be presented or at least perceived in a negative light: somebody was checking up on us, expecting to find deficiencies or complications. 'Quality (or process) improvement' gives this context a positive spin, which is attractive to most doctors. Essentially it is a way of helping us to do a better job—and of documenting the process.

Training

Flexible endoscopy is a manual technique like driving a car or playing a musical instrument; some people learn more quickly than others and some may never become particularly adept. Practice is essential, but it helps if correct habits are instilled at an early stage. Because patients are involved, some form of apprenticeship is essential, with an experienced endoscopist overseeing the early examinations during which patients (and instruments) are at risk. As well as performing endoscopies under supervision, a trainee should make use of available written, slide or video material, practice under supervision on teaching models, attend teaching courses and see several different endoscopy centres. All of these methods have their advantages.

It should be emphasized that—like driving a car or playing a musical instrument—the technical aspects of the procedures are not an end in themselves, merely a way of getting somewhere or making good music. Thus, learning endoscopy should be inte-

Run date: 03/11/95
Run time: 14:24:46
Run by:

Summary of ERCP procedures with follow-up due date between 01/01/95 – 30/06/95
Endo attending:
Follow up plan: stent removal/exchange

Exam date	MRN/Full Name	Endo doctor(s)	Endoscopic treatments	Final diagnosis	Follow up: Plan by	Follow up: Realized
06/10/95	891294		Biliary sphincterotomy Pancreatic stent insertion	Papillary stenosis/spasm Pancreatitis	06/11/95	11/10/95
11/10/95	892359		Minor papilla sphincterotomy Minor papilla orifice dilation Minor papilla stent insertion	Pancreas divisum Pancreatitis	11/11/95	
14/7/95	022149743		Biliary sphincterotomy Biliary stricture dilation Biliary stent insertion	? Biliary cancer (hilar)	14/11/95	
15/09/95	876131		Pancreatic sphincterotomy Pancreatic stricture dilation Pancreatic stent insertion	Pancreatitis/stone Pancreatic leak	15/11/95	
25/10/95	893162		Biliary sphincterotomy Pancreatic stent insertion	Papillary stenosis/spasm GB stone/disease	25/11/95	27/10/95
30/08/95	091284		Biliary sphincterotomy Biliary stent insertion	Pancreatitis Biliary other	30/11/95	
30/10/95	868668		Pancreatic sphincterotomy Pancreatic stent insertion	GB stone/disease Pancreatitis Papillary stenosis/spasm	30/11/95	
10/06/95	887061		Pancreatic stricture dilation Pancreatic stent insertion	Pancreatitis Pancreatitis/stone ? Biliary other	06/12/95	
09/10/95	352574		Biliary stent extraction Biliary stent extraction Biliary stent insertion	Pancreatitis/stone Biliary other	09/12/95	
08/10/95	807092		Biliary stent extraction Biliary stent insertion Biliary stone extraction	Bile duct stone(s) Dilated bile duct ?cause	10/12/95	
13/10/95	890902		Minor papilla stent insertion Minor papilla orifice dilation	Pancreas divisum Pancreatitis/stone	13/12/95	
13/10/95	863907		Biliary sphincterotomy Pancreatic sphincterotomy Pancreatic stone extraction	Pancreatitis/stone Papillary stenosis/spasm	13/12/95	27/10/95
16/08/95	882718		Biliary sphincterotomy Pancreatic stent insertion	Pacreatitis Papillary stenosis/spasm	16/12/95	
18/08/95	854491		Pancreatic sphincterotomy Pancreatic stent insertion	Pancreatitis/stone	18/12/95	

Total number of procedures:

Fig. 12.3 Computer-generated report for follow-up of ERCP stents.

grated into training in gastroenterology, with full appreciation of its clinical application (indications, risks and alternatives).

Apprenticeship

Watching an expert is useful, providing that the expert actively explains what he is doing and seeing. In countries where endoscopy is a well-established speciality with numerous staff, trainees may be expected to watch many procedures on video monitors before going 'hands-on'. In other places, the beginner may be thrown in at the deep end. He finds himself being asked to use an expensive instrument he does not understand in an organ with unfamiliar anatomy, and gets a poor view of appearances he cannot interpret. One answer is to 'phase' trainee introduction to a set period (e.g. 5–10 min) or a defined part of the examination (e.g. insertion to the cardia or the proximal sigmoid colon), with the extent of examination and responsibility being gradually lengthened. The trainee can be entrusted with some of the routine duties in the endoscopy room, helping the nurses and learning correct techniques in handling and cleaning the endoscopes. An old or broken instrument available in partly stripped-down form can help to demonstrate the complexity of the equipment and the need to treat it with respect.

The teacher needs considerable patience and the ability to adapt to the different physical and personality traits of different pupils. Some need calming down, to learn to be more cerebral and more humane in their actions; others need to be speeded up to become gradually more positive and fluent. Generally speaking, a slow, thoughtful endoscopist with integrity can learn to excel, whereas the aggressive and erratic often remain so.

Endoscopic technique builds up by learning to combine visual interpretation with the correct mechanical response. Attention to the detail of finger movements, shaft twist and even body position are all important. The teacher may need, for instance, to hold his own hand over that of the trainee on the shaft of the instrument to demonstrate the requisite amounts of to-and-fro or twisting movements, or to check that when the pupil intends to angle either up or down he is actually moving the control knob in the correct direction first time. Regrettably, there are too few experienced endoscopists combining the necessary skills themselves with the amount of time and interest required to teach successfully.

