
MSAC Application
1243:

Decision Analytic
Protocol (DAP) to
guide the assessment
of removal of
imbedded corneal
foreign body

September 2013

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MSAC and PASC

The Medical Services Advisory Committee (MSAC) is an independent expert committee appointed by the Australian Government Health Minister to strengthen the role of evidence in health financing decisions in Australia. MSAC advises the Commonwealth Minister for Health and Ageing on the evidence relating to the safety, effectiveness, and cost-effectiveness of new and existing medical technologies and procedures and under what circumstances public funding should be supported.

The Protocol Advisory Sub-Committee (PASC) is a standing sub-committee of MSAC. Its primary objective is the determination of protocols to guide clinical and economic assessments of medical interventions proposed for public funding.

Purpose of this document

This document is intended to provide a draft decision analytic protocol (DAP) that will be used to guide the assessment of a service to remove an imbedded corneal foreign body for any person presenting to an optometrist. The draft protocol will be finalised after inviting relevant stakeholders to provide input. The final protocol will provide the basis for the assessment of the intervention.

The protocol guiding the assessment of the health intervention has been developed using the widely accepted "PICO" approach. The PICO approach involves a clear articulation of the following aspects of the research question that the assessment is intended to answer:

- P**atients – specification of the characteristics of the patients in whom the intervention is to be considered for use;
- I**ntervention – specification of the proposed intervention;
- C**omparator – specification of the therapy most likely to be replaced by the proposed intervention; and
- O**utcomes – specification of the health outcomes and the healthcare resources likely to be affected by the introduction of the proposed intervention.

Purpose of application

An application requesting MBS listing of removal of imbedded corneal foreign body (CFB) for any person presenting to an optometrist was received from Optometrists Association Australia by the Department of Health and Ageing in February 2011. The application relates to a new item by which optometrists may bill for the service described. Under current arrangements billing occurs under MBS item number 42644 for provision of the service by general practitioners and ophthalmologists, and alternatively, the service is provided by hospital emergency departments. The applicants state that optometrists currently perform the removal of imbedded CFBs, and that the introduction of a new MBS item is unlikely to change practice to any large degree, but will allow optometrists to be reimbursed appropriately.

An independent evaluator group, as part of its contract with the Department of Health and Ageing, has drafted this decision analytic protocol to guide the assessment of the safety, effectiveness and cost-effectiveness of the proposed intervention in order to inform MSAC's decision-making regarding public funding of the intervention.

Background

Current arrangements for public reimbursement

Under current arrangements, ophthalmologists and general practitioners are able to bill for removal of CFB under MBS item number 42644 (Table 1). Medicare statistics¹ for billing of item 42644 provide an indication of the incidence of imbedded CFB injuries in Australia. Based on MBS data, this service was claimed a total of 26,457 times during the 2010-2011 financial year. Data from the BEACH survey of 2000-2007 reported a national annual estimate of general practice encounters involving a foreign body in the eye of 102,000 (AIHW 2009a).

However, it is acknowledged that patients have several options for accessing this service, and that billing of item 42644 by ophthalmologists or general practitioners does not provide the complete picture.

Alternatively, patients can access the service through a hospital emergency department (ED). The National Hospital Morbidity Database² indicates that there were a total of 84

¹ https://www.medicareaustralia.gov.au/statistics/mbs_item.shtml

² <http://www.aihw.gov.au/national-hospital-morbidity-database/>

procedures involving the removal of imbedded CFB during the 2009-2010 financial year, with data from previous years showing little change over time.

Furthermore, optometrists currently perform the procedure of removing imbedded CFBs, without a specific item number. It is therefore difficult to estimate the number of procedures currently being performed by optometrists under non-specific attendance items (such as 10900 and 10913). The applicants have suggested that optometrists currently perform this procedure 10 times per year. It is therefore estimated that approximately 35,000 CFB removal procedures are performed in Australia by optometrists per annum.³

Table 1: Current MBS item descriptor for item 42644

Category 3 - THERAPEUTIC PROCEDURES
<p>MBS 42644</p> <p>CORNEA OR SCLERA, removal of imbedded foreign body from – not more than once on the same day by the same practitioner (excluding aftercare) (Anaes.)</p> <p>Fee: \$72.15 Benefit: 75% = \$54.15 85% = \$61.35</p> <p>T8.80 Imbedded Foreign Body (Item 42644)</p> <p>For the purpose of item 42644, an imbedded foreign body is one that is sub-epithelial or intra-epithelial and is completely removed using a hypodermic needle, foreign body gouge or similar surgical instrument with magnification provided by a slit lamp biomicroscope, loupe or similar device.</p> <p>Item 42644 also provides for the removal of rust rings from the cornea, which requires the use of a dental burr, foreign body gouge or similar instrument with magnification by a slit lamp biomicroscope.</p> <p>Where the imbedded foreign body is not completely removed, benefits are payable under the relevant attendance item.</p>

Regulatory status

The proposed changes to provision of the service would fall under the current regulatory requirements for accreditation and training of optometrists. In order to practice optometry in Australia, it is a requirement that registration is first obtained from the Optometry Board of Australia (OBA), unless otherwise registered as a medical practitioner (OBA 2010a; OBA 2012).

³ Based on a 2006 ABS Census of Population and Housing, there were 3,329 FTE optometrists in the Australian health workforce AIHW (2009b). *Eye health labour force in Australia.*, Australian Institute of Health and Welfare, Canberra..

Intervention

Description

An imbedded corneal foreign body is any object which has entered and lodged within the tissues of the cornea. Typical examples include both organic and inorganic materials such as dirt, glass, wood, plastic and metal. These materials may be introduced into the eye by natural means such as the wind, during the operation of machinery or tools (e.g. hammering or grinding), or by any number of other accidental or even deliberate means. Patients generally present with unilateral symptoms including irritation or foreign body sensation, pain, tearing, blurred vision and red eye. Macroscopic signs may include obvious adherence of foreign material to the ocular surface, linear corneal scratches, presence of a corneal 'rust ring' due to a metallic CFB containing iron, oedema with corneal infiltrates and subconjunctival haemorrhage.

