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National Horizon Scanning Unit

Horizon scanning prioritising summary

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**Alternative site blood glucose meter, other
than finger-tip, for diabetic patients.**

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PRIORITISING SUMMARY

REGISTER ID: 000118

NAME OF TECHNOLOGY: ALTERNATIVE SITE BLOOD GLUCOSE METER

PURPOSE AND TARGET GROUP: ALTERNATIVE SITE TESTING, OTHER THAN FINGERTIP, FOR DIABETIC 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 type="checkbox"/> Investigational | <input type="checkbox"/> Should be taken out of use |
| <input checked="" type="checkbox"/> Nearly established | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | | |
|---|---|-------|
| <input checked="" type="checkbox"/> Yes | ARTG number | 99806 |
| <input type="checkbox"/> No | <input type="checkbox"/> Not applicable | |

Roche Diagnostics manufacture the Accu-Chek Go®, which has been approved by the Australian Therapeutic Goods Administration and received 510 (k) approval from the United States Food and Drug Administration in April 2004. The technology has been made available through pharmaceutical outlets and Diabetes Australia in the last month (July 2004), for people with either type I or type II diabetes.

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
United Kingdom	✓		
Italy	✓		
United States	✓		
Germany	✓		
Australia		✓	

IMPACT SUMMARY:

Several manufacturers produce blood glucose monitoring systems capable of utilising an alternative site, other than the fingertip, for blood glucose testing. Manufacturers who supply alternative site blood glucose meters, which have received approval from the United States Food and Drug Administration, include TheraSense, Bayer Diagnostics, LifeScan and MediSense.

BACKGROUND

Achieving tight glucose control as early as possible after diagnosis, in patients with diabetes, has great benefit for the reduction, or slowing of progression, of microvascular complications such as diabetic retinopathy and nephropathy caused by hyperglycaemia (Bate & Jerums 2003). Achieving tight glucose control for people with type I diabetes may require finger-

prick testing 3-4 times per day. However, barriers to frequent testing include the pain associated with the required finger-prick, due to the fingertip having more nerve endings, along with the accumulated trauma to the fingers. This may result in patients, especially young children, “forgetting” to monitor glucose levels regularly, which may have serious long-term consequences for their health (Altobelli et al 2000). The forearm, the fleshy part of the hand, upper arm, thigh, or calf may be used as alternative sites for testing (Figure 1). If glucose levels are rapidly changing there may be a difference in the glucose readings between the alternative sites and the fingertips due to blood flow to the fingertip being 3-5 times more rapid than blood flow to the arm or other sites. The possible difference in glucose readings between the fingertip and palm and alternative sites could delay detection of hypoglycaemia. Fingertip testing is recommended if it is suspected that blood glucose levels are rapidly changing, low (hypoglycaemia) or if the patient has a history of hypoglycaemia unawareness (FDA 2002).

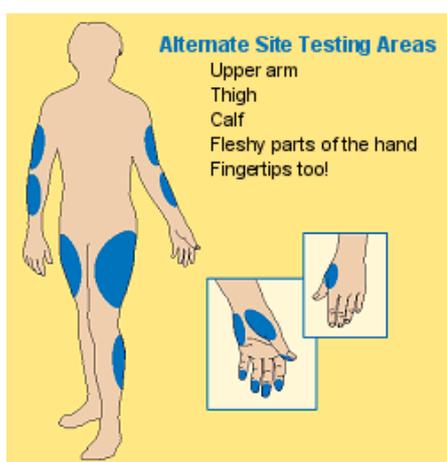


Figure 1 Alternate site testing areas
(Printed by permission: Children with Diabetes,
www.childrenwithdiabetes.com)



Figure 2 The Accu-Chek Go® glucose meter
(Printed with permission: Roche
Diagnostics)

Alternative site testing (AST) blood glucose meters are small, hand held, portable devices (Figure 2). The Accu-Chek Go® is capable of producing a blood glucose reading within five seconds and each reading requires only a small volume of blood (1.5 µl). In addition, the meter has an alternative site sampling option, an audible, programmable alarm system to prompt testing and a hypoglycaemia threshold warning (Roche Diagnostics 2004).

CLINICAL NEED AND BURDEN OF DISEASE

It is estimated that approximately one million people suffer from the three types of diabetes (Type-1, Type-2 and gestational diabetes) in Australia. Type-1 diabetes represents approximately 10-15 per cent of all diabetic patients, however 98 per cent of childhood diabetes is Type-1. In the year 2000, diabetes was the underlying cause of death of over 3,000 Australians, whilst over 10,000 deaths were recorded with diabetes as an underlying *or* associated cause. It is difficult to estimate the degree of morbidity associated with diabetes, however in 1999-2000 12 per cent of patients aged over 25 years with diabetes suffered a heart attack and nine per cent a stroke. In addition, 15 per cent of people with diabetes had retinopathy, 6 per cent kidney disease, approximately 10 per cent had neuropathy, 19 per cent were at risk of foot ulcers and 2 per cent had amputated limbs. The number of public hospital separations in Australia associated with diabetes in 2001-02, was 53,232 (AR-DRG numbers E10-E14) (AIHW 2004). In 1998 almost 64,000 Australians had a disability caused by diabetes (AIHW 2002).

