Abstract of thesis entitled

"Evidence-based Eye Care Protocol for ICU Patients with Altered Level of Consciousness"

Submitted by

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Life-sustaining measure is the top priority in the intensive care unit (ICU). Eye care is relatively a minor consideration for ICU patients. However, ocular surface diseases (OSDs) occur in 42 to 60 percent of the comatose, sedated, or paralysed patients in the ICU. The consequences of OSDs will lead to unnecessary and preventable suffering of the patients and should not be underestimated. Thus, a standardized and evidence-based eye care protocol is essential in the ICU.

OSDs include corneal or conjunctival abrasion, ulceration, or infection. The altered level of consciousness of patients removes the natural ocular surface defence mechanisms, together with the mechanical ventilation, ICU patients are at risk of OSDs. OSDs can lead to serious eye complications such as corneal perforation,

corneal scarring, or long-term visual deficits. Moreover, unnecessarily prolonged hospitalization can lead to complications like nosocomial infections and burden the healthcare system. In order to reduce the incidence and/or severity of OSDs, studies have suggested a variety of eye care practices, including the application of eye drops, eye ointment, eye cleansing, and eye covers. However, there is no consensus about the effectiveness of different practices, or an evidence-based practice. Moreover, studies have also showed that nurses' awareness of the OSDs and eye care, and a standardized eye care protocol are lacking in United Kingdom and Hong Kong (HK). In an adult ICU of a teaching hospital in HK, OSDs are frequently observed in approximately 40 percent of patients, but there is no standardized eye care protocol. As a result, an evidence-based eye care protocol is necessary to standardize the eye care practice in the target ICU.

The dissertation is a translational research that aims to develop an evidence-based eye care protocol for ICU patients with altered level of consciousness, with implementation and evaluation plans for an ICU setting. The Iowa Model is used to guide the dissertation.

To gather an empirical evidence on the effectiveness of eye care in reducing the incidence and/or severity of OSDs in ICU patients, a systematic literature search has been conducted from October, 2007 to July, 2008, using a number of electronic

searching engines [national guidelines clearinghouse, CMA infobase, Health service/technology assessment text, Guidelines advisory guidelines, Scottish Intercollegiate Guidelines Network, National Institute for Clinical Excellence, New Zealand Guideline Group, Joanna Briggs Institute, Cochrane library (1999-2008), Medline (Ovid SP) (1950-2008), Cumulative Index of Nursing and Allied Health Literature (Ovid SP) (1982-2008), Pubmed (1950-2008), and Yahoo and Google searches], hand searching (Australian Critical Care 2008), reference lists and related articles of the identified studies, and experts consultation. Finally, 13 studies have been selected, which are 1 clinical guideline, 1 systematic review, 6 randomized controlled trials, 2 controlled trials, 1 uncontrolled trial, 1 retrospective before and after interventional study, and 1 prospective cohort observational study.

Findings of the 13 studies have been extracted into the tables of evidence with reference to the “SIGN 50: A guideline developer’s handbook” and critically appraised using the Critical Appraisal Skills Programme (CASP) appraisal tools. The qualities of the studies were then rated, and the levels of evidence of studies were assigned according to “SIGN 50: A guideline developer’s handbook”.

The literature has suggested eye assessments, eye cleansing, eye drops or ointment, and eye covers to ICU patients who are at risk. The studies have showed that unstandardized eye care produced 55.4 percent of OSDs, and grade 1 to 4 OSDs.

However, eye lubricants reduced the incidence of OSDs to 4 to 32 percent, and produced 68 percent of grade 0 OSDs; while eye covers reduced the incidence to 0 to 8 percent and led to 92 percent of grade 0 OSDs. Therefore, eye covers provide a better protection to ocular surface than eye lubricants alone or unstandardized care.

The implementation potential of the eye care innovation has been assured in terms of target setting, target audience, transferability of findings, feasibility, and cost-benefit ratio. Then, the findings of the 13 studies have been translated into an evidence-based eye care protocol. The strengths of recommendations were assigned with reference to “SIGN 50: A guideline developer’s handbook”.

The main components of the protocol are the assessment of the risk factors for incomplete lid closure, the assessments of incomplete lid closure, lid cleanliness, corneal dryness, and signs of OSDs, and the application of soaked gauze lid cleansing, polyethylene cover, and Duratears. Eyes should be covered by polyethylene during tracheal or oropharyngeal suctioning. Medical and ophthalmic consultations are suggested for suspected OSDs. In addition, prevention of conjunctival edema and ventilator-associated pneumonia (VAP) are recommended.

An implementation plan of the protocol has been established from communication, pilot study, and evaluation plans. Communication plan involves decision makers, eye care team, nurses, audit control officer, doctors, clerical staff

and health care assistants in the ICU, and ophthalmologist. Following the communication plan, a pilot study is proposed to implement the eye care to 15 eligible patients in the target ICU. The pilot evaluates the incidence and severity of OSDs, nursing skill and compliance, family acceptance towards eye covers, costs, and unanticipated problems. If the pilot results support a larger-scale implementation, the eye care protocol will be delivered to all eligible ICU patients. An evaluation plan of the full implementation is developed, with a sample size of at least 55. The primary outcome of the evaluation is the incidence of corneal abrasions or ulcerations, while the secondary outcomes are nursing skills and compliance, incidence and severity of other OSDs, family acceptance towards polyethylene covers, and cost-effectiveness analysis.

With the implementation of the evidence-based eye care protocol, a reduction in the incidence and/or severity of OSDs, especially the corneal disorders, is expected in an ICU setting.

