

***Critical appraisal:
PillCam® capsule
endoscopy register
report***

August 24th 2007

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Summary of Critical Appraisal

The evidence discussed below should be interpreted with caution due to the extent of uncertainty surrounding the data presented in the report and the absence of reporting of statistical analyses discussed in the report. Independent assessment of these analyses is considered necessary to validate the evidence presented in the report. In addition, the results of the register study were not compared to evidence published since the previous assessment.

Safety

The register report is considered to provide evidence that adverse events associated with PillCam® capsule endoscopy are infrequent. The severity of these adverse events was not reported. The frequency of delayed passage in the register population is considerably less than that reported in the original assessment (0.5% vs. 5%) and is based on the use of PillCam® capsule endoscopy in Australian clinical practice.

Diagnostic performance

Gastrointestinal (GI) abnormalities were identified for 71.1% (2098/2949) of registered patients as a result of PillCam® capsule endoscopy: this value is considered as the overall diagnostic yield of the register population. There is evidence that suggest that PillCam® capsule endoscopy has a positive predictive value of 93%. However, definitive conclusions regarding this value cannot be made due to uncertainties in the data used to derive this value.

Patient management

Evidence is presented that indicates PillCam® capsule endoscopy alters patient management and may reduce hospitalisation for bleeding post-capsule endoscopy. This evidence should be interpreted with caution due to uncertainties in the data reported and inadequate reporting of procedures post-capsule endoscopy. There is also limited evidence that the number of prior tests has declined as a result of the introduction of this technology. Further statistical analysis is required to verify this evidence. Of all register patients with an abnormal GI finding, treatment was initiated for 52% of these patients. This indicates that PillCam® capsule endoscopy may have a positive impact on patient management. Long-term clinical outcomes of these patients were not reported.

Economic evaluation

Evidence is presented that suggests that the introduction of PillCam® capsule endoscopy has the potential to reduce the number and cost of previous investigations. From 2004 to 2006 the average reduction in the cost of previous investigations was \$631. Further statistical analysis is required to verify this evidence. Evidence that PillCam® capsule endoscopy reduces the cost of ongoing treatment is not based on data collected and/or presented in the register report. The economic impact of PillCam® capsule endoscopy on patients with an abnormal GI finding is not clear.

Recommendations

The evidence reported for the PillCam® capsule endoscopy register study is considered insufficient to support the first recommendation made in the report. Additional reporting and/or economic modelling are required to validate this recommendation. The evidence presented in the register report to support this recommendation is considered insufficient to satisfy the requirements of the MSAC. Due to inadequacies in reporting, it is unclear whether collection of patient data should be discontinued at this time. The third recommendation regarding listing of similar technologies is considered beyond the scope of this critical appraisal.

Introduction

Critical appraisal objectives

The objectives of this critical appraisal of the PillCam® capsule endoscopy register database report are as follows:

- To determine whether and to what extent the information presented in the report adds to the evidence presented in the original assessment of PillCam® capsule endoscopy (MSAC, 2003). This will require assessing the design and reporting of the PillCam® register study to identify potential biases and additional information that may be required from the applicant. Reporting of additional evidence on the safety, clinical effectiveness and economic impact of the use of PillCam® will be considered. The intention is to determine if this evidence eliminates, or reduces any uncertainties around the findings and key assumptions of the original report.
- To determine the value of any additional information presented in the PillCam® register report.
- To determine if the recommendations presented in the PillCam® register report are valid and supported by the evidence presented in the report.
- To provide advice on whether the information presented in the PillCam® register study satisfies the requirements of MSAC.

Reporting and design of the patient register

Register population versus eligible population

Potential bias; reporting and design issues

The selection of patients for inclusion on the PillCam® register database is considered as one of the key areas where bias may unintentionally be introduced. Bias in the selection of patients has the potential to reduce the validity of evidence on the safety, clinical effectiveness and economic impacts of PillCam® capsule endoscopy. This in turn will limit the applicability of this evidence to the patient population that are considered eligible for this diagnostic technology.