An estimate for the age-standardised prevalence of Type-1 diabetes for 1999-2000 was 298 per 100,000 (AIHW 2002). The National Diabetes Register (NDR) collects information on the

number of new users of insulin since 1999. There were 4,548 new cases of Type-1 diabetes, aged 0-39 years, for the years 1999-2001, 50 per cent of these cases were children aged 0-14 years. The most recent data on the incidence of childhood type I diabetes in Australia, for the years 2000-2001, indicate an incidence of 20.3 and 18.9 per 100,000 for males and females, respectively (AIHW 2003).

DIFFUSION

The Accu-Chek Go[®] is the only AST blood glucose meter available on the Australian market. Accu-Chek Go[®] was released to consumers in July 2004. In the month since its release 12,000 units have been sold (personal communication, Roche Diagnostics). Diffusion, therefore, would appear to be rapid.

COMPARATORS

The current gold standard for self monitoring blood glucose levels is the glucose meter, which is a small, portable battery operated device. To test glucose levels patients wash hands thoroughly to remove any trace of glucose and reduce risk of infection, prick the fingertip with a lancet and hold the finger until a large droplet of blood forms. The droplet of blood is placed onto a test strip, which is then inserted into the glucose meter. There are currently more than 25 different brands of commercially available glucose meters, including Accu-Chek[®] Advantage[®] (Roche Diagnostic), One Touch[®] (LifeScan Inc) and Accutrend[®] DM (Boehringer Mannheim).

EFFECTIVENESS AND SAFETY ISSUES

The cross-classification study by Greenhalgh et al (2004) (diagnostic level of evidence 4) compared AST to the reference of standard finger-prick testing, using the SoftSense (Abbott Laboratories) blood glucose monitor, which is capable of both conventional finger-prick and alternative site testing. Of the 47 children and adolescents (mean age 13 years of age, range 6-17 years) enrolled in the study, 46 had type I diabetes. AST glucose values correlated well with the reference standard ($r = 0.97$). In addition, 100% of measurements fell into areas A and B of a Clark Error Grid analysis (see Appendix). Sixty one per cent of children enrolled in this study found forearm testing to be less painful, although six per cent of children found it to be more painful. Fifty five percent of children thought that forearm testing would improve their regularity of blood glucose monitoring.

Similar results were reported by Fedele et al (2003) from a multi-centre trial using the One Touch Ultra AST (LifeScan Ltd) (diagnostic level of evidence 4). Blood glucose values taken from the forearm in 112 patients (58% with type I diabetes) correlated well with the reference finger-prick ($r = 0.95$), 89% and 10% of paired data points fell into area A and B of the Clark Error Grid, respectively, and the mean absolute relative error was 22% (SD = 22%).

The study by Lee et al (2002) (diagnostic level of evidence 4) used the FreeStyle AST (TheraSense). Blood glucose testing was conducted on 190 patients, with a total of 18,036 data points, at different times of the day: preprandial, 1-hour postprandial, 2-hour postprandial and bedtime. Readings at 1-hour postprandial showed a mean bias of -6.02 mg/dL, whereas readings at the other three times had a mean bias of less than 1mg/dL. The difference in bias between the 1-hour postprandial to the preprandial and postprandial was statistically significant ($p < 0.0001$), indicating that patients who test 1-hour postprandial should only use the conventional finger-prick test.

COST IMPACT

The Accu-Chek Go[®] glucose meter costs approximately \$109 (Roche Diagnostics Australia Pty Limited). Glucose test strips and lancets made available through the National Diabetic Supply Scheme, cost \$13 (packet 100) and A\$16 (packet of 200), respectively and would cost

a total of approximately 64 cents per day if patients tested three times daily (personal communication, Diabetes South Australia). A standard blood glucose monitor, such as the Roche Diagnostic Accu-Chek Advantage 3, currently costs \$70 and has a lifetime guarantee (Roche Diagnostics Australia Pty Limited).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

CONCLUSION:

The uptake of this technology in Australia has been rapid, with high patient satisfaction with the device. Low level evidence demonstrates a good correlation between blood glucose readings with the alternative site tester and the reference standard finger-prick test.

HEALTHPACT ACTION:

Therefore it is recommended that this technology be referred to the Diabetes section of the Department of Health and Ageing.

SOURCES OF FURTHER INFORMATION:

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SEARCH CRITERIA TO BE USED:

Diabetes Mellitus/*blood/complications/prevention & control

Patient Satisfaction

Pain/etiology/prevention and control

Glucose/administration and dosage/metabolism/pharmacology

Hypoglycemic Agents/*chemical synthesis/*therapeutic use

Insulin/*chemical synthesis/*therapeutic use

Hemoglobin A, Glycosylated/*analysis/metabolism

Blood Glucose/*analysis/metabolism

Blood Glucose Self-Monitoring/instrumentation/*methods

Body Fluid Compartments/physiology

Capillaries

Abdomen/blood supply

Fingers/blood supply

Forearm/blood supply

Leg/*blood supply

Arm/*blood supply

Skin/anatomy & histology/blood supply

Extracellular Fluid/physiology

APPENDIX

The Clarke error grid analysis

Paired data points are placed in five categories, where regions A and B are considered clinically accurate or acceptable, regions C to E show increasing error and the possibility of adverse clinical outcomes (Clarke et al 1987).