Evidence-based Eye Care Protocol for ICU Patients with Altered Level of Consciousness

by

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Bachelor of Nursing (Honours) *H.K.U.*

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Declaration

I declare that this thesis represents my own work, except where due acknowledgement is made, and that it has not been previously included in a thesis, dissertation or report submitted to this University or to any other institution for a degree, diploma or other qualifications.

Signed _____

Yim Wai Yi

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I am also very grateful for the big-hearted sharing of the important unpublished information on the topic of eye care in the intensive care unit in Hong Kong by Dr. Vico Chiang. In view of the scanty investigation in Hong Kong, missing any available information can be a big flaw.

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Abbreviations

95% CI(s)	95% confidence interval(s)
ACO	audit control officer
APACHE II score	Acute Physiology And Chronic Health Evaluation II score
APN	advance practice nurse
ARF	acute renal failure
Ax	assess
BD	twice a day
Cal 95% CI	calculated 95% confidence interval
CASP	Critical Appraisal Skills Programme
CINAHL	Cumulative Index of Nursing and Allied Health Literature
CMV	Continuous mandatory ventilation
CNE	Continuous Nursing Education
COS	Chief of Service
CQI	Continuous Quality Improvement
CXR	chest X-ray
DOM	Departmental Operational Manager
EBP	evidence based practice
ETA	endotracheal aspirate
exam	examination
FiO2	fraction of inspired oxygen
GCS	Glasgow Coma Scale
h	hour(s)
HCA(s)	health care assistant(s)
HI	head injury
HK	Hong Kong
HL combination	hypromellose (drops) and Lacrilube (ointment) combination
ICH	intracranial hemorrhage
ICU(s)	Intensive Care Unit(s)
IgA	immunoglobulin A
ITT	intention-to-treat
IQR	Inter-quartile range
LOC	level of consciousness
LOS	length of stay

MRSA	methicillin resistant staphylococcus aureus
NA	not applicable
Neuro	neurological
NG	nasogastric
NHMRC	National Health and Medical Research Council
NMB	Neuromuscular blockers
NS	normal saline
OP	oropharyngeal
OR	odd ratio
OSD(s)	ocular surface disease(s)
OS	ocular surface
p	level of significance
PAER	pseudomonas aeroginosa
PC	pressure control
PEEP	positive end expiratory pressure
post-op	post-operative
prn	whenever necessary
PS	pressure support
QD	daily
q2/4/6/8/12h	every 2/4/6/8/12 hours
R	randomization
RCT(s)	randomized controlled trial(s)
Resp	Respiratory
RN(s)	registered nurse(s)
RTA	road traffic accident
SD	standard deviation
SDR	Staff Developmental Report
SIGN	Scottish Intercollegiate Guidelines Network
SIMV	Synchronized intermittent mandatory ventilation
TV	tidal volume
UK	United Kingdom
US	United States
VAP	ventilator associated pneumonia
vs	versus
V/Q ratio	ventilation-perfusion ratio
WM	ward manager

CHAPTER 1 INTRODUCTION

A systematic review (Joyce, 2002) concludes that ocular surface diseases (OSDs) are common in the Intensive Care Unit (ICU) patients with altered level of consciousness (LOC). OSDs are conjunctival or corneal disorders (Desalu et al., 2008) including abrasion, ulceration, or infection (Merceica, Suresh, Morton & Tullo, 1999), which can proceed to corneal perforation or visual deficits. Studies have suggested different types of eye care to prevent the OSDs. In this chapter, the background knowledge of the OSDs, the significance and the need of practice change in ICU, and the aim and objectives of the dissertation will be discussed.

1.1 BACKGROUND

Ocular surface diseases in ICU

ICU patients are mostly comatose, sedated, or paralysed. The altered LOC eliminates the natural defence mechanisms of the ocular surface (OS) and puts patients at risk of OSDs. The rate of OSD in ICU patients is 42% to 60% (Desalu et al., 2008; Ezra, Lewis, Healy & Coombes, 2005; Hernandez & Mannis, 1997; Imanaka, Taeneka, Nakamura, Aoyama & Hosotani, 1997). Studies have showed that eye care like methylcellulose eye drops or polyethylene eye covers reduced the OSD incidence to 3.3% to 26% (Cortese, Capp & McKinley, 1995; Coyer, Wheeler, Wetzig & Couchman, 2006). Eye care also significantly reduced the pseudomonas eye infection from 26% to 5.1% (Coyer et al., 2006; Laight, 1996; Parkin, Turner, Moore, & Cook, 1997).

Natural defence mechanisms of ocular surface

Eye lids, intact conjunctiva, tears, and the eye immune systems form the natural defence mechanisms of the OS (McClellan, 1997; Mercieca et al., 1999). Eye lids physically protect the eyes from dehydration and injury. Eye closure concentrates tear proteins and immunoglobulin A (IgA) by 40 folds. Tears lubricate the eye lids and the OS, flush out stimuli and organisms, and allow leukocytes passage (Dua, 1998; McClellan, 1997; Mercieca et al., 1999). IgA prevents bacterial attachment, reduces antigen absorption, and neutralizes toxins and virus. Besides, tears contain lysozyme (40%) and lactoferrin (25%). Lysozyme is an enzyme responsible for bacterial hydrolysis, while lactoferrin enhances the function of natural killer cells and deprives nutritionally essential iron of bacteria (Dua, 1998; McClellan, 1997; Mercieca et al., 1999). As a result, eye closure and tears prevent desiccation, damage, and bacterial growth of the OS. However, long-term eye closure reduces tears secretion, causes hypoxia and hypercapnia, and retards reepithelization (Baum, 1997; McClellan, 1997). Blinking is therefore important for distributing tears (Dua, 1998) and maintaining a healthy OS. Furthermore, intact conjunctiva provides physical protection to the OS. The mucosal immune system of the lacrimal gland and conjunctiva-associated lymphoid tissue produce IgA and cell-mediated lymphoid response which prevent eye infection (Dua, 1998; McClellan, 1997; Mercieca et al., 1999).