The validation of the PillCam® register database is described in part 2 of the report (pages 2 and 4). The authors acknowledge that discretionary data collection has the potential for selective reporting. The discussion on the results of database validation is largely limited to a single paragraph:

“The data was found to be largely free of bias and systematic distortions. Those discrepancies that were identified statistically were referred to Given Imaging and in all cases were attributable to differences in the patient mixes of the endoscopists’ practices. In some cases these differences were substantial, but when referred to a normed sample with the same presentation characteristics, no significant differences were apparent. In particular, endoscopists who had reported very few cases did not differ in their findings from those with many more reports thus enabling the full data set to be considered collectively.”

No data, information or statistical analysis is presented to support the statements made in this paragraph. The authors state that logistic regression was used to assess the relationship between patient characteristics and the findings. However, the results of this analysis are not presented. The evaluators consider it inappropriate to present claims in a research report without supportive evidence.

Details of sex, age and a comparison of the register population with the general population are presented (Table 1, register report). These data are considered to be of limited value unless statistical analysis is used to explore the relationship between patient characteristics and the findings of the report. For example, to identify any possible confounding factors. The report acknowledges that an over-representation of elderly patients occurred, but no meaningful analyses are presented.

In the results described for part 1 (page 3), it is clearly evident that there is a considerable difference between the number of patients reported in the register and the number of MBS item no 11820 claims made since listing of PillCam® since May 2004. The evaluators recognise that this is no doubt due to the impossibility of recording all patients on the register. In 2004, 2005 and 2006, patients recruited to the register represented approximately 48%, 43% and 22% of all patients who received PillCam® (assuming one procedure per patient). More evidence is required to ensure that this does not represent selective reporting. It is also unclear why fewer patients were recruited in 2006 than the other years. This may of course be due to differences in recruitment period as compared to listing period. However, the start and end dates of register recruitment were not reported.

The authors also state that: *“Part of the feedback process has been the provision of comparative reports to the doctors in order for them to compare their data to the full cohort, thus providing them with a valuable*

quality management tool.” It is also possible that this process may have led to selective reporting.

The description of the operation of the Pillcam® register database presented in the report is extensive. A review of an example of a data form is considered necessary to ensure that the design of the form itself has not led to any selective reporting of patient information. However, the evaluators recognise that the database was developed in consultation between the applicant and clinical experts.

Recommendations for additional information

- Attachment A: PillCam Data Collection Register outline and associated documentation
- Attachment B: Data collection forms
- To support statements made regarding validation of the database: results and details of statistical analyses are required.

Follow-up population versus register population

Potential bias and reporting issues

Of the 2,949 patients recruited to the register at the time of the compilation of the report, follow-up information was described for 420 patients. It is considered essential to show that provision of follow-up information was not discretionary and no selection bias could have occurred.

The report states:

“The follow-up cases were far from a random sample of the database, one endoscopist alone being responsible for 26% of the follow-ups. However, in terms of the patient mix, presentation indications and GI findings, the follow-up cases were found to be representative of the whole data set.....”

Although it is acknowledged that follow-up cases were not random, no statistical analysis is presented to support the statement that the follow-up group are representative of the whole data set. The evaluators consider it inappropriate to present such claims without supportive evidence. For example, an exploration of possible confounding factors in the selection of these patients could have been presented. The applicability of the evidence relating to the follow-up patients cannot reliably be assessed until further information is provided.

Recommendations for additional information

- Statistical analysis that shows that follow-up cases are representative of the whole data set.

