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Australia and New Zealand Horizon Scanning Network

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AN INITIATIVE OF THE NATIONAL, STATE AND
TERRITORY GOVERNMENTS OF AUSTRALIA
AND THE GOVERNMENT OF NEW ZEALAND

Horizon Scanning Technology Prioritising Summary

Smartinhaler™ with audiovisual reminder for asthma medication

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The production of this Horizon scanning prioritising summary was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from departments in all states and territories, the Australia and New Zealand governments; and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

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PRIORITISING SUMMARY

REGISTER ID: 000342

NAME OF TECHNOLOGY: SMARTINHALER™ WITH AUDIOVISUAL
REMINDER FOR ASTHMA MEDICATION

PURPOSE AND TARGET GROUP: FOR THE MANAGEMENT OF ASTHMA PATIENTS

STAGE OF DEVELOPMENT (IN AUSTRALIA):

- | | |
|---|---|
| <input type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established |
| <input type="checkbox"/> Experimental | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input checked="" type="checkbox"/> Investigational | <input type="checkbox"/> Should be taken out of use |
| <input type="checkbox"/> Nearly established | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | |
|---|-------------|
| <input type="checkbox"/> Yes | ARTG number |
| <input checked="" type="checkbox"/> No | |
| <input type="checkbox"/> Not applicable | |

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
New Zealand	✓		
Australia	✓		

IMPACT SUMMARY:

Nexus6 Ltd provides the Smartinhaler™ device, an electronic monitoring device for measuring medication compliance in asthmatics. The Smartinhaler™ is distributed in New Zealand by Nexus6 Ltd and in Australia by CMS alphatech. The Smartinhaler™ is currently not registered on the Therapeutic Goods Administration and therefore may only be used for research purposes. Nexus6 Ltd is currently applying for European CE marking and an application for TGA approval will follow (personal communication).

BACKGROUND

Asthma is a chronic inflammatory disease that is characterised by paradoxical narrowing of the bronchi (lung passageways) making breathing difficult. Symptoms include wheezing, difficulty breathing (particularly exhaling air) and tightness in the chest due to the widespread narrowing of the airways within the lungs and obstruction of airflow. Factors which can exacerbate asthma include rapid changes in temperature

or humidity, allergies (especially to house dust mites and mould spores), upper respiratory infections, exercise, stress or smoke (cigarette). Treatment includes bronchodilators which are given orally or delivered as an aerosol (inhaled). Corticosteroids are reserved for more difficult cases (AIHW 2006).

An important component in the clinical management of children with asthma is being able to assess compliance with prescribed medication. The usual method to assess compliance is simply to ask the patient how often they took their medication, a method which may be affected by recall bias. Other methods include recording medication use in a diary, however studies have found that diarised entries are routinely recorded as higher than those recorded by monitoring devices (Burgess et al 2007b).

The Smartinhaler™ is a monitoring device which replaces the plastic holder of a standard pressurised metered dose inhaler used by asthmatics (Figure 1). A small electronic circuit is placed within the plastic casing of the Smartinhaler™ and the device is placed in a docking station (Figure 2). A switch is activated each time the canister is depressed, recording the time. The docking station can be linked to a PC and data can be down loaded. The device can not evaluate whether the patient has inhaled the medication or if their technique is effective (Burgess et al 2007a; Burgess et al 2007b). In addition, the Smartinhaler™ has an audiovisual reminder function, which emits an audible reminder at preset designated times to remind patients to take their medication. There is also a visual cue which shows patients (or parents) whether the medication has been taken during a specified time (Charles et al 2007).



Figure 1 The Smartinhaler™ device
(printed with permission Nexus6 Ltd)



Figure 2 The Smartinhaler™ in its docking station

CLINICAL NEED AND BURDEN OF DISEASE

Based on figures obtained in 2004-05, it has been estimated that over two million Australians, or approximately 10 per cent of the population, currently have asthma. The highest prevalence is reported in individuals aged 15-24 years (12.4%) (AIHW 2006). The prevalence in Australia and New Zealand is high by international standards (ranked 7th and 8th) (Masoli et al 2004). Although asthma is not a major cause of mortality in Australia, with 0.2 per cent of deaths in 2004 attributed to asthma, the death rate is considered high by international standards. The risk of dying from asthma increases with age. During the period 1998-99 to 2003-04, the average number of general practitioner encounters was 14.5 per 100 persons, representing 2.8 per cent of all GP encounters for that period. Children aged 0-4 years had the highest rate of asthma-related GP encounters (AIHW 2006). Asthma represents a significant burden of disease in Australia with a total number of public hospital separations for bronchitis and asthma (AR-DRG numbers E69A, E69B, E69C) for 2004-05 of 43,238. The average length of stay for these three AR-DRG numbers was 6.0, 3.4 and 1.7 days (AIHW 2007).

DIFFUSION

The Smartinhaler™ is currently being used for research purposes in Australia and New Zealand. If the device is registered on the TGA it is expected that this device will diffuse widely due to the large numbers of asthmatics in Australasia.

COMPARATORS

Compliance to asthma medication as outlined above would usually be measured by simply asking the patient. This may be difficult for children to answer accurately. Other methods of assessing medication compliance would include patients maintaining a diary, which again may prove to be inaccurate in children.