Risk factors for OSDs

ICU patients with altered LOC have common predisposing factors for OSDs. Incomplete lid closure is the major significant predisposing factor (Bates et al., 2004;

Cunningham & Gould, 1998; Dua, 1998; Johnson, Sagraves, Field, Block, & Cheatham, 2000; Marshall, Elliott, Rolls, Schacht & Boyle, 2008; Parkin & Cook, 2000; Sivasankar et al., 2006). It removes the physical and chemical protections of the eye lids, tears, and conjunctiva. Neuromuscular relaxants or sedatives use and conjunctival edema (chemosis or ventilator eye) in the ICU patients contribute to incomplete lid closure and subsequent OS exposure.

Sedatives or neuromuscular relaxants are commonly used in ICU patients to reduce pain or airway discomfort, and facilitate mechanical ventilation (Mackinnon, 1987; Richman, Baram, Varela & Glass, 2006). They relax the orbicularis oculi (eye muscle that keeps the lids closed) and eliminate the blinking and corneal reflexes. Incomplete lid closure and the loss of protective reflexes expose the OS constantly, leading to an increase in tear film evaporation, and subsequent risk of OS desiccation, abrasion, or eye infection (Coyer et al., 2006; Desalu et al., 2008; Laight, 1996; Mercieca et al., 1999; Parkin et al., 1997). Sedatives and neuromuscular relaxants increase the incidence of OSDs by 20% to 28% (Imanaka et al., 1997), which is directly related to the duration of sedation (Desalu et al., 2008).

Conjunctival edema protrudes the conjunctiva that impedes lids closure and exposes OS. It is common in ventilated patients, especially those who are ventilated in prone position, or having cardiac or renal failure (Mercieca et al., 1999). Longer duration of ventilation significantly increases the incidence of OSDs (Desalu et al., 2008). Mechanical ventilation causes conjunctival edema (Desalu et al., 2008; Dua, 1998) by increasing the intra-thoracic pressure, and reducing venous return and eye circulation (Laight, 1996). Positive end-expiratory pressure (PEEP) is a common

ventilator setting that prevents alveolar collapse, improves functional residual capacity, enhances alveolar gaseous exchange, and assists heart functioning by increasing the intra-thoracic pressure (Neligan, 2002). The usual PEEP setting, 5 to 15cmH_2O (Institute of Advanced Nursing Studies, 2007), encourages sodium and water retention (Dua, 1998) and causes edema. In addition, intubation and tight securing taping for the artificial airways increase the intraocular pressure and aggravate the conjunctival edema (Asburt, 1997; Farrell & Wray, 1993; Hunt, 1991). Prone ventilation is useful in patients who have difficult ventilation by improving the ventilation-perfusion (V/Q) ratio. However, it puts patients at risk of OS exposure and facial and conjunctival edema (Suresh, Mercieca, Morton & Tullo, 2000). Cardiac or renal failure predisposes OS desiccation, poor circulation, and conjunctival edema due to body fluid fluctuation (Desalu et al., 2008).

Ventilator-associated pneumonia (VAP) is a common complication of mechanical ventilation. Eye infection is commonly caused by the inoculation of respiratory pathogen such as pseudomonas aeruginosa (PAER) (Desalu et al., 2008; Mercieca et al., 1999; Parkin et al., 1997). Virulent PAER eye infection liquefies and perforates cornea within 48 hours (Desalu et al., 2008; Dua, 1998; Hutton & Sexton, 1972; Johnson et al., 2000; Mercieca et al., 1999; Ommeslag, Colardyn & DeLaey, 1987; Parkin et al., 1997).

Critical condition of the ICU patients also predisposes OSDs. Multi-organ failure, immunodeficiency, and steroid therapy increase the risk of respiratory or eye infection (Desalu et al., 2008; Farrell & Wray, 1993; Hunt, 1991; Hutton & Sexton, 1972; Lloyd, 1990).

1.2 AFFIRMING THE NEED AND SIGNIFICANCE

Significance of OSDs for ICU patients

Eye care is perceived as less important in ICU patients when compared to other life-sustaining measures (Laight, 1996). However, by observation, OSDs occur in approximately 40% of the sedated, paralysed, or comatose patients in the target ICU where the proposed protocol is to be implemented. The serious consequences of OSDs should not be overlooked. OSDs can proceed to corneal perforation requiring corneal transplant (Ommeslag et al., 1987), corneal scarring, or long-term visual deficits. Patients will suffer from preventable poor quality of life (Desalu et al., 2008; Parkin et al., 1997). Preventable OSDs also burden the healthcare costs by unnecessary treatments and prolonged hospital length of stay (LOS). Prevention is always better than cure.