Clinical effectiveness and economic evaluation

Safety

Previous findings: MSAC Assessment 1057

The original assessment of PillCam® capsule endoscopy (then known as M2A® capsule endoscopy) reported that adverse events associated with this technology appeared to be infrequent and mild (eg, abdominal pain, nausea) (MSAC, 2003). This assessment considered that delayed passage or lodgement of the capsule was not strictly an adverse event, but reported that it was observed in less than 5% of patients in the studies assessed at that time. In 37% of these cases the capsule was surgically removed, however surgery was planned in the majority of these cases (60%) (MSAC, 2003).

PillCam® register database report

The report states that complications were reported in 1.1% (33/2949) of procedure performed. Therefore this report provides additional evidence that adverse events associated with the technology are infrequent. Delayed passage (described as not passed within a period of more than 2 weeks from date of procedure) was reported in 0.5% (14) of procedures with 43% (6/14) requiring a procedure to remove the capsule. It is likely that scheduled surgery was used to remove the capsule, although this was not explicitly stated. The frequency of delayed passage in the complete register population is 10 times less than that reported in the original assessment.

The original assessment considered that the rate of small intestine (SI) strictures may be lower in the study populations (where patients had received an extensive number of previous tests), than in new patients receiving capsule endoscopy as a 3rd line test. The data presented in Table 4 of the register report suggest that PillCam® was used as a 3rd line test in the majority of patients registered. In contrast, the rate of delayed passage in the register population is lower than that reported in the original assessment. The reasons for this difference are not clear.

The report states that a wealth of literature on capsule endoscopy has been published since the original MSAC assessment. However, there was no comparison of any safety data reported in these studies with that of register patients.

Potential bias and reporting issues

The applicability of these results to the eligible population cannot be known until statistical analysis is presented that confirm the register population is comparable to the eligible population. Details of complications were not reported. Although these are infrequent, it cannot be assumed that these are mild in nature.

Recommendations for additional information

- Details of complications reported
- Details of procedures to remove retained capsules

In addition, details of safety data reported in the literature since the original assessment could provide evidence to support the data reported in the patient register.

In summary: The register report is considered to provide evidence that adverse events associated with PillCam® capsule endoscopy are infrequent. The severity of these adverse events was not reported. The frequency of delayed passage in the register population is considerably less than that reported in the original assessment (0.5% vs. 5%) and is based on the use of PillCam® capsule endoscopy in Australian clinical practice

Diagnostic Performance

Previous findings: MSAC Assessment 1057

Due to the absence of a suitable reference standard for capsule endoscopy, the diagnostic yield (number of patients with a pathological lesion identified/the total number of patients assessed) was used as a measure of diagnostic performance. This measure does not account for false positive and false negative results and therefore has the potential to overestimate diagnostic capability. The diagnostic yield was determined from a meta-analysis of a limited number of studies (comparative and indirect evidence was considered): the summary point estimate of diagnostic yield for capsule endoscopy was 58% (95% CI, 46.3 – 67.7%). Small bowel series radiology (SBS) was considered the comparator test in the original assessment: the summary point estimate of diagnostic yield for SBS was 4% (95% CI, 0.5-12.0%).

PillCam® register database report

Gastrointestinal (GI) abnormalities were identified for 71.1% (2098/2949) of registered patients as a result of PillCam® capsule endoscopy: this value is considered as the overall diagnostic yield of the register population. The authors claim that this value of diagnostic yield is statistically significantly higher than that reported in the original assessment. No statistical analysis was reported to support this claim. No statistical analyses were presented that explored the relationship between patient characteristics and importantly the sequence of prior tests on the diagnostic yield of PillCam® capsule endoscopy.

The data presented in diagram 1 of the register report indicate that this diagnostic yield is independent of patient sex or whether GI bleeding was overt or occult. The data presented for the follow-up population in diagram 2 (register report) suggest a general trend towards a higher diagnostic yield in this population. No statistical analysis was reported to identify whether this trend was significant.