Management of a patient presenting with a CFB in the first instance requires irrigation with saline, which may be sufficient to clear loosely adherent particles, and identification of all particles. Slit lamp examination is then used to determine how deeply the CFB has lodged. Following application of a topical anaesthetic, a hypodermic needle, spud or other purposely designed instrument is used to remove the foreign body (see Figure 1). The aim is to remove the foreign body with as little as possible disruption of the surrounding tissues. This reduces the risk of corneal scar tissue formation and provides the best conditions for uncomplicated recovery (COO 2011; NSWDH 2009).



Figure 1 Examples of spuds used in the removal of corneal foreign bodies (GLC 2012).

In cases of metallic CFB, recent clinical guidelines suggest that rust rings should be removed with an appropriate rotary burr (e.g. Algerbrush) (COO 2011). Rust which remains deposited

in the cornea after the foreign body removal is believed to delay healing of the residual defect to the corneal epithelium (Jayamanne & Bell 1994).

Delivery of the intervention

In the clinical setting, guidelines developed in Australia suggest that the initial examination for a patient presenting with a possible CFB should include a visual acuity test and slit lamp examination to assess the size, site(s), nature and depth of the imbedded material (NSWDH 2009). Eversion of the eyelids is also recommended to exclude multiple foreign bodies which could be retained in the conjunctival tissues as well as the cornea. Any loose material can be washed away with saline irrigation, while foreign bodies on the conjunctiva can be removed with the aid of a cotton bud. The extent of epithelial damage to the cornea is conventionally assessed by instilling fluorescein. At this point, a range of tests are carried out to rule out penetrating injuries, which would require referral to an ophthalmologist. Typically, the anterior chamber, iris, pupil and lens are examined, but a test of intraocular pressure (IOP) may also be performed. A negative Seidel test is considered necessary to exclude the leakage of aqueous humour which is an indication of penetrating ocular trauma (Cao & Hackett 2011; COO 2011; NSWDH 2009).



Figure 2 Foreign body removal using a 25 gauge needle as viewed from the slit lamp. Note the tip of the needle is angled away from the globe, minimising the risk of perforation to the cornea (NSWDH 2009).

Having ruled out penetrating trauma, a topical anaesthetic such as amethocaine (1% solution) is applied prior to removing the foreign body with an appropriately selected instrument. A hypodermic needle is common, and in order to avoid corneal perforation, a tangential approach as shown in Figure 2 is required. During the procedure, it is also important that patient's head is kept steady on the head rest of the slit lamp. Following CFB removal, debridement of the corneal epithelium may be performed to eliminate any rust ring that may be present. Low-speed burrs (e.g. an Algerbrush, see Figure 3) are commercially available for this purpose, but in the case of superficially imbedded CFBs, a needle tip can also be used. The Algerbrush has an inbuilt mechanism that leads to shut-off as soon as

contact is made with Bowman's layer, the corneal layer directly below the epithelium, and therefore perforation of the cornea with this device is rare (COO 2011; NSWDH 2009; Smay 2002).



Figure 3 The Algerbrush with 0.5mm burr attachment (STAR 2012).

Following removal of the CFB, visual acuity testing is repeated and the remaining epithelial defect is reassessed. The defect is analogous to a corneal abrasion, and therefore prescription of topical antibiotics is generally included as routine aftercare to prevent infection. In the case of large remnant defects, a cycloplegic agent such as homatropine prevents pupil spasm and helps with patient comfort. Systemic analgesia is provided as necessary. The practice of padding the eye appears controversial and of limited utility based on evidence from a recent Cochrane review, and therefore current guidelines recommend that this practice is avoided. If the patient is accustomed to wearing contact lenses, it has been suggested that lens wear is discontinued until full healing of the defect has occurred and normal sensation has been re-established for a week (COO 2011; NSWDH 2009; Turner & Rabiou 2006).

Removal of a CFB is unlike the treatment of ongoing conditions which require a continuing course of treatment, and therefore the frequent repetition of the procedure for a given patient is considered to be improbable within the course of single year. However, a CFB is acquired independently of previous occurrences of CFB injury and previous successful treatment (i.e. it is a random event). Therefore the service cannot be considered a "once yearly" or "once-off" lifetime intervention.

To ensure safe and effective patient care it is necessary to identify potential limitations to the provision of CFB removal through optometrists. There are several clinical indications where it is likely to be inappropriate for patients to be treated within optometric practice, and referral to an ophthalmologist will therefore be necessary in cases with more complex clinical profiles. For example, the College of Optometrists⁴ (COO) guideline on CFB management recommends that referral to an ophthalmologist is warranted in instances of deeply imbedded bodies (COO 2011). The definition of what is considered to be deep is not provided in the guideline, however some ophthalmologists have suggested penetration through more than 25 per cent of the cornea should not be removed using the procedures specified above (Bashour 2010). This is supported by the expert advice of an optometrist on HESP⁵. Expert advice further suggests that depth of penetration is able to be judged with reasonable accuracy using a slit lamp. Deeply imbedded bodies require that the patient is admitted to the operating theatre for removal under sedation or general anaesthesia. If an ophthalmologist is not available, optometrists may refer to an emergency department for treatment.

Other reasons for referral (i.e. clinical scenarios contraindicating intervention by an optometrist) include:

- presence of hyphaema (blood in the anterior chamber);
- laceration of the cornea or sclera;
- lid oedema;
- diffuse subconjunctival haemorrhage;
- dilation or abnormal shape of pupil;
- and abnormally shallow or deep anterior chamber in comparison to the other eye (Bashour 2010).

These conditions are frequently indicative of a penetrating injury, a condition necessitating management by an ophthalmologist.

Matters concerning appropriate referral and patient indications for this service would need to be determined as part of the evaluation.

Prerequisites

All optometrists who are registered with the Optometry Board of Australia (OBA) are accredited to remove an imbedded CFB, with no additional accreditation legally necessary to perform this procedure. However, the clinical skill sets of individual optometrists vary

⁴ United Kingdom

⁵ Expert advice optometrist and HESP member , received via email 12th November, 2012

considerably and therefore not all practising optometrists are confident and willing to remove CFBs. A survey targeting all optometrists within the Queensland division of the Optometry Association of Australia (OAA) found that education was the most significant factor influencing the number of procedures those optometrists were comfortable performing (51% were confident to remove a CFB), and that optometrists who were accredited to prescribe therapeutic medications were more familiar with the range of procedures they were questioned about in the survey ($p=0.002$) (Schmid et al 2000).