Variety and effectiveness of the eye care practices

Eye care practices maintain eye hygiene, OS moisture, and lids closure, so as to prevent OS desiccation, injuries, or infection (Ward, 2008). Literature has suggested a variety of eye care applying every 2 to 6 hours (Parkin et al., 1997), or 4 times daily (Coyer et al., 2006). Normal saline (NS) eye cleansing, eye lubricants such as hypromellose, and topical antibiotics like chloramphenicol have been mentioned (Laight, 1996). Farrell & Wray (1993) supported topical antibiotics use for any signs of eye infection. Coyer et al. (2006) agreed on the use of NS irrigation, eye drops, and eye ointment. However, Lloyd (1990) rejected the use of artificial tears unless incomplete eye closure, and suggested eye cleansing with sterile water soaked cotton balls. Regarding eye covers, eye pads, taping (Laight, 1996), Geliperm covers (Farrell & Wray,

1993; Mercieca et al., 1999), polyethylene covers (Joyce, 2002), or Frost suture for patients with facial injury or severe conjunctival edema (Suresh et al., 2000) have been suggested. Coyer et al. (2006) also suggested taping, paraffin gauze, and polyethylene cover. However, Suresh et al. (2000) suggested eye lubricants rather than eye covers for patients having occasional blinks.

There is no consensus about the effectiveness of different eye care practices. A guideline suggested NS for crusts softening (Laight, 1996); while Trees & Tomlinson (1990) showed that NS eye drops would increase the tear evaporation rate, which was supported by another animal trial (Lloyd, 1990). An eye hospital suggested possible corneal scratching by cotton wool balls (Laight, 1996). Moreover, there are criticisms on different eye covers. Parkin et al. (1997) concluded that, Geliperm cover was insufficient for conjunctival edema; gauze cover predisposed corneal abrasion; and eye taping was insufficient for eye closure and predisposed skin irritation. Suresh et al (2000) also emphasized the skin injury caused by repeated removal of eye taping. Farrell & Wray (1993) implemented Geliperm cover and eye hygiene every 2 to 6 hours but Suresh et al. (2000) have criticized on this unjustified time-consuming protocol.

Therefore, an evidence-based eye care protocol is necessary to standardize and guide the eye care practices for the patients in ICU.

Nurses' recognition of OSDs and current eye care practices in the ICUs

Several surveys have been conducted in United Kingdom (UK) to investigate the practicing eye care (Cunningham & Gould, 1998; Farrell & Wray, 1993; King & Healy, 2003). In the latest survey conducted in 30 ICUs, despite the prevalence of OSDs was

40%, only 10% of the nurses perceived OSD as a common ICU problem, and 7 ICUs did not have any eye care protocols (King & Healy, 2003). Another survey has showed that 75% of the 20 involved ICUs performed NS eye cleansing, 85% used eye covers, while 65% used eye lubricants. Geliperm covers (70.5%) and hypromellose drops (46.2%) were most commonly used (Farrell & Wray, 1993). In another survey, nurses performed eye assessment in only 43% of the 30 eye care episodes in an ICU. They also performed NS eye cleansing in 83% of the episodes, and applied hypromellose drops to all patients (Cunningham & Gould, 1998).

Eye care practices in Hong Kong (HK) also vary. A survey has been conducted in the ICUs of 5 public and 1 private hospitals. Three percent of the nurses did not perform any eye care; 82.1% performed NS eye cleansing with cotton wool balls every 2 to 8 hours; 30.6% used eye lubricants with doctor's initiation. The commonly used eye lubricants were 2- to 4-hourly chloramphenicol or methylcellulose, or 6- to 8-hourly Duratears. Only 14.8% of nurses provided eye protection. Gauze cover was the most common nurse-initiated practice, while polyethylene cover was used with doctor's initiation (Chiang et al., 2007).

In conclusion, in both UK and HK, eye care practices vary, in which eye cleansing and eye lubricants are dominating. Nurse-initiated eye care protocol is not common because of the nurses' unawareness of the OSDs. There is no standardized or evidence-based eye care practice guideline, due to the lack of rigorous evidence (Joyce, 2002) and consensus about eye care interventions (Mercieca et al., 1999).

Life-saving issues are emphasized in the ICU. In the target ICU, a 20-bed adult ICU of a large teaching public hospital in HK, although the risk factors for OSDs exist and OS damages are frequently observed in around 40% of the patients during pupil assessments, nurses' recognition of OSDs is insufficient. There was a case suffering from eye inoculation of respiratory Klebsiella species, and the ophthalmology team was consulted only when the eye infection became serious. There is no eye care protocol in the target ICU. Routine face hygiene is performed every 8 hours with towel and tap water. The lack of preventive measures and serious consequences of the OSDs urge a need to develop an evidence-based nurse-initiated eye care protocol in the target ICU.

1.3 RESEARCH QUESTION, AIM, AND OBJECTIVES OF THE DISSERTATION

With the affirmed significance and need of the practice change, according to the Iowa Model (Melnyk & Fineout-Overholt, 2005; Polit & Beck, 2008; Titler, 2002) (see Appendix 1), research question, aim, and objectives of the dissertation are determined for the subsequent literature search.

Research question

Is an evidence-based eye care protocol more effective than the routine care in reducing the incidence and/or severity of OSDs in ICU patients with altered level of consciousness?

Aim

To develop an evidence-based eye care protocol for ICU patients with altered level of consciousness, with implementation and evaluation plans for an ICU setting.

Objectives

1. To gather empirical evidence on the effectiveness of eye care protocols in reducing the incidence and/or severity of OSDs in the ICU patients with altered level of consciousness.
2. To conduct a quality assessment of the selected research.
3. To develop an evidence-based eye care protocol for ICU patients with altered level of consciousness.
4. To assess the implementation potential of the proposed eye care protocol.
5. To plan for the implementation and evaluation of the proposed eye care protocol.