SAFETY AND EFFECTIVENESS ISSUES

Burgess et al (2006) examined the reproducibility and accuracy of ten Smartinhaler™ devices compared to five previously validated dosage devices, the Doser (level IV diagnostic evidence). Both devices were actuated twice, on two occasions per day for 30 days (a total of 120 doses). The Smartinhalers™ were fitted with several types of standard pressurised metered dose inhalers. Five of the Smartinhalers™ were 100 per cent accurate with no additional or missed actuations. One failed to record the first dose and four failed to record the first two doses, however this was rectified by placing the medication canister more firmly into the device. The following doses were then all recorded accurately. All five Dosers were 100 per cent accurate. In addition, six Smartinhalers™ were actuated 30 times in rapid succession to determine how the device would record “dumping” of medication. The device successfully recorded all 30 actuations but recorded the same time for each dose (Burgess et al 2006).

A randomised controlled trial was conducted by Charles et al (2007) to determine whether or not an audiovisual reminder device would improve medication adherence in asthmatic adolescents and adults (aged 12-65 years). After eligibility criteria were applied, 110 subjects were randomised to receive asthma medication (one dose, twice daily) for 24 weeks. Subjects were randomised to receive their medication either via a standard Smartinhaler™ (n=55) or via a Smartinhaler™ with an audiovisual reminder (n=55) (level II intervention evidence). Both groups had their adherence covertly monitored by the Smartinhaler™ which recorded the date and time of dose administration. The mean percentage of medication taken in the last 12 weeks of the study was 88 per cent (± 16) and 66 per cent (± 27) in the audiovisual reminder and control groups, respectively. The absolute difference between the two groups was significant at 18 per cent, 95% CI [10, 20] ($p < 0.001$). The proportion of subjects taking >90 per cent of their medication was 28/44¹ (63.6%) in the audiovisual reminder group, compared to only 9/46 (19.6%) in the control group. The proportion of subjects taking >80 per cent of their medication was 88.6 per cent in the audiovisual reminder group, compared to 39.1 per cent in the control group. In both groups, adherence to medication fell in the first 12 weeks of the study but remained stable for the remaining 12 weeks. Adherence to medication was higher in the audiovisual group at all time points compared to the control group. During the last four weeks of the study, the audiovisual reminder group underestimated missed doses by a mean of 3 ± 10.8 doses, compared to the control group who underestimated missed doses by 12.2 ± 13.1 doses. The authors conclude that an audiovisual reminder can significantly improve medication adherence for asthma patients (Charles et al 2007).

The study by Burgess et al (2007, in press) recruited 51 asthmatic children, aged 18 months to seven years (mean age 3.4 years), who were taking preventative asthma medication on a regular basis (level IV intervention evidence). The correct use of the Smartinhaler™ device was demonstrated to parents and they were informed that the device would count the number of doses dispensed. Patients used the Smartinhaler™ for four weeks. Parents were then interviewed and completed a questionnaire concerning their child's use of medication. Adherence was measured as a percentage of prescribed doses of medication registered by the Smartinhaler™. During the study period the median percentage of doses as determined by the Smartinhaler™ was 70.5 per cent (range 21.4-100%). Thirty-two patients took less than 80 per cent of the agreed number of doses and 13 took less than 50 per cent. Medication usage was over estimated in the verbal report provided by parents (85.1%) and by the parental questionnaire (84.2%). In the verbal report, 32 parents reported that their child took 90 per cent or more of the agreed number of doses. The Smartinhaler™ indicated that only four children reached that level of compliance. There was no reported

¹ 11/55 (20%) of the audiovisual reminder group and 9/55 (16.4%) did not provide data in the last 12 weeks of the study

relationship found between the age or sex of the child, and their prescribed dose of medication and adherence, however, two of the three *least* adherent children were prescribed the highest doses of medication. The most common reasons given by parents for non-compliance were forgetfulness and being dissuaded by their child's reaction to being given the medication. This study indicates that reduced adherence to medication may be a factor in uncontrolled or poorly controlled asthma. Subjective measures of adherence perform poorly in comparison to more objective measurements (Burgess et al 2007b).

COST IMPACT

The Smartinhaler™ can be purchased from Nexus6 Ltd for use with either ventolin, fixotide or serevent for NZ\$99.50 (Nexus6 2007). The docking station for the device costs NZ\$39.95. In addition, personal asthma management software can be purchased for NZ\$99.50.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

OTHER ISSUES

A randomised controlled trial utilising the Smartinhaler™ is currently underway in Australia. This study aims to provide adherence feedback to the intervention arm of the study to measure any changes in medication compliance. This RCT is in the early recruitment stage (personal communication, University of Queensland).

SUMMARY OF FINDINGS

The Smartinhaler™ combined with an audiovisual reminder system appears to be an effective method of increasing patient adherence to asthma medication. The Smartinhaler™ performed better than parental recall, and therefore may be an important tool in assisting parents to assist their children in medication adherence.

HEALTHPACT ACTION:

HealthPACT has recommended that further assessment of this technology is no longer warranted.

NUMBER OF INCLUDED STUDIES

Total number of studies	
Level II intervention evidence	1
Level IV intervention evidence	1
Level IV diagnostic evidence	1

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SEARCH CRITERIA TO BE USED:

Anti-Asthmatic Agents/*administration AND dosage

Asthma/*drug therapy

Paediatric asthma

Child

*Inhalation Spacers