Over the last 15 years optometric practise and education has changed considerably as a result of legislative measures. Prior to the appointment of the OBA as the national body, optometry was governed by state and territory legislation alone. In 1996, legislative changes by the Victorian state government allowed appropriately trained optometrists to prescribe Schedule 4 drugs, and teaching of optometry at both undergraduate and postgraduate levels moved in response to the new law. The University of Melbourne made changes to accommodate relevant content on the use of pharmaceuticals in optometric practice as part of its Bachelor of Optometry degree, and similarly, tertiary institutions in Queensland and New South Wales (NSW) introduced postgraduate courses in ocular therapeutics. Since then, the regulation of optometry practice in Australia has transitioned to a model of registration at the national level rather than registration occurring within the individual states and territories. The OBA is the national body whereby optometrists are accredited under the authority of the Health Practitioner Regulation National Law (2009). Pursuant to this law, the Australian Health Workforce Ministerial Council (AHWMC) authorises all the board's executive actions, including endorsements, training, continuing professional development (CPD) and listing drugs approved for use in optometry settings (DOVS 2011; OBA 2010a; OBA 2010b). In addition to OBA accredited university-based training, organisations such as the Australian College of Optometrists (ACO) offer a range of education opportunities that can count towards the CPD requirements for national registration. Formats include seminars, clinical workshops, refresher courses, national conferences and webinars (ACO 2012). Conceivably, optometrists who do not currently have sufficient skills for CFB removal but want to acquire this expertise could gain the required experience through these types of courses and workshops. PASC was advised that the ACO has recently developed a protocol for CFB removal and that this should be described in the assessment. PASC also advised that training requirements for optometrists with respect to CFB removal should be documented in the assessment but that no further consideration of training would be necessary.

Co-administered and associated interventions

Examination and management of CFB by an optometrist usually requires services in addition to removal of the foreign body itself. The cornea is highly innervated, and any procedure where an instrument contacts the surface of the globe generally requires anaesthesia.

At the examination stage, application of fluorescein is required to assess the extent of the corneal or epithelial damage. Examination can be conducted using visual acuity and slit lamp tools. A cycloplegic agent (e.g. homatropine 2%, (NSW Department of Health 2009)) may be applied to assist in observation of the posterior segment to rule out intraocular penetration, but can also assist in relieving discomfort for the patient. Orbital x-rays may be indicated for high velocity injuries (Feizerfan A 2010).

Topical anaesthesia is used prior to CFB removal due to pain associated with the injury and the procedure. Suggested medications are amethocaine 1% (NSW Department of Health 2009), and tetracaine 0.5% (Feizerfan A 2010). The amount required may be determined by individual patient need and by the injury involved. Oral analgesia may also be required (NSW Department of Health 2009).

In most cases of imbedded CFB removal, prophylactic treatment with topical antibiotics would be prescribed. Broad spectrum antibiotics are often recommended such as chloramphenicol and fucithalamic (as ointments four times daily and twice daily respectively) and were suggested by Accident and Emergency CFB management recommendations published in *Clinical Governance: An International Journal*, in 2010 (Feizerfan A 2010)⁶. In one study of presentation and treatment of metal CFB in an emergency department, patients were given prophylactic antibiotic treatment with either chloramphenicol 1% ointment, chloramphenicol 0.5% eye drops or topical ofloxacin hydrochloride 0.3% (Ramakrishnan et al 2012).

Removal of rust rings may be necessary if the CFB is metallic in nature. Item 42644 provides for the removal of rust rings from the cornea which normally requires the use a dental burr or similar tool and would be carried out under magnification by a slit lamp biomicroscope.

Removal of CFB usually requires a follow-up consultation. The treating optometrist should check for adequate healing, complete removal of rust rings, previously undetected FBs or other problems. One source recommends follow-up within 72 hours of treatment in EDs but to return earlier if there is no improvement within 24 hours. Referral to an ophthalmologist is recommended when examination detects a penetrating trauma, an injury of size or difficulty factor beyond the skills of the optometrist, or if the treated patient does not improve or develops complications such as infection or ulceration (NSW Department of Health 2009; Feizerfan A 2010).

Details of the identified healthcare resources are summarised in Table 7, page 22.

⁶ These are UK recommendations. Note that fucithalamic ointments/eye drops (active ingredient fusidic acid) are do not have ARTG listing for ophthalmic indications.

Listing proposed and options for MSAC consideration

Proposed MBS listing

The proposed MBS item descriptor for removal of CFB by optometrist is shown in Table 2. The wording of the proposed item is based on MBS item 42644, for removal of CFB by an ophthalmologist (with the omission of the word 'sclera'). Should the proposed MBS item be approved, the Department of Health and Ageing recommends that additional explanatory notes be added to para O6 of the Medicare Benefits Schedule Book Optometrical Services Schedule, as shown in Table 2.

A fee of \$90.25 was proposed by the applicants, based on direct and indirect practice costs and modelling data. The fee was proposed to cover the procedure, which could be claimed as a stand-alone item, or could be used in conjunction with consultation items. In contrast, GPs and ophthalmologists would always use item 42644 in conjunction with consultation items. PASC recommended the proposed fee of \$90.25 be reduced to \$72.15 in alignment with the fee charged by the same service when performed by GPs and ophthalmologists (Table 2). This fee may be able to be charged alongside consultation items 10900, 10913 or 10916, as appropriate.

Table 2: Proposed MBS item descriptor for removal of CFB by optometrist

Group A10 – OPTOMETRIC SERVICES	
MBS item [xxxxx]	
CORNEA, removal of imbedded foreign body from – not more than once on the same day by the same practitioner (excluding aftercare).	
Fee: \$72.15	85% = \$61.33
For the purpose of item [xxxxx], an imbedded foreign body is one that is sub-epithelial or intra-epithelial and is completely removed using a hypodermic needle, foreign body gouge or similar surgical instrument with magnification provided by a slit lamp biomicroscope, loupe or similar device.	
Item [xxxxx] also provides for the removal of rust rings from the cornea, which requires the use of a dental burr, foreign body gouge or similar instrument with magnification by a slit lamp biomicroscope.	
Where the imbedded foreign body is not completely removed, benefits are payable under the relevant attendance item (10916, 10900 or 10913).	
When charging item [xxxxx], the optometrist should document the nature of the imbedded foreign body, sub-epithelial or intra-epithelial, and whether removal was undertaken using a hypodermic needle, foreign body gouge or similar surgical instrument with magnification provided by a slit lamp biomicroscope, loupe or similar device. The optometrist should also document whether rust rings were removed from the cornea using a dental burr, foreign body gauge or similar instrument with magnification by a slit lamp biomicroscope.	
Item [xxxxx] is to be billed in association with MBS item 10916 or item 10900 or 10913 depending on the length of consultation required to remove the foreign body.	