CHAPTER 2 CRITICAL APPRAISAL

The previous chapter has affirmed the need and significance of developing an evidence-based eye care protocol for patients with altered LOC in the target ICU setting. According to the Iowa Model, the next step is to assemble relevant research and related literature, and to critique and synthesize the research base for practice (Melnyk & Fineout-Overholt, 2005; Polit & Beck, 2008; Titler, 2002) (see Appendix 1). In this chapter, the search strategies, evidence extraction, critical appraisal, quality assessment, and the summary and synthesis of data will be elaborated.

2.1 SEARCH STRATEGIES

Study selection criteria

Inclusion criteria

Patient types

- ICU patients
- Altered LOC, with Glasgow Coma Scale (GCS) 3 to 12 (Teasdale & Jennett, 1974)
    - Comatose or semi-comatose
    - Sedated or paralysed with the use of sedatives or neuromuscular relaxants
- Mechanical ventilated
- Staying in ICU for at least 24 to 48 hours
- Have no or limited spontaneous blinking for at least 24 hours, unless upon stimulation such as suctioning

Interventions

- Eye care regimens

Outcome measures

- Incidence and/or severity of OSDs, including corneal or conjunctival abrasion, ulceration or infection, exposure keratopathy, and keratitis

Article types

- Primary or secondary, interventional or observational studies

Studies involving patients who have stayed in ICU for less than 24 hours, or regained spontaneous blinking within 24 hours are excluded. With reference to the early onset time of OSDs, ranging from 24 hours to 1 week (So et al., 2008; Suresh et al., 2000), and 65% to 95% of OSDs develop within 48 hours (Desalu et al., 2008; Sivasankar et al., 2006), patients who regain spontaneous blinking within 24 hours are not at risk of OSDs. On the other hand, OSDs develop within the first 24 hours of ICU stay are probably a preexisting disorder that has been developing before the ICU admission, and thus not an outcome of the eye care.

Exclusion criteria

- Animal trials
- Studies targeting only ICU infants or children below age of 12
- Studies targeting only burn patients
- Patients with underlying facial injury, eye disease, or eye injury due to such as burn or trauma

Studies targeting only infants or children under age of 12 are excluded. Firstly, in the target adult ICU, the proposed eye care protocol will be implemented in patients aged 12 or above. Secondly, the risk of OSD is different between adults and children. Lower immunity in children and infants predisposes higher risk of OSD. The risk of infection in pediatric ICU is inversely related to age (Milliken et al., 1988), while age puts no significant effect on the incidence of OSDs in adults (Desalu et al., 2008; Lenart & Garrity, 2000). Moreover, different age-dependent dosage of muscle relaxants or sedatives used in children (Khilnani & Kaur, 2003) and different elimination half-life and clearance of drugs in infants (Bartolomé, López-Herce Cid & Freddi, 2007) put them at different risk of OSDs.

Studies targeting only burn patients or involving patients with facial injury or eye diseases are also excluded. Burn, trauma, or preexisting eye or facial injuries lead to lid contracture or damage. Preexisting incomplete lid closure (the major risk factor for OSDs) and subsequent constant OS exposure impose a greater risk of OSD than the target population who have intact eye lids and OS (Astori, Muller & Pegg, 1998; Spencer, Hall & Stawell, 2002).

Searching engines

A systematic search of the empirical evidence has been conducted from October, 2007 to 25th July, 2008, by means of multiple searching engines. A Clinical Guidelines search has been conducted in the national guidelines clearinghouse, CMA infobase, Health service/technology assessment text, Guidelines advisory guidelines, Scottish Intercollegiate Guidelines Network, National Institute for Clinical Excellence, New Zealand Guideline Group, and Joanna Briggs Institute. All yielded no relevant studies except Joanna Briggs Institute yielded 1 systematic review (Joyce, 2002). Four electronic engines yielded 75 title-relevant studies, which included the Cochrane library (1999-2008), Medline (Ovid SP) (1950-2008), Cumulative Index of Nursing and Allied Health Literature (CINAHL) (Ovid SP) (1982-2008), and Pubmed (1950-2008). Hand searching found 1 eye care guideline in the Australian Critical Care 2008 (Marshall et al., 2008). Reference lists and related articles of the identified studies were assessed for relevance by titles, with 43 additional studies identified. Yahoo and Google searches were conducted using keywords “ocular surface disorder” and “eye care”, with 2 more relevant studies yielded. Two experts have been contacted personally, including Dr. Vico Chiang and a nurse specialist of a large teaching public hospital in HK. Dr. Chiang was a former ICU practitioner and is currently a university teaching consultant in HK. He provided the findings of an unpublished survey conducted in 6 HK hospitals (Chiang et al., 2007) and 1 HK randomized controlled trial (RCT). The nurse specialist contacted has implemented the only eye care protocol in HK. However, guideline sharing was refused. Detailed searching strategies are provided in Appendix 2.

Keywords used

Initial search was started with the keywords “eye care”, “corneal abrasion”, “eye disease”, “intensive care”, “critical care”, and “unconscious or semiconscious”. Further keywords were identified from the titles and abstracts of the identified studies to ensure a thorough search. The keywords were categorized into 4 groups, including interventions, settings, patients, and outcome measures. A full set of keywords used is presented in Appendix 3.

Different combinations of the 4 groups of keywords, with the use of “explode” and MeSH headings, yielded 123 title-relevant studies. Searching has stopped when no additional publications appeared in the reference lists. According to the selection criteria, abstracts were reviewed, and full texts were obtained and assessed for relevance. Finally, 13 studies were selected.

