

Reader Extender of Capsule Endoscopy

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Capsule endoscopy has been a major advance in gastrointestinal imaging. The evidence of its clinical utility has led to an exponential growth in clinical application, and demand for new services is high. Image review and interpretation is time consuming, and finding the additional resource to develop these services is difficult for the physician with a high workload. Physicians are now looking to increase capacity by training nurses to support capsule endoscopy reading. A new role of capsule reader extender is emerging; however, there is a lack of clarity on role definition, scope of practice, and medico-legal issues. Early indications from a small number of studies suggest that, at a basic reading level, nurses can safely detect significant pathology, without compromising diagnostic accuracy. Prescreening of capsule videos can significantly reduce the physician viewing time. Through a reallocation of resources, health care costs may be reduced and capacity increased. This article reviews the current evidence base on the effectiveness of capsule reader extenders, describes a framework for the development of practice, and explores the role in the context of service delivery models.

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Since its introduction, the clinical application of capsule endoscopy has continued to expand rapidly, which is reflected in a steady growth in global uptake. Services are now widely available throughout the world, and as of July 2006, more than 340,000 capsules have been swallowed worldwide.¹ Although this constitutes a major diagnostic advance in gastrointestinal imaging, the integration of a resource-intensive service into practice is indeed a challenge for the gastroenterologist working in a high-volume speciality, already trying to balance competing demands against finite resources.

In the UK, British gastroenterologists have attempted to reach an equilibrium by embracing the concept of “new ways of working,” a concept that is central to current British health policy.^{2,3} In addition, political pressure to reshape and modernize gastroenterology services has resulted in significant expansion of the roles of non-medical personnel, particularly the nursing role.^{4,5} Role expansion requires nurses to be dynamic and responsive to changing health needs, new knowledge, and technological advancement.⁶ At the forefront of gastrointestinal technological advancement, capsule endoscopy is a revolution that is challenging the future of clinical imaging. Nurses have already responded to this challenge in a number of ways: working with physicians to support the development of new capsule endoscopy services,⁷ as well as

fulfilling the conventional nursing role of delivering patient care throughout the procedure. However, the nursing contribution to capsule endoscopy is changing and a new role of non-physician reader extender is evolving.

Drivers for Change

The drivers for this development lie primarily with resource restrictions. Capsule endoscopy image review and interpretation is time consuming and hence costly. The mean time to review images is high, ranging from 60 to 120 minutes per patient.⁸ Finding the time to do this can be difficult for physicians with a high workload. The problem is compounded further by the growing interest in other small bowel endoscopic developments, such as double balloon enteroscopy. This is also time intensive, but the two are inextricably linked, and some physicians with an interest in the small bowel are keen to undertake both procedures.

With the increasing burden of gastrointestinal disease, the demand for these new procedures is rising.⁵ However, the finite resource availability means there is a risk of limited access to services, diagnostic bottlenecks, and ensuing delays in treatment. In Britain, with new medical working time restrictions placing further strain on physician capacity,⁹ many physicians are looking to absorb the volume by training nurses to provide support with capsule endoscopy reading. As with conventional endoscopy performed by nurses, this development gives rise to a number of questions regarding competency, diagnostic accuracy, and clinical safety. Despite

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Table 1 Diagnostic Accuracy of Nurse Reader Extenders

Author/Year	No. of Videos	Comparators	Training	End Point	Interobserver Agreement
Levinthal, 2003 ¹⁹	20	EN Dr (CE experienced)	15 training videos	Quality of exam	93% sensitivity of nurse: Significant lesions
Niv, 2005 ²⁰	50	GN Dr (CE expert)	15 training videos	1. Quality of exam 2. Cost	97% sensitivity of nurse: Significant lesions
Bossa, 2006 ⁸	39	EN Dr (no CE experience)	5 day course Both trained	1. Quality of exam 2. Cost	Overall agreement $k > 0.85$ Negative studies $k = 1$
Fernandez-Urién Sainz, 2005 ²²	20	EN, CE resident Dr (CE experienced)	Not known	Quality of exam	Significant lesions $k = 1$
Ponferrada, Abstr 2005 ²³	32	EN Dr	Not known	Quality of exam	Significant lesions $k = 0.93$
Kar, Abstr 2005 ²⁴	50	EN Dr (CE experienced)	None	Quality of exam	No significant difference: Relevant or uncertain lesions
Schofield, Abstr 2005 ⁷	20	NP Dr	Not known	1. Quality of exam 2. Diagnosis	Reporting differences Total agreement of diagnosis