Any person presenting to and receiving treatment from an optometrist for an imbedded corneal foreign body would be eligible to receive subsidy covered under the proposed MBS item.

In the case of a person with CFB presenting to a GP who is unable to remove the object themselves, the patient may need to be referred to the closest available optometric service or emergency department (Christopher Hodgeg 2008). People living in rural areas are more likely to be treated by an optometrist than an ophthalmologist, given the scarcity of ophthalmologists in rural areas⁷.

Any person presenting with a CFB would be eligible to access optometric services for removal of the body. If the complexity of the operation was beyond the skill of the optometrist, or if other complications were present (e.g. globe perforation, penetration >25%, or if the patient is unable to hold still due to pathological anxiety, nystagmus, or tremor etc, without some form of systemic medication⁸) it would be expected that the patient would be referred to an ophthalmologist.

Clinical place for proposed intervention

CFB is a common cause of eye injury and a frequent cause for attendance at a general practitioner clinic, optometrist or emergency service. A large proportion of CFB occurs in the male population, of working age, employed in industrial type settings where metallic fragments are created, or who work at home with grinding equipment or other metal working tools (Ramakrishnan et al 2012; Feizerfan A 2010; Australian Safety and Compensation Council 2008).

A CFB normally requires prompt removal as it can induce an inflammatory reaction within the eye. Symptoms can include a gritty sensation, lacrimation (reflex tears), blurred vision and photophobia, and the patient will usually require pain relief. Infection and tissue necrosis can occur without treatment.

Under the current treatment algorithm (illustrated in Figure 4) a patient would normally seek assistance from a convenient service provider such as an emergency department, GP clinic or an optometrist, following which the CFB will be removed. If removal is beyond the skill of the practitioner or other complications are present, the patient will be referred.

In the current scenario the optometrist will claim the service under a non-specific attendance fee item (10900, 10913 or 10916). If removal is beyond the skill of the optometrist, they would claim a standard consultation item (MBS item 10916) and refer patients to either an ophthalmologist or, in the absence of an ophthalmologist, an

⁷ Expert advice from optometrist and HESP member , received via email 12th November, 2012

⁸ Expert advice from optometrist and HESP member , received via email 12th November, 2012

emergency department, or hospital eye department⁹, if available. If removed by an ophthalmologist, the service would be claimed under consultation item 104 and procedure item 42466, and if removed within a public hospital (emergency or eye department), the service would be claimed through the appropriate pathway.

If a patient were to attend a GP clinic, the practitioner may assess the injury, and either treat it if she/he had the skills to do so (claiming consultation item 23 and procedure item 42466), or refer the patient to optometric, ophthalmologic or emergency department/eye department, claiming just the consultation item (item 23). Similarly if a patient attended an emergency department, a practitioner may assess and remove the CFB, forward onto an eye department within the hospital if available, or refer the patient to an ophthalmologist or possibly an optometrist.

In the proposed treatment algorithm (illustrated in Figure 5) pathways will be identical to the current scenario with the exception that optometrists will claim a specific fee for the removal of corneal foreign bodies using the new item number, which may be used in conjunction with currently available consultation items.

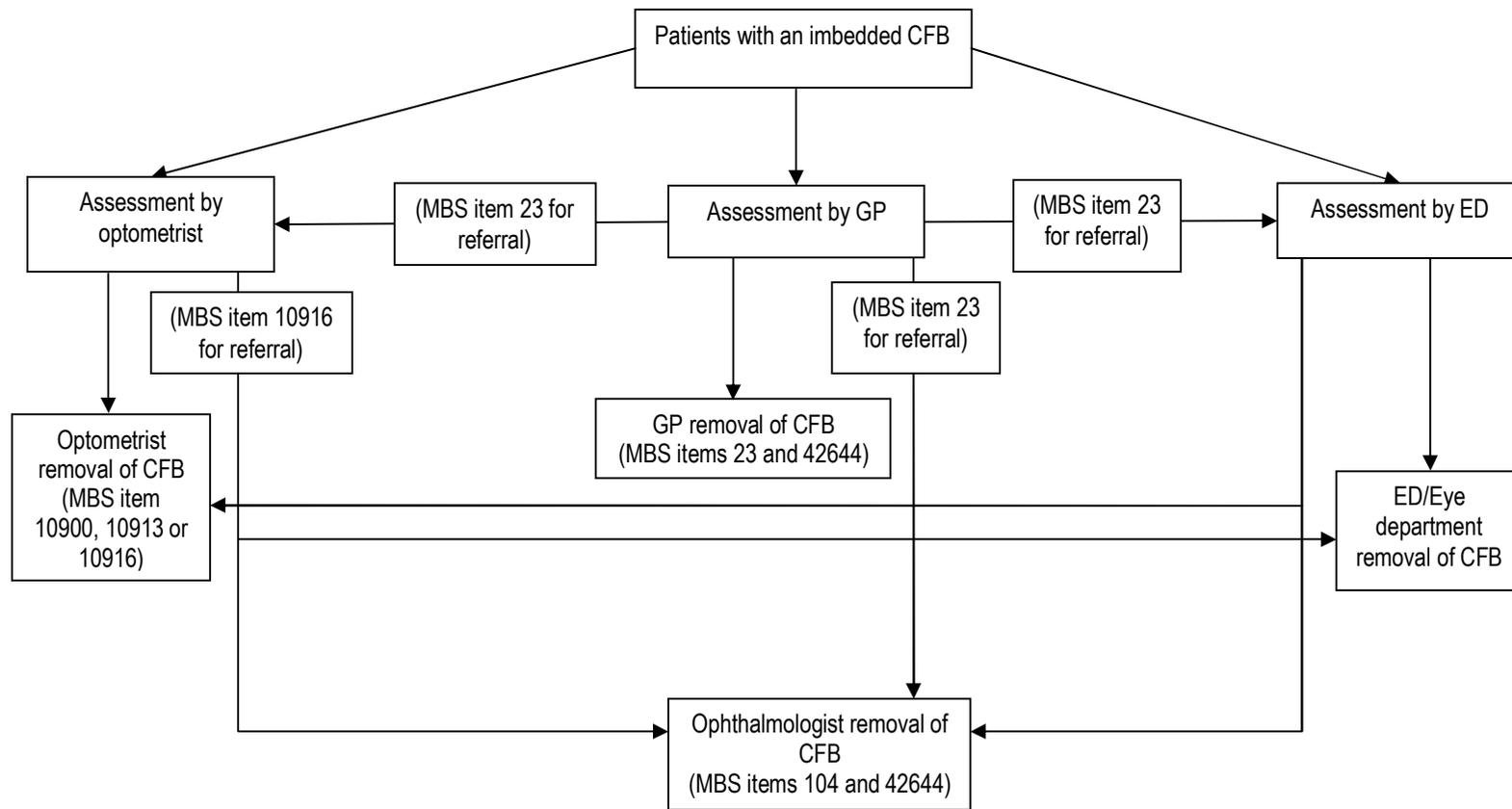
It is proposed that by providing an additional MBS item under which an optometrist can claim for removal of a CFB, there is unlikely to be a change in practice, as optometrists currently perform the procedure. Expert advice supports this statement¹. However, the applicants have suggested that if public knowledge increases that optometrists may perform CFB removal, then there may be an increased proportion of these services performed by optometrists. The applicants claim that the most effective clinical care pathway for removal of CFB is through an optometrist consultation as there are reduced waiting times for optometric appointments, in comparison to ophthalmologists.