Extraction of evidence

Findings of the selected studies have been extracted into tables of evidence with reference to the “SIGN 50: A guideline developer’s handbook Annex D” (Scottish Intercollegiate Guidelines Network, 2008a, 2008c). Tables of evidence are presented in Appendix 4.

2.2 APPRAISAL STRATEGIES

Critical appraisals and quality assessments of studies

Critical Appraisal Skills Programme (CASP) appraisal tools have been used for the critical appraisals of the selected studies (Public Health Resources Unit, National Health Service, 2007) (see Appendices 5A to 5D). Different tools were used according to the study types. Appraisal tool for systematic review (see Appendix 5A) was used for the clinical guideline. Appraisal tool for RCT (see Appendix 5B) was used for the non-RCT interventional studies because of their interventional nature, with the questions regarding randomization (questions 2 and 3) omitted. Tables of critical appraisal are presented in Appendix 4 following the tables of evidence of each study.

Rating scheme for quality assessment

After the critical appraisal, the quality of each individual study was rated according to the SIGN coding system (Scottish Intercollegiate Guidelines Network, 2008a, 2008d) (see Appendix 6A). Together with the study type, the levels of evidence of studies were assigned according to "SIGN 50: A guideline developer's handbook Annex B" (Scottish Intercollegiate Guidelines Network, 2008a, 2008b) (see Appendix 6B). The percentage of CASP criteria fulfilled was given at the end of each critical appraisal table.

2.3 RESULTS

Overview of study characteristics

The 13 selected studies include 1 clinical guideline (Marshall et al., 2008), 1 systematic review (Joyce, 2002), 6 RCTs (Bates et al., 2004; Cortese et al., 1995; Lenart & Garrity, 2000; Koroloff et al., 2004; Sivasankar et al., 2006; So et al., 2008), 2 controlled trials (Ezra et al., 2005; Laight, 1996), 1 uncontrolled trial (Suresh et al., 2000), 1 retrospective before and after interventional study (Parkin et al., 1997), and 1 prospective observational cohort study (Desalu et al., 2008). Four studies were conducted in Australia and UK respectively. Other studies were conducted in the following places, including United States, Ireland, South India, Sub-Saharan, and HK. Seven studies were conducted in large teaching hospitals (Bates et al., 2004; Cortese et al., 1995; Desalu et al., 2008; Koroloff et al., 2004; Lenart & Garrity, 2000; Sivasankar et al., 2006; So et al., 2008).

The range of analyzed sample size is large. For the studies implementing eye care on the contralateral eyes, the sample size ranged from 6 to 50. The remaining studies included 9 to 124 participants.

Summary of quality assessment

The levels of evidence range from 1++ to 2- (see Appendix 7). The systematic review (Joyce, 2002) is rated at the highest evidence level 1++, while the clinical guideline (Marshall et al., 2008) is at the level 1-. For the RCTs, half are at level 1+, and the remaining are at level 1-. All non-RCT studies are at level 2-. The levels of evidence

were determined by the following judgments, and the summary of quality assessment is presented in Appendices 8A to 8D.

Clinical guideline & systematic review (2 studies) (see Appendices 4, 7, and 8A)

The clinical guideline (Marshall et al., 2008) is at the evidence level 1- with 45% of CASP criteria fulfilled, while the systematic review (Joyce, 2002) is at the level 1++ with 75% of the criteria met. The literature search of both clinical guideline (Marshall et al., 2008) and systematic review (Joyce, 2002) was limited to English language, and used insufficient and inconsistent keywords in different databases. Moreover, Marshall et al. (2008) did not conduct any conference proceedings or dissertations search, hand searching, or personal expert contacts. Therefore, their search might exclude considerable sources of information. Nevertheless, Joyce (2002) conducted an extensive search using all other possible strategies. Moreover, Joyce (2002) assessed and combined the studies appropriately, while Marshall et al. (2008) did not mention the critical appraisal checklist or combination strategies. Therefore, the systematic review (Joyce, 2002) is at a higher level of evidence than the clinical guideline (Marshall et al., 2008).

Although the presentations of the 2 studies are satisfactory and their conclusions are applicable to the local settings, the precision of their results is poor, and the evidences of both studies are insufficient for any policy change. Joyce (2002) presented wide 95% confidence intervals (95% CIs), while Marshall et al. (2008) presented none. Furthermore, with reference to the original study of Lenart & Garrity (2000), Joyce (2002) has wrongly calculated the number of participants and OSD incidences in the

Duratears and passive closure groups, and thus the odd ratio and 95% CIs. However, Joyce's (2002) conclusion on the effectiveness of Duratears in reducing the corneal abrasion over passive eye closure is still correct. Therefore, the level of evidence of the systematic review (Joyce, 2002) is still higher than that of the clinical guideline (Marshall et al., 2008).

RCTs (6 studies) (see Appendices 4, 7, and 8B)

RCTs are at the evidence levels 1+ to 1-, with 25% to 70% of CASP criteria fulfilled. There are common factors contributing to their qualities. Four studies have unclear randomization (Bates et al., 2004; Cortese et al., 1995; Lenart & Garrity, 2000; Sivasankar et al., 2006). Three studies have inadequate allocation concealment (Bates et al., 2004; Cortese et al., 1995; So et al., 2008), while the remaining 3 RCTs have none. Nevertheless, the 3 studies having higher levels of evidence showed an equalization effect of randomization between the comparison groups (Cortese et al., 1995; Koroloff et al., 2004; So et al., 2008). In addition, 2 studies have inadequate measure of confounders (Cortese et al., 1995; Sivasankar et al., 2006) while 2 have none (Bates et al., 2004; Lenart & Garrity, 2000). The lack of confounder measure makes the effectiveness of the interventions doubtful. It is acceptable for the study of Lenart & Garrity (2000) as the comparison groups are the matched contralateral eyes.