The report states that of 420 follow-up cases, 275 had an abnormal GI tract and a definite diagnosis was made in 256 of the 420 cases. If it is assumed that these definitive diagnoses were made in the 275 patients who had an abnormal GI tract, then the positive predictive value (PPV) of capsule endoscopy can be estimated at 93.1%. (PPV = true positives/total test positives). However, this analysis should be interpreted with caution due the assumptions used: it is unclear if definitive diagnoses can be considered a reference standard and whether definitive diagnoses were made in any follow-up patients who were not classified as GI abnormal.. Note that PPV is also prevalence dependent, therefore can vary between study populations.

The original assessment indicated that the population described in included studies was likely to represent the prevalent obscure GI bleeding population in Australia (MSAC, 2003). It was discussed that incremental estimates of diagnostic yield derived from this population may overestimate the apparent benefit of capsule endoscopy in an incident population where the test is performed as a third line investigation. In contrast, the diagnostic yield values presented in the register report suggest that the benefit of PillCam® capsule endoscopy is maintained in an incident population.

The report states that a wealth of literature on capsule endoscopy has been published since the original MSAC assessment. However, there was no comparison of any diagnostic performance data reported in these studies with that reported in the register study.

Potential bias and reporting issues

The applicability of these results to the eligible population cannot be known until statistical analysis is presented that confirm the register population is comparable to the eligible population. In addition, statistical analysis is required to verify that the follow-up population is representative of the complete register population.

Recommendations for additional information

- Evidence to support claims of statistical significance of diagnostic yield for register population in comparison to previous estimate of diagnostic yield.
- Details of the definite diagnoses in the follow-up group. This would allow verification of the above estimate of PPV.

It is possible that estimates of additional diagnostic performance measures may be possible from the register data. For example, long-term patient outcomes (eg, ≥ 12 months) could be considered as a reference standard. The impact of treatment and possible spontaneous cessation of GI bleeding would need to be considered in this approach to avoid misleading estimates of diagnostic performance (MSAC, 2003).

In addition, details of diagnostic performance data reported in the literature since the original assessment could provide evidence to support the data described in the register study.

In summary, the data presented in the register report indicates that PillCam® capsule endoscopy has a diagnostic yield of approximately 71%. There is evidence that suggest that PillCam® capsule endoscopy has a positive predictive value of 93%. However, definitive conclusions regarding this value cannot be made due to uncertainties in the data used to derive this value.

Patient management and clinical outcomes

Previous findings: MSAC Assessment 1057

The original assessment of capsule endoscopy reported that there was little available data on the impact of capsule endoscopy on patient management and long-term clinical outcomes.

PillCam® register database report

The authors reported that PillCam® capsule endoscopy altered patient management in 56% of patients in the follow-up group (235/420). However, it is unclear from the evidence presented in the report how patient management was altered after capsule endoscopy. Of the follow-up patient group, 19% (79/420) were described in case reports as bleeding/anaemic after capsule endoscopy. It is not reported whether these patients had an abnormal or normal finding on capsule endoscopy.

Details of several investigations performed after capsule endoscopy are described (page 8, register report). It is unclear whether these investigations were performed in patients with or without GI abnormality detected.

The report initially states that GI abnormalities were reported in 275 of 420 follow-up cases (page 7). In the conclusions section the report states that GI abnormalities were reported in 327 of 420 follow-up cases. Evidence that capsule endoscopy changes patient management and clinical outcomes is discussed: it is claimed that hospitalisation for bleeding is reduced for these 327 follow-up patients post capsule endoscopy (page 12). Until the number of follow-up cases with GI abnormalities is clarified, this evidence cannot be considered reliable.

Table 8 (page 10, register report) presents data that suggests that all 420 patients in the follow-up group had further investigative procedures post-capsule endoscopy. This suggests that the follow-up group was selected based on patients who had investigative procedures post-capsule endoscopy. Further analysis is required to ensure that the follow-up group is representative of the wider register patient group.

The economic evaluation presented in the original assessment stated that the reliability of the results of the economic model would be improved by reduction in uncertainty on three key questions. One of these was whether a positive yield by capsule endoscopy would prevent all further diagnostic procedures in practice. The evidence presented in the register report is not considered to answer this question.