It is assumed that currently, GPs may refer people to ophthalmologists more than optometrists, given that optometrists are unable to treat the more complex cases, however, data on referral patterns would need to be included in the evaluation. Expert advice suggests that a new MBS item is unlikely to directly change referral patterns for removal of imbedded CFBs¹⁰.

⁹ Expert advice from optometrist and HESP member , received via email 15th November, 2012

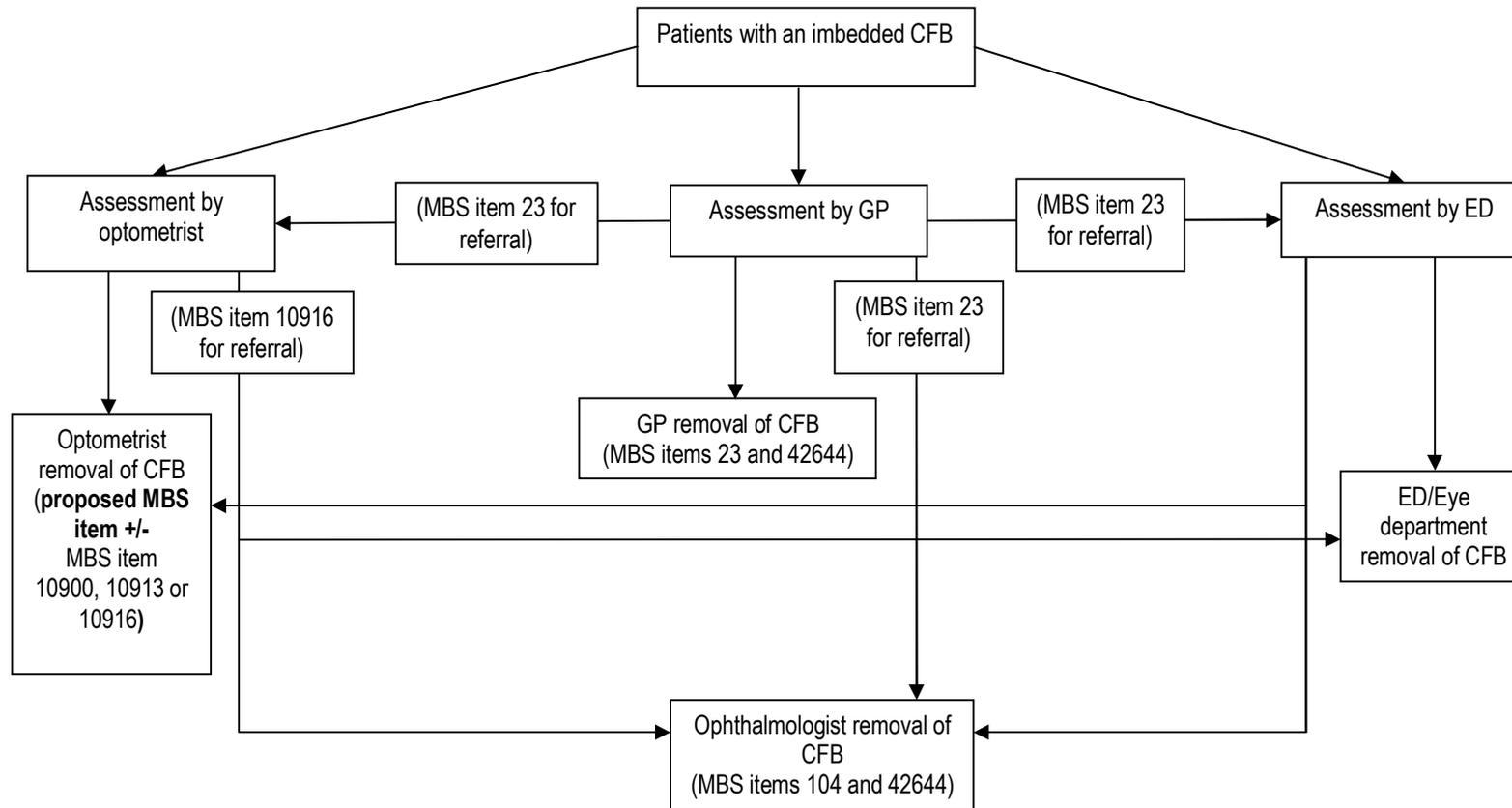
¹⁰ Expert advice from optometrist and HESP member , received via email 12th November, 2012