Blinding of the comatose, paralysed, or sedated patients is not important as they cannot alter the outcomes. Blinding of nurses is impossible; therefore the unblinded nurses might produce a high risk of performance bias towards their preferred eye care. Five studies have no intervention or compliance checks to ensure an appropriate

intervention delivery (Bates et al., 2004; Cortese et al., 1995; Lenart & Garrity, 2000; Sivasankar et al., 2006; So et al., 2008). As a result, there might also be a confusion of the contralateral eye interventions in 2 studies (Bates et al., 2004; Lenart & Garrity, 2000). Observer blinding is possible in 5 studies (Bates et al., 2004; Cortese et al., 1995; Koroloff et al., 2004; Lenart & Garrity, 2000; So et al., 2008), however, only Bates et al. (2004) did. Assessing the OSDs by qualified assessors and objective measurement tools (Cortese et al., 1995; Koroloff et al., 2004; Sivasnakar et al., 2006; So et al., 2008) and the assurance of the interrater reliability (Koroloff et al., 2004) have minimized the possible observer bias.

The subjects were probably not followed in the same way, due to the lack of skill training on eye care for nurses (all studies), absence of the measurement of pupil assessment (manual blinking) (all studies), unclear eye care protocols (Bates et al., 2004; Cortese et al., 1995; Koroloff et al., 2004; Sivasankar et al., 2006; So et al., 2008), and the use of unknown data collectors (Bates et al., 2004; Lenart & Garrity, 2000).

Most studies have fair to poor presentations. All studies presented no risk indexes, 3 have no significance testing on confounders (Bates et al., 2004; Cortese et al., 1995; Sivasankar et al., 2006), 2 have unclear or inappropriate significance testing (Koroloff et al., 2004; Lenart & Garrity, 2000), some studies have wrong calculations on the incidences of OSDs (Bates et al., 2004) and chemosis (Sivasankar et al., 2006), and 1 presented inconsistent results in tables and text (Lenart & Garrity, 2000).

The precision of results is fair to poor. Although comparable and objective measurement tools were used (all studies) with reasonable follow-up periods (Bates et

al., 2004; Cortese et al., 1995; Koroloff et al., 2004; Sivasankar et al., 2006; So et al., 2008), all studies did not present the 95% CI, with wide calculated 95% CIs.

Three studies have not mentioned about the sample size calculation (Cortest et al., 1995; Lenart & Garrity, 2000; Sivasankar et al., 2006), and Bates et al. (2004) calculated the sample size using an inadequate power of 0.75. Insignificant results together with the wide calculated 95% CIs showed a high possibility of type II error due to the inadequate sample sizes in 4 studies (Bates et al., 2004; Koroloff et al., 2004; Sivasankar et al., 2006; So et al., 2008). Moreover, 4 studies excluded 3.3% to 40% of participants in analysis due to reasonable ineligibility, without intention-to-treat (ITT) (Bates et al., 2004; Cortese et al., 1995; Sivasankar et al., 2006; So et al., 2008). The exclusion is acceptable in 3 studies as their intervention and comparison groups were still comparable after excluding the ineligible participants (Bates et al., 2004; Cortese et al., 1995; So et al., 2008).

Nevertheless, most interventions and results are applicable to the local settings (Bates et al., 2004; Cortese et al., 1995; Koroloff et al., 2004; Lenart & Garrity, 2000; So et al., 2008).

Clinical trials & before and after interventional study (4 studies) (see Appendices 4, 7, and 8C)

All the studies are at the evidence level 2-, with 25% to 43.8% of CASP criteria met. In view of the interventional nature of the studies, the CASP critical appraisal tool for RCT was used with the non-applicable questions omitted. The factors contributing to their low levels of evidence are similar to those of the RCTs.

All studies did not show the comparability between groups in demographics (Ezra et al., 2005; Parkin et al., 1997; Suresh et al., 2000) or confounders (Parkin et al., 1997; Suresh et al., 2000). It is reasonable for the study of Laight (1996) as the comparison groups are the matched contralateral eyes.

All studies did not mention about blinding and were at risk of performance and measurement biases. Only 2 studies have presented the intervention checks (Laight, 1996; Suresh et al., 2000) which showed poor nursing compliance (Laight, 1996). The measurement bias was reinforced by the unknown assessors (Ezra et al., 2005; Parkin et al., 1997; Suresh et al., 2000), and the use of researcher assessor who might produce a researcher's intended results (Laight, 1996). All studies did not mention the skill training on eye care for nurses, pupil assessment measurement, or clear eye care protocols.

All studies have no sample size calculation, which is only acceptable in the pilot study (Laight, 1996). One study (Suresh et al., 2000) excluded 32% of the participants who have received inappropriate interventions and developed OSDs. The absence of ITT might underestimate the true OSD incidence.

The lengths of follow up of the studies were either unknown (Parkin et al., 1997), too long (Ezra et al., 2005; Suresh et al., 2000), or too short (Laight, 1996) for an accurate detection of OSD incidence or severity. Different assessment time intervals might also be a confounder (Suresh et al., 2000).