The authors' state that 37% (1082) of the abnormalities identified by PillCam® were subsequently treated (page 7, register report). However, the number of abnormalities identified by PillCam® was 2098 – therefore 52% (1082/2098) were subsequently treated. Data is presented for a total of 1185 procedures for 1082 patients. It is unclear which patients had more than one investigation post-capsule endoscopy.

In addition, the report states that:

“The second stage of analysis concerned trends in time of demographic data, presentation indications and findings. This would indicate whether experience of endoscopists was changing the application of the test and whether success rates were changing. The year in which the test was conducted was used to classify the tests so that analysis of variance and regression methods could be used.”

No data, information or statistical analysis was reported that indicated that the experience of endoscopists did indeed change the application of the test. Such analyses have the potential to provide additional evidence on how the use of PillCam® impacts on patient management. Data presented in Table 6 of the register report suggest that since the introduction of PillCam® in 2004 the number of investigations prior to capsule endoscopy has decreased. Further statistical analyses are considered necessary to explore the significance of this trend.

The report states that a wealth of literature on capsule endoscopy has been published since the original MSAC assessment. However, no additional evidence of the impact of PillCam® capsule endoscopy on patient management and/or clinical outcomes was discussed.

Potential bias and reporting issues

The applicability of these results to the eligible population cannot be known until statistical analysis is presented that confirm the register population is comparable to the eligible population. In addition, statistical analysis is required to verify that the follow-up population is representative of the complete register population.

Recommendations for additional information

- Further details on how patient management was altered after PillCam® capsule endoscopy. For example what happened to patients with and without an abnormal GI finding?
- Clarification of the number of follow-up patients who had an abnormal GI finding.
- Clarification of the proportion of identified GI abnormalities that were subsequently treated.
- Statistical investigation of the decline in number of previous investigations
- Data relating to longer term clinical outcomes (eg, clinical outcomes of patients recruited to the register in 2004)

The patient register could have been used to carry out a pre-test, post-test patient management study. In brief, endoscopists would need to provide patient management plans based on prior tests results. This assumes that PillCam® was unavailable. This could then be compared with patient management after PillCam® was performed.

In summary: evidence is presented that indicates PillCam® capsule endoscopy alters patient management and may reduce hospitalisation for bleeding post-capsule endoscopy. This evidence should be interpreted with caution due to uncertainties in the data reported and inadequate reporting of procedures post-capsule endoscopy. Of all register patients with an abnormal GI finding, treatment was initiated for 52% of these patients. This indicates that PillCam® capsule endoscopy may have a positive impact on patient management. Long-term clinical outcomes of these patients were not reported.

Economic analysis of the PillCam® register database

Previous findings: MSAC Assessment 1057

The economic analysis of the register study includes this extract from MSAC Assessment Report 1057 (page 38).

“A modelled economic evaluation assessing the value for money of the introduction of PillCam® Capsule Endoscopy relative to SBS radiography found that PillCam® Capsule Endoscopy was associated with lower total health care costs overall, with an estimated saving of \$1007 per patient. However, this result should be interpreted with respect to the key assumptions used in the economic model. In particular, a reduction in the uncertainty around the following key questions would improve the reliability of the results of the economic model.

- 1. Will the mean yield of PillCam® Capsule Endoscopy observed in the clinical studies and applied to the economic model (59.9%) be repeated in practice?*
- 2. Will a positive yield with PillCam® Capsule Endoscopy prevent all further diagnostic procedures in practice?*
- 3. Are the ongoing treatment costs of obscure GI bleeding at least \$683 per patient per year?”*

Point 3 relates to an analysis included in the original economic evaluation that illustrated that for the introduction of PillCam® capsule endoscopy to be cost neutral, the ongoing costs would have to be at least \$683 patients per year. A key economic benefit of PillCam® capsule endoscopy was the potential for this technology to be cost saving due to the reduction in ongoing costs.