Figure 4 Algorithm for current pathways for assessment and treatment of patients with an imbedded CFB



GP=general practitioners; ED=emergency department; CFB=corneal foreign body

Figure 5: Algorithm for proposed pathways for assessment and treatment of patients with an imbedded CFB



GP=general practitioners; ED=emergency department; CFB=corneal foreign body

Comparator

The comparator for this application is current clinical practice. In current clinical practice the optometrist claims the service as a standard attendance item following assessment and treatment of a patient with an imbedded CFB (MBS item 10900 or 10913; see Table 3). If the attendance is less than 15 minutes, then optometrists would claim MBS item 10916. Alternatively the optometrist refers the patient to an ophthalmologist and claims under a short standard attendance fee item (MBS item 10916, see Table 3). The ophthalmologist would claim for removal of imbedded CFB under item 42644 (see Table 4) in addition to a consultation fee for professional attendance (item 104). In cases where an ophthalmologist is not available, optometrists may also refer patients to the emergency department or hospital eye department. These pathways are demonstrated in Figure 4 and Figure 5.

Note that not all patients with CFB are currently assessed and treated by optometrists. Some patients are initially assessed by a GP or emergency department and treatment may also be received in those environments. GPs may claim MBS item 42644 for removal of the CFB (see Table 4) in addition to a consultation fee (item 23). Alternatively the GP or emergency department may refer the patients to an ophthalmologist or optometrist. If this is the case, the GP would claim just the consultation item (see Table 3). The ophthalmologist would claim item 42644 plus a professional attendance consultation fee (item 104), whereas the optometrist would currently claim item 10900, 10913 or 10916. These treatment pathways are also part of current clinical practice.

It should be noted that a direct comparison of the safety and effectiveness of CFB removal by optometrists against other specialties (or a comparison of CFB removal under slit-lamp versus loupe) is only relevant if the introduction of the MBS item is likely to change which specialty patients are treated by.

Table 3: MBS item descriptors for relevant professional attendances

Category 1 – PROFESSIONAL ATTENDANCES	
MBS 10900	<p>COMPREHENSIVE INITIAL CONSULTATION</p> <p>Professional attendance of more than 15 minutes duration, being the first in a course of attention - not payable within 24 months of an attendance to which item 10900, 10905, 10907, 10912, 10913, 10914 or 10915 applies</p> <p>Fee: \$71.00 Benefit: 85% = \$60.35</p> <p>(See para O6 of explanatory notes to this Category)</p>
MBS 10913	<p>Professional attendance of more than 15 minutes duration, being the first in a course of attention,</p>

where the patient has **new signs or symptoms**, unrelated to the earlier course of attention, requiring comprehensive reassessment within 24 months of an initial consultation to which item 10900, 10905, 10907, 10912, 10913, 10914 or 10915 at the same practice applies

Fee: \$71.00 **Benefit:** 85% = \$60.35

(See para [O6](#) of explanatory notes to this Category)

MBS 10916

BRIEF INITIAL CONSULTATION

Professional attendance, being the first in a course of attention, of not more than 15 minutes duration, not being a service associated with a service to which item 10931, 10932, 10933, 10940, 10941, 10942 or 10943 applies

Fee: \$35.55 **Benefit:** 85% = \$30.25 (See para [O6](#) of explanatory notes to this Category) (See para [O6](#) of explanatory notes to this Category)

MBS 23

CONSULTATION AT CONSULTING ROOMS

Professional attendance at consulting rooms

Fee: \$36.30 **Benefit:** 100% = \$36.30 (See para A5 of explanatory notes to this Category)

MBS 104

SPECIALIST, REFERRED CONSULTATION – SURGERY OR HOSPITAL

(Professional attendance at consulting rooms or hospital by a specialist in the practice of his or her specialty where the patient is referred to him or her)

INITIAL attendance in a single course of treatment, not being a service to which ophthalmology items 106, 109 or obstetric item 16401 apply.

Fee: \$85.55 **Benefit:** 75% = 64.20 85% = \$72.75

Table 4 MBS item descriptor for relevant procedure (item 42644)

Category 3 – THERAPEUTIC PROCEDURES	
MBS 42644	<p>CORNEA OR SCLERA, removal of imbedded foreign body from – not more than once on the same day by the same practitioner (excluding aftercare) (Anaes.)</p> <p>Fee: \$72.15 Benefit: 75% = \$54.15 85% = \$61.35</p> <p>T8.80 Imbedded Foreign Body (Item 42644)</p> <p>For the purpose of item 42644, an imbedded foreign body is one that is sub-epithelial or intra-epithelial and is completely removed using a hypodermic needle, foreign body gouge or similar surgical instrument with magnification provided by a slit lamp biomicroscope, loupe or similar device.</p>

Item 42644 also provides for the removal of rust rings from the cornea, which requires the use of a dental burr, foreign body gouge or similar instrument with magnification by a slit lamp biomicroscope.

Where the imbedded foreign body is not completely removed, benefits are payable under the relevant attendance item.

Outcomes for safety and effectiveness evaluation

The health outcomes, upon which the comparative clinical performance of

Optometrist removal of an imbedded CFB (claimed using proposed optometric procedural item with/without the current consultation item 10900, 10913 or 10916) in addition to current clinical practice,

versus

Optometrist assessment and removal of an imbedded CFB (claimed using the current consultation item 10900, 10913, or 10916), in addition to current clinical practice - involving an assessment by an optometrist, GP or hospital emergency department and subsequent referral to an ophthalmologist for removal (claimed under item 42644), or assessment and removal of an imbedded CFB by a GP or hospital emergency department/eye department, or assessment by a GP or emergency department and subsequent referral to an optometrist for removal (claimed under item 10900, 10913 or 10916), or assessment by optometrist and referral to emergency department/eye department for removal of imbedded CFB,

in patients with an imbedded object injury to the cornea will be measured, are:

Effectiveness

Primary outcomes:

Visual acuity

Secondary outcomes:

Time to resolution of eye injury

Patient satisfaction

Additional follow-up visits required

Safety

Adverse events from procedure

Adverse events due to miscalculating depth of penetration or perforation (error in diagnosis)

Summary of PICO to be used for assessment of evidence (systematic review)

Table 5 provides a summary of the PICO used to:

- (1) define the question for public funding, and
- (2) select the evidence to assess the safety and effectiveness of introducing a specific MBS item for optometrists to remove an imbedded CFB, to be used in addition to the current consultation items and current clinical practice.