Abbreviations: EN, endoscopy nurse; GN, gastroenterology nurse; NP, nurse practitioner.

the obvious technical differences, capsule image reading is comparable with conventional endoscopy, and it is from extensive experience of non-physician endoscopy that some assertions may be drawn.

Experience from Non-Physician Conventional Endoscopy

The ability of nurses and other professional groups, such as radiographers, to safely undertake a range of diagnostic endoscopic procedures has been extensively reported in the last 30 years.¹⁰⁻¹⁵ Early pioneering of the nurse endoscopist role in the US to provide colorectal cancer screening by flexible sigmoidoscopy has been largely superseded by screening colonoscopy performed by physicians. In contrast, there has been rapid acceleration in numbers of British nurse endoscopists, providing a range of upper and lower diagnostic and therapeutic procedures, including colonoscopy and endoscopic ultrasound.¹⁵ Nurse endoscopists are now widely accepted as highly competent and safe independent practitioners.^{15,16} This has been confirmed in a recent UK multicenter, randomized, controlled trial comparing the clinical effectiveness of doctors and nurses.^{16,17} Data from 23 centers and 1888 patients demonstrated no difference in clinical effectiveness between medical and nurse endoscopists, and in EGD examination, nurses were found to be more thorough.

Given these observations, it would be reasonable to suggest that the core diagnostic skills required for endoscopic practice are transferable to wireless imaging. Capsule endoscopy is a new field of endoscopy, but it is endoscopy nevertheless.¹⁸ However, the modality differences, particularly the level of operator dependence, may influence diagnostic accuracy. The absence of a "look back" option, insufflation, and multiangle viewing are limiting in the capsule assessment of pathology. Interpretation may rely solely on a single image, potentially increasing the risk of missed lesions. Study criteria for determining the clinical significance of lesions has also been variable. In considering factors that are unique to wireless

imaging, the effectiveness and diagnostic accuracy of the capsule reader extender need to be examined as a discrete entity.

Effectiveness of Reader Extenders

The current evidence base is sparse, with only three small peer-reviewed studies (Table 1),^{8,19,20} one published commentary,²¹ and four abstracts presented at international meetings in 2005.²²⁻²⁵ With a common endpoint of examination quality, all three published studies aimed to examine the accuracy of a nurse in detecting abnormal small bowel images compared against the findings of a physician.^{8,19,20} Niv and Bossa also evaluated the cost benefits of reducing physician reading time by reviewing only the images preselected by the reader extender.

The nurses in all series were experienced in either endoscopy or gastroenterology and were formally trained with review of 10 to 15 capsule videos in advance of the study. The capsule experience of the physician comparators varied, with 2 studies comparing the findings against experienced physicians^{19,20} and 1 against a CE physician with no previous experience of capsule endoscopy.⁸

A high level of interrater agreement was observed in all three studies. Levinthal and Niv reported 93% to 97% sensitivity of the nurse in detecting clinically significant lesions.^{19,20} In the Bossa series, agreement was excellent ($k > 0.85$) for all lesions, and complete ($k = 1$) for active bleeding, stenosis, and negative examinations.⁸ Similar results were reported in the four abstracts,²²⁻²⁵ consistently demonstrating a high level of nurse/physician agreement in the identification of significant lesions (Table 1).