PillCam® register database report

The evidence presented in the economic analysis of the register study was reviewed to determine whether the uncertainties discussed above were addressed. The register report was also reviewed for any additional evidence on the economic impact of PillCam® capsule endoscopy. Evidence relating to points (1) and (2) was discussed previously with relation to diagnostic performance and patient management respectively (see above).

The data presented in Table 5 (page 9, register report) indicate that the average cost of previous investigation was \$3183 for registered patients. The sources of the costs presented in Table 5 are not discussed. Data presented in Table 6 (page 10, register report) indicates that the average costs of previous investigations decreased by \$631 from 2004 to 2006. The evidence presented suggests that this is driven by a decrease in the number of investigations performed prior to PillCam® capsule endoscopy. Note that the sources of costs presented in Table 6 are not reported and no statistical analyses are presented that explore whether the decrease in the number of previous test is significant. Therefore, the evidence that PillCam® capsule endoscopy may reduce the number and costs associated with previous tests should be interpreted with caution.

Data presented in Table 8 shows the decrease in costs following PillCam® capsule endoscopy for all follow-up patients. The average cost of tests before and after capsule endoscopy were \$3214 and \$298 respectively. This decrease is considered to be driven by the MBS requirement for upper GI endoscopy and colonoscopy prior to PillCam® capsule endoscopy and is not considered as evidence for an economic benefit of PillCam® capsule endoscopy. Data for patients with positive or negative GI abnormality finding is

reported together in Table 8– therefore the extent of potential cost saving following a positive GI finding is unclear.

Although PillCam® capsule endoscopy has the potential to reduce ongoing cost following the test; there is minimal discussion of this in the report. The 3rd paragraph of the conclusions (page 12, register report) includes a crude estimation of the potential cost savings due to the reduction in patient hospitalisation following the test in the follow-up group. However, due to the uncertainty surrounding the number of follow-up patients who had a positive abnormal GI finding (275 or 327), the value of this crude estimate is unclear. It is unclear why ongoing costs were not collected and/or reported, this would have added considerable value to this report.

The report states that a wealth of literature on capsule endoscopy has been published since the original MSAC assessment. However, there was no discussion of any economic analyses reported in these studies.

Potential bias and reporting issues

The applicability of these results to the eligible population cannot be known until statistical analysis is presented that confirm the register population is comparable to the eligible population. In addition, statistical analysis is required to verify that the follow-up population is representative of the complete register population.

Recommendations for additional information

- Clarify the sources of costs of prior investigations
- Statistical analyses to determine the significance of decrease in the number of prior tests from 2004 to 2005.
- Report pre and post capsule endoscopy test costs separately for follow-up patients with and without abnormal GI finding
- Clarify uncertainty surrounding the number of follow-up patients with an abnormal GI finding

In summary: the introduction of PillCam® capsule endoscopy has the potential to reduce the number and cost of previous investigations. From 2004 to 2006 the average reduction in the cost of previous investigations was \$631. Further statistical analysis is required to verify this evidence. Evidence that PillCam® capsule endoscopy reduces the cost of ongoing treatment is not based on data collected and/or presented in the register report. The economic impact of PillCam® capsule endoscopy on patients with an abnormal GI finding is not clear.

Critical appraisal of report recommendations

The recommendations included at the end of the report are considered in turn.

Recommendation One

Based on this wealth of evidence and in the interest of improving the cost-effectiveness of PillCam® Capsule Endoscopy, it is recommended that::

1. The requirement for a previous upper gastrointestinal endoscopy and colonoscopy (combined cost \$1,930) be removed;

OR

2. The requirement that the PillCam® Capsule Endoscopy is performed within 6 months of the upper gastrointestinal endoscopy and colonoscopy be amended to:

(d) The service is performed within 12 months of the upper gastrointestinal endoscopy and colonoscopy or hospitalisation for bleeding.