Table 5 Summary of PICO to define research questions that assessment will investigate

Patients	Intervention	Comparator	Outcomes to be assessed
Patients with an imbedded object in the cornea	Assessment and removal of an imbedded CFB by optometrist, claiming funds using a proposed new procedural item as a stand-alone item or in combination with an optometric consultation item in addition to current clinical practice (see Comparator column)	a) Assessment and removal of an imbedded CFB, claiming funds using an optometric consultation item, in addition to current clinical practice - involving b) Assessment by Optometrist, GP or ED and referral to ophthalmologist for removal; or c) Assessment and removal by GP or ED/eye department; or d) Assessment by optometrist or GP and referral to ED/eye department for removal; or e) Assessment by ED or GP and referral to optometrist for removal	Safety Adverse events from procedure Adverse events due to miscalculating depth of penetration or perforation Effectiveness Primary: Visual acuity Secondary: Time to resolution of eye injury Patient satisfaction Additional follow-up visits required Cost-effectiveness Cost
Questions			
1. Is the assessment and removal of an imbedded CFB by an optometrist, claiming a specific optometric CFB removal item (as a stand-alone item or in addition to a consultation item), in addition to current clinical practice, as safe, and effective as assessment by an optometrist and removal of an imbedded CFB, claiming an optometric consultation item, in addition to current clinical practice?			

Note: CFB = corneal foreign body; GP = general practitioner; ED=hospital emergency department

Clinical claim

The applicants claim that that current clinical pathway is identical to the proposed clinical pathway, as optometrists already perform removal of imbedded CFBs. They also state that removal of imbedded CFBs by optometrists would be non-inferior to removal of imbedded

CFBs by ophthalmologists or general practitioners, as funded under MBS item 42644. However, the addition of a new MBS item for the procedure, which may be used in addition to the consultation item, would result in an increase in fees to the MBS. The economic analysis is therefore likely to be purely a financial incidence analysis, outlining the additional cost of adding the proposed MBS item number, for no additional health benefits.

Expert advice suggests that CFB removal which occurs with the use of a slit lamp (i.e. by optometrists or ophthalmologists) rather than a loupe¹¹ (i.e. by a GP or emergency department), is likely to be associated with fewer complications and better healing. However, these considerations are only relevant to the MSAC submission if the new MBS item is likely to result in a shift of patients choosing to see an optometrist rather than a GP or emergency department.

Should evidence be available that this change in management is likely to occur, or that the introduction of a new MBS item is likely to alter management in a different way as to impact on the safety or effectiveness of CFB removal, then a cost-effectiveness analysis or cost utility analysis would be required.

Table 6: Classification of a new item for CFB removal for determination of economic evaluation to be presented

		Comparative effectiveness versus comparator					
		Superior		Non-inferior	Inferior		
Comparative safety versus comparator	Superior	CEA/CUA		CEA/CUA		Net clinical benefit	CEA/CUA
						Neutral benefit	CEA/CUA*
						Net harms	None [^]
	Non-inferior	CEA/CUA		CEA/CUA*	None [^]		
	Inferior	Net clinical benefit	CEA/CUA	None [^]			
		Neutral benefit	CEA/CUA*				
Net harms		None [^]					

Abbreviations: CEA = cost-effectiveness analysis; CUA = cost-utility analysis

* May be reduced to cost-minimisation analysis. Cost-minimisation analysis should only be presented when the proposed service has been indisputably demonstrated to be no worse than its main comparator(s) in terms of both effectiveness and safety, so the difference between the service and the appropriate comparator can be reduced to a comparison of costs. In most cases, there will be some uncertainty around such a conclusion (i.e., the conclusion is often not indisputable). Therefore, when an assessment concludes that an intervention was no worse than a comparator, an assessment of the uncertainty around this conclusion should be provided by presentation of cost-effectiveness and/or cost-utility analyses.

[^] No economic evaluation needs to be presented; MSAC is unlikely to recommend government subsidy of this intervention

¹¹ Expert advice from optometrist and HESP member , received via email 12th November, 2012 and second optometrist and HESP member , received via email 15th November, 2012

Outcomes and health care resources affected by introduction of proposed intervention

Outcomes for economic evaluation

Given that it is not expected that a new MBS item for optometrists to remove imbedded CFB would result in any differential patient outcomes, the outcomes for economic evaluation are expected to be reduced to a financial incidence analysis.

Health care resources

The applicants have stated that when the public become more aware that optometrists are able to provide the service of removing CFBs, they are more likely to consider optometrists as the first point of contact, rather than their general practitioner or an emergency department. There may also be a shift towards being referred to optometrists rather than ophthalmologists, given a reduction in waiting times. Under this scenario, the shift in costs from general practice, emergency departments, and ophthalmologists to optometrists would need to be considered. However, expert advice suggests that a new MBS item is unlikely to change referral patterns or clinical outcomes¹².

The applicants have stated that health care resources are unlikely to change as a consequence of public funding for CFB removal by optometrists, stating that practice procedures are not expected to differ greatly. The proposed item will simply be an additional fee to assist in covering the costs associated with performing the procedure.

Table 7: List of resources to be considered in the economic analysis for imbedded CFB removal

	Provider of resource	Setting in which resource is provided	% of patients receiving resource	Number of units of resource per relevant time horizon per patient receiving resource	Disaggregated unit cost					
					MBS	Safety nets*	Other govt budget	Private health insurer	Patient	Total cost
<i>Additional resources provided for an optometrist to remove imbedded CFB with proposed MBS item</i>										
- CFB removal by optometrist	Optometrist	Out-patient		Once (expert opinion)	New item \$61.35					\$61.35 (bulk billed)
<i>Resources provided for an optometrist to remove imbedded CFB under existing MBS item</i>										
- Optometrist consultation (>15 minutes)	Optometrist	Out-patient			items 10900, 10913 \$60.35					\$60.35 (bulk billed)

¹² Expert advice from optometrist and HESP member , received via email 12th November, 2012