Although not yet peer reviewed, 2 of these abstracts raise points of interest. A small British study went beyond preliminary reporting and looked at the ability of the nurse to interpret the abnormal images and provide a final diagnosis.²⁵ Although there were reporting differences, total agreement in diagnosis was achieved. The second abstract of interest differs from other studies in that the nurse received no training

in capsule reading before reviewing 50 capsule studies.²⁴ The nurse identified all relevant or uncertain lesions. Cautious reporting of uncertain or minor lesions by nurses is a consistent theme in the published literature. In all studies, the nurses were found to overreport minor lesions of no clinical significance. Although more time consuming, this cautious approach is a useful risk reduction strategy for reader extenders.

Missed Lesion Rate

The assessment of risk of missing lesions with clinical significance is crucial in the evaluation of diagnostic accuracy. Levinthal reported that 2/27 significant lesions seen by the physician were missed by the nurse.¹⁹ The 2 lesions were small angioectasia seen in 1 image (with other angioectasias detected), and a subtle small bowel erosion that did not alter clinical management. However, significant lesions (3/28 seen by the nurse) were missed by the physician. Missed lesions by both comparators were also reported by Niv.²⁰ The nurse missed 3/96 significant lesions: suspected short Barrett's esophagus, and 2 flat mucosal lesions. Four were missed by the physician: gastric clot, suspected short Barratts, ileal aphthous lesion, and ileal polyp. No significant lesions were missed by the nurse in the Bossa study.⁸ Among conventional endoscopists, it is accepted that some lesions will be missed, regardless of the discipline of the endoscopist. Previous trials have shown that the nurse endoscopist miss rate is no different from the physician's, with up to 20% polyp miss rate for both doctors and nurses performing screening flexible sigmoidoscopy.²⁶

Defining the Reader Extender

An agreed definition of the non-physician reader extender does not yet exist. Development of the role has been ad hoc, with no defined criteria on who the reader should be, how they should be trained, and to what level of competence. Reader extenders have so far emerged from the nursing workforce, with a variety of clinical backgrounds and depth of experience, ranging from endoscopy unit staff nurses to more advanced practitioner grades.^{8,19,20,22-25} Although there have been no reports of capsule reader extenders outside of nursing, there are a number of existing physician extender groups to whom this role extension would be well suited. The use of physician assistants is a logical progression, and the precedent has already been set within diagnostic imaging in the US. Physician assistants have already been successfully trained to perform flexible sigmoidoscopy¹¹ and have a well-established function in radiology.²⁷ In the UK, the National Health Service is currently creating a similar role to increase workforce capacity, the Medical Care Practitioner (MCP).²⁸ With a diagnostic component to the role, an MCP reader extender in capsule endoscopy may be a future alternative. Another option in the UK which is more specific to the endoscopy setting may soon be available. Following the success of a British pilot program to train non-health professionals as graduate endoscopists, a novel Endoscopy Technician role is also being developed with consultation on statutory regulation currently in progress.²⁹

Based on the limited evidence available, early indications

suggest that nurses with different experience can reach a similar level of diagnostic accuracy in the detection of abnormal capsule images.^{8,19,20,22-25} The diagnostic skills of the nurse readers studied were at the most basic level, which enabled them to preview capsule studies and demarcate the areas of suspected pathology for further assessment by the physician. If the nurse reader is required to diagnose and interpret at a higher level, then the entry grade, knowledge, and previous experience of the nurse become more relevant. To define a higher level of practice for the reader extender, there is a need for a model that provides a skill-based framework for the development of practice.

A Framework for Practice Development

In practice, there are four levels of skill and competency that a reader extender may reach (Fig. 1). At its simplest level, the development of technical and basic cognitive skills enable the reader to preview and edit the images, identify any abnormalities, and create nondescriptive thumbnails for physician review. Progression to level 2 requires advancement of cognitive skill to an intermediate level. Moving away from the language of lumps and bumps to a rudimentary stage of interpretation, the reader extender is better able to understand what they see and describe their findings using standardized terminology. Descriptive thumbnails are then reviewed by the physician for final reporting. To practice at the third level, advanced cognizance is necessary to independently interpret the images and make an accurate diagnosis. At this point, there is a division in the extender/physician interface that is dependent on the level of autonomy held by the reader extender. The physician may briefly review and "sign off" the final report, or the reader extender may practice independently with no input from the physician. In such a scenario, the role of reader extender would thus be metamorphosed to that of a non-physician reader, with the potential for progression to an expert level. As a clinical expert at the pyramidal peak of level 4, the non-physician reader is now in a position to train others.