Is this recommendation valid?

The register report is considered to have insufficient evidence to support these recommendations, for the following reasons:

- It is suggested that the ‘*wealth of evidence*’ generated since the previous assessment supports these recommendations. This evidence is not reported. A review of this evidence is considered beyond the scope of this critical appraisal.
- Evidence of the diagnostic performance of PillCam® capsule endoscopy in patients who have not had prior upper gastrointestinal endoscopy and colonoscopy is not reported.
- Evidence of the diagnostic performance of PillCam® capsule endoscopy performed within 12 months of prior upper gastrointestinal endoscopy and colonoscopy performed is not reported.
- Evidence of the diagnostic performance of PillCam® capsule endoscopy performed within 12 months of hospitalisation for bleeding is not adequately reported.
- The economic consequences of the recommendation, based on evidence from the register study is not modelled

The evidence presented in Tables 6 and 7 (page 10, register report) is likely to be the reason for this recommendation, although this is not clear. Despite a decrease in the number of prior upper gastrointestinal endoscopies and colonoscopies from 2004 to 2006, the diagnostic yield of PillCam® capsule endoscopy did not increase. It is suggested that this would not be the case if PillCam® capsule endoscopy was detecting abnormalities that would have been detected by these previous investigations. In contrast to the recommendation, there is a trend towards a *decrease* in the diagnostic yield of capsule endoscopy from 2004 to 2006: this could happen because the *incremental* benefit of PillCam® capsule endoscopy is reduced as a result of the

decrease in prior upper gastrointestinal endoscopy and colonoscopy procedures. However, the statistical significance of this trend, if any, is unclear.

The data presented in Table 3 (page 6, register report) compares the rate of abnormal GI findings between register patients who were hospitalised for bleeding before the last 12 months prior to capsule endoscopy with those hospitalised within the last 12 months prior to the test. Patients admitted within the last 12 months had a higher rate of abnormal GI findings in comparison to patients admitted before the last 12 months (78.4% vs. 60.9%, respectively). The statistical significance of this difference is not reported. The relationship between prior test sequence and diagnostic yield of PillCam® capsule endoscopy in relation to time of hospitalisation for bleeding is not reported. The effect of other possible confounding factors is not reported.

<p>The evidence presented in the register report to support this recommendation is considered insufficient to satisfy the requirements of the MSAC.</p>
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Recommendation 2

Based on the co-operation of the Australian PillCam® endoscopists in submitting data to the Register for in excess of 3,300 patients, the requirement for data collection be officially discontinued as soon as possible.

The evidence presented in the report indicates that PillCam® capsule endoscopy is safe, has a diagnostic yield of 71% and has a positive impact on patient management. However, the reporting of the register data is considered somewhat inadequate. The absence of reporting of statistical analyses does not allow an independent assessment of whether the register population represents the eligible population. It is unclear whether discontinuing the requirement for data collection is necessary at this time due to the absence of statistical reporting and uncertainty around data.

Recommendation 3

In the absence of any published evidence supporting the clinical significance or efficacy of its own performance, it is recommended that any other Capsule Endoscopy device be requested to submit an individual application to MSAC for health economic assessment for suitability of listing on the MBS or at the very minimum, provide clinical equivalence to the pre-existing and assessed Capsule Endoscopy device, in this case PillCam® Capsule Endoscopy by providing data to the same level, quantity and standard by way of an MSAC application or a similar data collection requirement before being funded under MBS Item Number 11820.

This issue is considered beyond the scope of this critical appraisal. It is recognised that clinical equivalence of other brands of capsule endoscopy cannot be assumed unless there valid reasons and/or evidence.

References

Medical Services Advisory Committee (2003).M2A® Capsule Endoscopy: For the evaluation of gastrointestinal bleeding in adult patients: Assessment Report (MSAC Application 1057), Canberra.