	Provider of resource	Setting in which resource is provided	% of patients receiving resource	Number of units of resource per relevant time horizon per patient receiving resource	Disaggregated unit cost						
					MBS	Safety nets*	Other govt budget	Private health insurer	Patient	Total cost	
- Optometrist consultation (<15 minutes)	Optometrist	Out-patient			items 10916 \$30.25						\$30.25
- Drugs (anaesthetic, antibiotic, cycloplegic)	Optometric practice	Out-patient									
- Consumables (bandage contact lens, lubricant)	Optometric practice	Out-patient									
- After care appointment	Optometrist	Out-patient									
Resources provided to refer to ophthalmologist to remove imbedded CFB											
- Assessment and referral	Optometrist	Out-patient			Item 10916 \$30.25						\$30.25
	GP	Out-patient			item 23 \$36.30						\$36.30
- Ophthalmologist consultation	Ophthalmologist	Out-patient			item 104 \$72.75			\$12.80	gap		\$85.55 plus gap
- CFB removal by ophthalmologist	Ophthalmologist	Out-patient			item 42644 \$61.35			\$10.80	gap		\$72.15 plus gap
- After care appointment	Ophthalmologist	Out-patient									
Resources provided for a general practitioner to remove imbedded CFB under existing MBS item											
- GP consultation	General practitioner	Out-patient			Item 23 \$36.30						\$36.30
- CFB removal by GP	General practitioner	Out-patient			item 42644 \$61.35			\$10.80	gap		\$72.15 plus gap
Resources provided for emergency department/eye department to remove imbedded CFB											
- C12 - Other corneal, sclera and conjunctival procedures (AR-DRG v6.0, round 14)*	Public Hospital	Inpatient (ALOS 1.24 days)						\$3,140			\$3,140

*http://www.health.gov.au/internet/main/publishing.nsf/Content/Round_14-cost-reports

Proposed structure of economic evaluation (decision-analytic)

As there is not expected to be any differences in the safety or effectiveness of the removal of CFB using an additional item number, a decision-analytic has not been proposed.

References

- ACO (2012). *Continuing Professional Development – General Information* [Internet]. Australian College of Optometrists. Available from: <http://www.aco.org.au/professional-development/general-information> [Accessed 31 May 2012].
- AIHW (2009a). *Eye-related injuries in Australia*, Australian Institute of Health and Welfare, Canberra.
- AIHW (2009b). *Eye health labour force in Australia*, Australian Institute of Health and Welfare, Canberra.
- Australian Safety and Compensation Council (2008). *Work related eye injury in Australia*.
- Bashour, M. (2010). *Corneal foreign body* [Internet]. WebMD LLC. Available from: <http://emedicine.medscape.com/article/1195581-overview> [Accessed 30 May 2012].
- Cao, C. E. & Hackett, T. S. (2011). *Corneal Foreign Body Removal* [Internet]. WebMD LLC. Available from: <http://emedicine.medscape.com/article/82717-overview#a01> [Accessed 24 May 2012].
- Christopher Hodgeg, M. L. (2008). *Ocular Emergencies*, Sydney.
- COO (2011). *Clinical Management Guidelines, Corneal (or other superficial ocular) foreign body* [Internet]. College of Optometrists. Available from: <http://www.college-optometrists.org/en/utilities/document-summary.cfm/docid/3BA7AC39-4E62-4145-81BA66262CD39DF0> [Accessed 24 May 2012].
- DOVS (2011). *Postgraduate Certificate in Ocular Therapeutics* [Internet]. Department of Optometry and Visual Sciences, University of Melbourne. Available from: http://www.optometry.unimelb.edu.au/courses/PgCert_OcularTh.html [Accessed 31 May 2012].
- Feizerfan A, W. S., Maryosh J, Liyanage SE, (2010). 'Corneal foreign body management in an A & E department', *Clinical Governance: An International Journal*, 15 (4), 266 - 271.
- GLC (2012). *Spud Foreign Body Style* [Internet]. Good-Lite Company. Available from: <https://www.good-lite.com/Details.cfm?ProdID=707> [Accessed 24 May 2012].
- Jayamanne, D. G. & Bell, R. W. (1994). 'Non-penetrating corneal foreign body injuries: factors affecting delay in rehabilitation of patients', *J Accid Emerg Med*, 11 (3), 195-197.
- NSW Department of Health (2009). *Eye Emergency Manual, An Illustrated Guide*, Sydney.
- NSWDH (2009). *Eye Emergency Manual* [Internet]. 2nd. New South Wales Department of Health. Available from: http://www.aci.health.nsw.gov.au/_data/assets/pdf_file/0013/155011/eye_manual.pdf [Accessed 24 May 2012].
- OBA (2010a). *Endorsement for scheduled medicines registration standard* [Internet]. Optometry Board of Australia. Available from: www.optometryboard.gov.au/documents/default.aspx?record=WD10%2f158&dbid=AP&chksum=uA2c3Oie3cwpQqUMXLHfKg%3d%3d [Accessed 23 May 2012].
- OBA (2010b). *Guidelines for use of scheduled medicines* [Internet]. Optometry Board of Australia. Available from: <http://www.optometryboard.gov.au/Policies-Codes-Guidelines.aspx> [Accessed 31 May 2012].

OBA (2012). *When it is necessary to be registered as an optometrist?* [Internet]. Optometry Board of Australia. Available from: <http://www.optometryboard.gov.au/Registration.aspx> [Accessed 23 May 2012].

Ramakrishnan, T., Constantinou, M. et al (2012). 'Corneal metallic foreign body injuries due to suboptimal ocular protection', *Archives of environmental & occupational health*, 67 (1), 48-50.

Schmid, K. L., Schmid, L. M. et al (2000). 'A survey of ocular therapeutic pharmaceutical agents in optometric practice', *Clin Exp Optom*, 83 (1), 16-31.

Smay, J. (2002). *Tools of the Trade: A Review. Optometric Management 2002* [Internet]. Available from: <http://www.optometricmanagement.com/articleviewer.aspx?articleid=70418> [Accessed 24 May 2012].

STAR (2012). *Alger Brush II* [Internet]. STAR Ophthalmic Instruments. Available from: http://www.starophthalmic.com/store/shop/product_info.php?cPath=80_38&products_id=272 [Accessed 24 May 2012].

Turner, A. & Rabiou, M. (2006). 'Patching for corneal abrasion', *Cochrane Database Syst Rev*, (2), CD004764.