There is a range of teaching material which can be used between endoscopic sessions. A collection of books, atlases and selected reprints can be assembled with little effort. Teaching video tapes and education slide tapes liven up the topic and help to show that there are different approaches to endoscopy. Home-made slide–tape sequences are also not difficult to produce and help the teacher to avoid tedious repetition. National endoscopic

societies can ensure availability of teaching material (e.g. the American Society for Gastrointestinal Endoscopy (ASGE) Teaching Library).

Models and simulators

No model can simulate exactly the varying and variable anatomy of the human gastrointestinal (GI) tract, especially its combination of elasticity and contractility. None the less, half an hour spent working on a stomach or colon model under expert guidance, followed by some practice alone, is very helpful in understanding spatial relationships and co-ordinating the view down the endoscope with the correct movements of the controls. It is easy to see, explain and practice on a model how to perform retroversion at the cardia, why the pylorus must be correctly positioned with a side-viewer, why upwards angling approximates to the papilla, or why clockwise rotation undoes an alpha loop. Once seen and understood, these things are never forgotten and with the opportunity to practice them repeatedly without involving a patient, the trainee develops self-confidence and better understanding of correct instrument handling.

A newer approach, not yet either fully developed or evaluated, is the use of electronic endoscopy simulators. The severe constraints of the limited budgets available for medical teaching mean that the sophisticated but enormously expensive simulators available to train pilots in aviation are regrettably not applicable to endoscopy. The prototypes available currently for endoscopy teaching make use either of video-disc technology to show actual endoscopic images or computer-graphic techniques to produce a cruder image simulated mathematically in real time. The trainee handles a dummy endoscope, the steering controls, shaft movements and air/water/suction buttons which are converted by transducers and switches into electrical outputs so as to modify the image display according to the handling of the instrument. The computer, in addition to controlling the image, will produce screen prompts and a 'score' to give interactive teaching without the presence of an expert teacher, and can also evaluate the progress of the trainee in different simulated circumstances on an objective basis without patient trauma or danger of instrument damage.

Certification of competence

Professional organizations in many countries have struggled with the need to certify when endoscopists are competent. This is an issue with complex ramifications, and it is pertinent sometimes to remember that most specialities (including surgery) do not certify competence specifically by procedure. In addition,

certification is only meaningful if there is any disadvantage in not being certified.

Both the UK and US national organizations with which we are familiar have discussed these issues repeatedly. The perspectives are different. In the UK, the relative lack of medical staff means that most trainees gain a lot of experience, but often with relatively little supervision. The British Society of Gastroenterology (BSG) is setting up a mechanism for certifying trainees in four different groups of techniques: diagnostic upper GI endoscopy, therapeutic upper GI endoscopy, colonoscopy and ERCP. Certification will be done by accredited trainers, who have to prove their own competence and the adequacy of their facilities. In the USA, fellows may do less procedures, but the much shorter period of training and both medicolegal and financial concerns mean they are fully supervised. They keep a log book of all endoscopies, and expect to be certified as competent at the end of the training (now 3 years). This is the responsibility of a designated 'endoscopy training director'. It is not one to be undertaken lightly, for heads of gastroenterology and endoscopy departments have actually been held partly responsible for complications of procedures performed by people they have certified to be competent. The ASGE has published 'threshold' numbers, below which it is judged unlikely that any endoscopist will be fully competent in any particular procedure. The training director is expected to make an informed judgement once these threshold numbers have been achieved, and to advise trainees when (and what) further instruction is required. It is self-evident that learning should be a life-long process, and that competence is a relative term. Defining minimal or threshold numbers is controversial, and requires a compromise between reality and idealism. There has been a tendency for professional societies to agree on the lowest common denominator. This tendency should be resisted; it is our responsibility to define appropriate training and to insist that guidelines are followed. We also have the responsibility to provide that training, which can be time-consuming and frustrating.

In practice, the crucial question is whether the particular hospital (or healthcare system) to which attachment is sought will award 'privileges' for performing these procedures. The issues here become even more complex, since they involve not only the question of competence but also the perceived needs of the community and also of the established specialists.

Levels of training

It must be recognized that not all trainees can expect to become competent in all of the GI procedures. Furthermore, at least in the USA, the number of specialists within a single community may be such as to dilute the work load for any individual below

the threshold for continuing competence. It is therefore logical to consider different levels of endoscopic training. Most clinical gastroenterologists will be trained in upper endoscopy and colonoscopy with their standard therapeutic applications (polypectomy, sclerotherapy and endoscopic haemestasis). This level can be called *standard* training. Some family practitioners may wish to be trained only in flexible sigmoidoscopy; some surgeons and research gastroenterologists may need only to perform diagnostic upper GI endoscopy and flexible sigmoidoscopy. A small proportion of trainees will go on after standard to *advanced* training in more specialized (rarer and more dangerous) procedures, including ERCP and its therapeutic applications, laser therapy, laparoscopy, etc. Restricting advanced techniques to a selected group of trainees is not universally popular, since many wish to keep their options open. However, such selection is inevitable if quality is to be maintained and if we are to produce experienced trainers for the next generation. Another emphasis is that (with rare exceptions at the basic level) no one should be taught diagnostic procedures without learning the therapeutic applications. It is illogical to do a colonoscopy without being able to perform polypectomy, and equally so (as well as potentially hazardous) to undertake ERCP in a patient with jaundice without the skills to provide drainage. It follows that these endoscopic trainees will spend additional time in attaining competence—whilst their colleagues may obtain specialized training in other directions, such as clinical or laboratory research.

Endoscopy is a valuable tool; it is worth doing well.

Further reading

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