In reality, the scope of practice for reader extenders will be influenced by and depend on a range of extrinsic factors, such as the type of health economy and reimbursement, physician capacity, and clinical demand. Although there appears to be an increasing number of nurses who are reading at levels 1 and 2, we haven't yet seen the independent capsule nurse endoscopist. With our past experience of nurse endoscopy, it is likely that, in Britain, level 3 readers will become a reality.

Medico-Legal Issues

The development of this role has generated a range of medico-legal concerns around scope of practice, accountability, and competency. In most Western countries, the scope of nursing practice is defined within a regulatory framework, with clear codes of conduct.³⁰ In the UK, once a nurse is registered, with the exception of some legal constraints (for example, nurse prescribing), they may extend their roles to

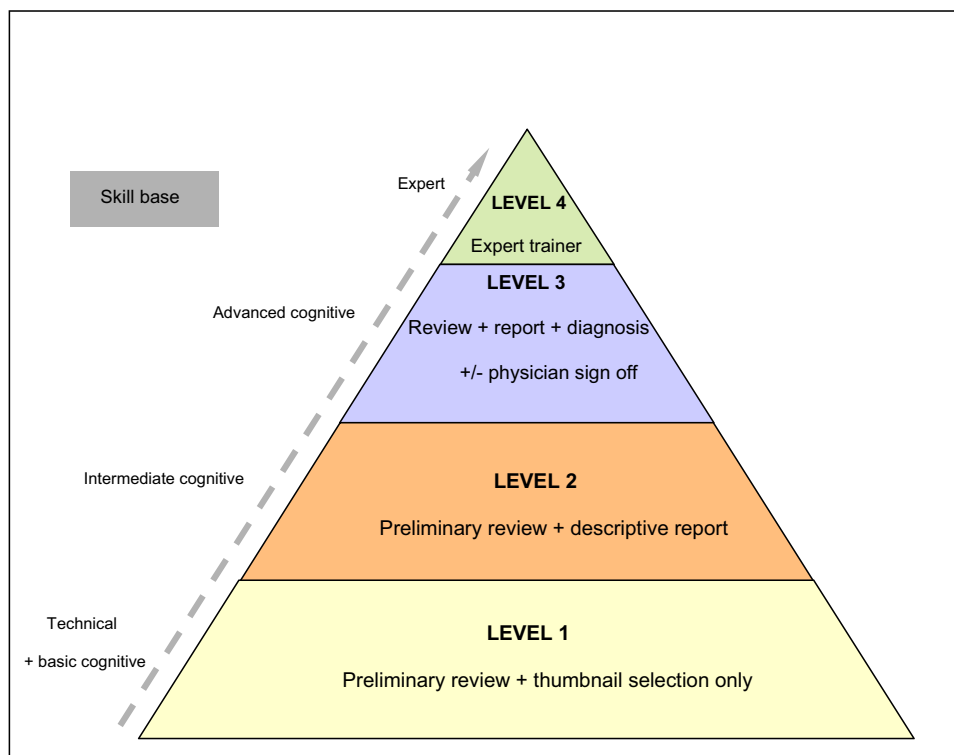


Figure 1 Framework for the development of practice. (Color version of figure is available online.)

perform any procedures or tasks as long as the employing authority allows them to do so. This must be done within the confines of the local governance framework and their own professional code of conduct, the key principle of which is accountability.

