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Horizon Scanning Technology Prioritising Summary

Velscope® for oral cancer screening

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PRIORITISING SUMMARY

REGISTER ID: **000396**

NAME OF TECHNOLOGY: **VELSCOPE® FOR ORAL CANCER SCREENING**

PURPOSE AND TARGET GROUP: **ORAL CANCER SCREENING DURING ROUTINE MEDICAL EXAMINATIONS**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

☒	Yet to emerge	☐	Established
☐	Experimental	☐	Established *but* changed indication or modification of technique
☐	Investigational	☐	Should be taken out of use
☐	Nearly established		

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☒	Yes	ARTG number 147035
☐	No	
☐	Not applicable	

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Canada	✓		
USA	✓		
Australia		✓	

IMPACT SUMMARY:

INLINE Systems - Australia markets the Velscope® as a device for screening for oral cancer. Oral cancer has a low survival rate mostly due to late stage diagnosis. A device to screen non-invasively for oral cancers at an early stage may facilitate a lower death rate from the disease.

BACKGROUND

Oral cancer is under diagnosed and is often mistaken for non-cancerous oral manifestations such as ulcers. By the time oral cancer is symptomatic the disease has progressed too far and the prognosis is poor. Normal diagnosis is initiated only if a medical practitioner suspects a lesion is potentially malignant. As the manifestation of oral cancer is similar to other frequent, and non-life threatening mouth abnormalities, such as ulcers, true oral cancer may not be properly investigated. It is not feasible to biopsy and diagnose every potential lesion as the vast majority of suspected lesions

are benign. Performing unnecessary biopsies would impact negatively on the patient and also increase health care costs.

The Velscope® device is marketed as a screening tool for use by medical practitioners to investigate potentially malignant lesions in the clinic. The device consists of a light source and a visualisation handpiece through which suspect tissue is examined. The diagnostic capability of the device is based on the differing fluorescence profiles of normal and abnormal (potentially cancerous) tissue within the oral cavity. A blue light is shone into the oral cavity and the resulting fluorescence of the tissue is visualised through the handpiece. Normal tissue appears with a bright apple-green glow, and abnormal tissue appears dark under the blue light. If abnormal tissue is discovered a biopsy can be performed on the patient for definitive histological diagnosis.

CLINICAL NEED AND BURDEN OF DISEASE

Oral cancer rates in Australia have been published in several studies and range from 2,000 to 2,500 new cases per year (Cox 2000; Sugerman & Savage 2002). The AIHW data for 2004 reports approximately 2,300 new cases of oral cancer (AIHW 2004). The 5-year survival rate for oral cancer diagnosed patients is approximately 50 per cent. In Australia, approximately 400-500 deaths, or one per cent of all cancer deaths, occur annually from oral cancer (Farah & McCullough 2008).

Data available from New Zealand reports on rates of lip, mouth and pharynx (LMP) cancer. The number of new LMP cancer registrations are declining with the corresponding decline in tobacco consumption. In 1996, the number of new cases recorded for the New Zealand population was 179 and 89 for males and females, respectively, reflecting the difference in cigarette consumption between the sexes. These numbers translate to an age standardised incidence rate of 12 and five per 100,000 males and females, respectively. In 1997 the age standardised mortality rate was four (68 deaths) and two (35 deaths) per 100,000 for males and females, respectively. Taking into account the expected rise in the New Zealand population, it was estimated that by 2012 the age standardised mortality rate for LMP cancer would decrease to three (65 deaths) and one (39 deaths) per 100,000 for males and females respectively (Public Health Intelligence Unit 2002).

DIFFUSION

The device has TGA approval (see footnote above) and private clinicians are using the Velscope® in Australia. (personal communication INLINE Systems - Australia).

COMPARATORS

No current screening methods for oral cancer diagnosis are extant in Australia. If a general practitioner or dentist suspects a lesion has potential for becoming or is cancerous a biopsy is taken and sent to a pathology lab for histological diagnosis (Scully et al 2005).

SAFETY AND EFFECTIVENESS ISSUES

Several studies have investigated the Velscope® device for diagnosing oral cancer in different populations of patients. The initial pilot study by Lane et al reported on a population of 44 subjects. Histology of the suspected lesions was used as the gold standard. Normal mucosa was able to be distinguished from severe dysplasia/carcinoma in situ or invasive carcinoma with a sensitivity of 98 per cent and a specificity of 100 per cent (Lane et al 2006) (Level III-2 diagnostic evidence).

A small case series of only three patients conducted in an oral dysplasia clinic, investigated the Velscope® as a screening tool to identify tissue that has loss of autofluorescence and has therefore the potential to be cancerous or precancerous. The three patients were being monitored after having previous procedures to remove dysplasias or carcinomas. The oral cavities of all three cases appeared normal under ordinary light inspection. When the Velscope® was used, regions of abnormal tissue were evident and biopsies were taken. Histopathology revealed that all three cases had clinically significant pathology with severe dysplasia in the first patient and cancer in the second and third patient (Poh et al 2007) (Level IV diagnostic evidence).

A second study by Poh et al (2006) investigated the ability of the Velscope® to identify cancerous tissue in patients with known cancers and also to identify the margins of abnormal tissue around the known lesion. Twenty patients were consecutively recruited as they were being assessed prior to removal of a known cancer. The Velscope® was used to assess the cancer and its margins. Biopsies of tissue with abnormal and normal fluorescence were then taken for histopathology. All tumours showed loss of fluorescence and this extended outside the normal visual margin for all tumours except one. When the fluorescing and non-fluorescing tissue was analysed 32 of 36 non-fluorescing tissue samples were found to be histologically abnormal, whereas of the 66 fluorescing samples only one was histologically abnormal. Using an arbitrary resection margin of 10mm around the tumour would have left 6/20 cases with cancerous or highly abnormal tissue remaining, making recurrence a high probability. This study demonstrates that the Velscope® is useful to identify abnormal tissue that may appear normal under regular lighting (Level III-2 diagnostic evidence).

No safety issues were reported in the literature examined.

The studies reviewed in this summary demonstrate that the Velscope® has the potential to diagnose abnormal tissue that appears normal using standard inspection techniques. Tissue flagged as abnormal by the Velscope® has a high likelihood of being histologically abnormal e.g. showing dysplasia or cancerous properties. Conversely, tissue flagged as normal by the Velscope® is rarely abnormal by histopathology. Despite this promising data, there is a need for the device to undergo further trials with larger groups of subjects and better study designs.

COST IMPACT

The Velscope® kit includes: Velscope® unit, operation manual, examination guide, training DVD, powerpoint presentation, patient brochures, patient mailer inserts, waiting room posters.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

OTHER ISSUES

No issues were identified/raised in the sources examined.

SUMMARY OF FINDINGS

Several small scale studies show the Velscope® has good potential to identify abnormal oral tissue that appears normal under standard inspection and to also allow better planning of surgical resection of known tumours. The device may have potential as a screening device in the future.

HEALTHPACT ACTION:

The Velscope® shows promise to fill a necessary gap in current diagnostic capabilities. Yet there is a need for more and higher quality data to demonstrate better patient outcomes. HealthPACT therefore recommended that this technology should be monitored for further information in 24-months time.

NUMBER OF INCLUDED STUDIES

Total number of studies	
Level III-2 diagnostic evidence	2
Level IV diagnostic evidence	1

REFERENCES:

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SEARCH CRITERIA TO BE USED:

Mouth Neoplasms/ diagnosis/genetics/ surgery
Risk Assessment
Tumor Markers, Biological/genetics
Fluorescence