In the context of capsule endoscopy reading, once a reader extender is deemed to be competent by the trainer, they are personally accountable for their part in the reading process, whatever that may be. Nurses are accountable for their actions and omissions, and doctors do not accept responsibility for their actions, only their own delegation.³¹ In a recent report on non-medical endoscopists, the British Society of Gastroenterology highlights the physician responsibility for ensuring competence and standards of medical care when delegating medical duties.¹⁵ In delegating care “you must be sure that the person to whom you delegate care or treatment is competent to carry out the procedure.” Medico-legal risks arise if nurses undertake procedures for which they are not competent, and an employer is at risk if it fails in its governance, risk management, and training arrangements.¹⁵ The British Society of Gastroenterology concludes that organizations must ensure proper training, adequately mentoring, and quality assurance with regular audit of performance.

Training and Competency

There is a need to formalize training of reader extenders, with the development of national training standards and the application of a standardized reporting system to optimize image interpretation. A number of multidisciplinary “hands on” training courses with standardized content are now available from the British and American GI Societies. Comprehensive national training standards have been slower to materialize.

In Europe, the European Society of Gastrointestinal Endoscopy is currently developing a core curriculum for training, and the American Society of Gastrointestinal Endoscopy has published basic guidelines for credentialing.³² However, the curriculum and credentialing developments are specific to physicians, with an assumption of existing competency in upper and lower conventional endoscopy and completion of a GI fellowship. In the UK, there are no national training standards for capsule endoscopy. To address this, a UK steering group has been recently established, which aims to link to the European curriculum workstreams. As well as training, competency development should be supported with the common use of a standardized reporting system. A uniform approach to endoscopic vocabulary and reporting structure improves the ability to interpret and communicate findings.³³ The CEST (Capsule Endoscopy Structured Terminology) system³⁴ provides a valuable resource for the reader extender with limited training in small bowel pathology.

Emerging Service Models

The current number of capsule reader extenders is unknown; however, there is anecdotal evidence that such roles have been launched in units throughout Europe and the United States and are now being integrated into mainstream services.³⁵ Reports suggest that these roles are being used in clinical practice at levels 1 and 2 only, with prescreening of capsule videos by the reader extender before physician review.^{8,19,20,35} In doing so, the physician viewing time can be reduced to less than 15 minutes to review the preselected images.⁸ This rational use of health care resources means that service delivery costs may be reduced with a simultaneous increase in capacity to meet clinical demand.^{8,20} The resource benefits of this approach,

combined with new satellite software, have led to a growing interest in the development of commercial reading services, a potentially attractive proposition for the physician who needs a small bowel evaluation for his/her patient but lacks the necessary resources to provide it "in house." Commercial models of centralized diagnostic imaging interpretation are not new. Comparable business models have been developed within other diagnostic services, such as radiology. Teleradiology allows electronic distribution of radiological images to any location.³⁶ A number of models are available in the US, for example: *nighthawk/on call coverage*, providing out of hours radiology coverage while taking advantage of the time difference. With an expanding application of capsule endoscopy in the emergency evaluation of active gastrointestinal bleeding,³⁷ a capsule endoscopy nighthawk service is a worthy consideration. Without a time difference, the applicability to European countries may be less beneficial. Other models include *stand alone teleimaging*, which transmits images to a centralized network of reading sites, and *global virtual radiology services*, a system of workload sharing within the same health care system such as the military.³⁶ The principles of such models could feasibly be adapted to a commercial capsule endoscopy reading service supported by a pool of non-physician reader extenders.

Summary

Capsule endoscopy lends itself well to reading by non-physician reader extenders. It is a procedure that does not rely on operator skill in determining the quality of diagnostic images and yields a permanent record of images that may be reviewed repeatedly by multiple readers. Although the role and scope of the reader extender practice are yet to be formally defined, a proposed framework for the development of practice identifies four key levels of practice based on different levels of technical and cognitive skill and competency. More studies are needed to better evaluate the safety, clinical and cost effectiveness of reader extenders with different skill bases. However, early indications from the limited data suggest that, at a basic reading level, reader extenders can save time and money without compromising diagnostic accuracy, thus potentially releasing specialist physician time for more complex practice. All of which may improve clinical acceptance, improve access to services, reduce delays in diagnosis, and thus support improved clinical outcome.

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