The presentations and precision of results are fair to poor. No risk indexes or 95% CI was presented. The wide calculated 95% CIs, especially in the study of Parkin et al. (1997), have reduced the clinical significance of the results. Laight (1996) did not

present the OSD incidence or p-value, while Suresh et al. (2000) did not perform significance testing of the results. The lack of detailed results (Ezra et al., 2005; Laight, 1996) or patient details (Ezra et al., 2005; Laight, 1996; Parkin et al., 1997), weak casual relationship (Parkin et al., 1997), inadequate sample sizes, and inappropriate follow-up periods have reduced the generalizability of the findings.

Cohort study (1 study) (see Appendices 4, 7, and 8D)

The cohort study of Desalu et al. (2008) is at the evidence level 2- with 50% of CASP criteria met. The factors contributing to its quality are similar to those of the other studies, including the absence of the confounder measure, possible exposure or outcome biases produced by unknown assessor and measurement tool, the absence of specified follow-up period, risk indexes and 95% CI, and the wide calculated 95% CI. Although the results fit with the existing evidence, the weak causal relationship between OSDs and eye care interventions has affected the applicability of the results.

2.4 SUMMARY AND SYNTHESIS

Based on the results and levels of evidence of the selected studies, the summary and synthesis of data are presented as follow.

Data summary

Eye care protocol

Eye assessments (4 studies)

Only 4 studies have mentioned about eye assessments (Laight, 1996; Marshall et al., 2008; Parkin et al., 1997; Suresh et al., 2000). Firstly, Marshall et al. (2008) suggested assessing the risk factors for incomplete lid closure, including the reduced conscious level, tracheal intubation, and significant metabolic derangement. Secondly, 4 studies assessed the risk factors for OSDs. Assessment of the incomplete lid closure (the major predisposing factor for OSDs) was suggested to perform daily (Marshall et al., 2008) or every 8 hours (Suresh et al., 2000) or 2 hours (Laight, 1996; Parkin et al., 1997). Laight (1996) also suggested assessing the lid cleanliness, corneal dryness, and moisture of Geliperm covers 2-hourly.

Lastly, the studies recommended the assessment of the signs of OSDs. Marshall et al. (2008) suggested assessing OSDs at least weekly, while Parkin et al. (1997) suggested a regular assessment of lid swelling, conjunctival hyperaemia, corneal clouding, and epithelial loss. Parkin et al. (1997) and Laight (1996) suggested assessing the signs of eye infection 2-hourly, especially for the patients suffering from respiratory PAER infection (Parkin et al., 1997).

Eye care interventions

A variety of eye care interventions were identified from the 13 studies as follow.

Eye hygiene (9 studies)

Nine studies applied routine eye hygiene to all patients (Bates et al., 2004; Cortese et al., 1995; Desalu et al., 2008; Ezra et al., 2005; Koroloff et al., 2004; Laight, 1996; Marshall et al., 2008; So et al., 2008; Suresh et al., 2000), while 2 studies suggested eye hygiene for patients with incomplete lid closure (Marshall et al., 2008) or unclean lids only (Laight, 1996). Two studies performed NS eye toilet (Cortese et al., 1995; Ezra et al., 2005) 2-hourly (Cortese et al., 1995) and 1 study implemented NS irrigation (Desalu et al., 2008). Lid cleansing by soaked gauze with different solutions and frequencies appeared in 6 studies. Laight (1996) used sterile water 2-hourly; four studies used NS every 2 hours (Koroloff et al., 2004; Marshall et al., 2008), every 4 hours (So et al., 2008), or daily (Bates et al., 2004); while Suresh et al (2000) used either NS or sterile water every 2 to 6 hours.

Eye lubricants (12 studies)

Five studies suggested the instillation of eye lubricants (Sivasankar et al., 2006) at least twice daily (Bates et al., 2004), 4-hourly (Suresh et al., 2000), or 2-hourly to incompletely closed eye lids (Marshall et al., 2008; Parkin et al., 1997). Different kinds of eye lubricants were suggested. Four studies applied methylcellulose (hypromellose) drops every 2 hours (Cortese et al., 1995; Joyce,

2002; Koroloff et al., 2004) or every 1 to 6 hours with respective to corneal dryness (Laight, 1996). Ezra et al. (2005) introduced Lacrilube ointment. Two studies mentioned the use of a combination of 2-drop hypromellose and 1-cm Lacrilube (HL combination) every 2 hours (Joyce, 2002; Koroloff et al., 2004). Three studies mentioned 4-hourly application of 1-cm (Joyce, 2002; So et al., 2008) or 1.27-cm Duratears ointment (Joyce, 2002; Lenart & Garrity, 2000).

Eye covers (12 studies)

A clinical guideline suggested that a complete lid closure should be maintained by passive eye closure or mechanical methods (Marshall et al., 2008). Passive closure was investigated in 2 studies (Joyce, 2002; Lenart & Garrity, 2000); while a variety of mechanical eye covers appeared in 10 studies. Sivasankar et al. (2006) implemented eye taping with eye lubricants; while Parkin et al. (1997) and Suresh et al. (2000) suggested taping for patients with incomplete lid closure only. Two studies used Micropore taping (Laight, 1996; Suresh et al., 2000). Four studies used polyethylene covers (Cortese et al., 1995; Joyce, 2002; Koroloff et al., 2004; So et al., 2008) with Micropore sealing edge (Koroloff et al., 2004; So et al., 2008) and a changing frequency of daily (Cortese et al., 1995; So et al., 2008), every shift (Koroloff et al., 2004), or whenever necessary. Three studies introduced Geliperm cover (Bates et al., 2004; Ezra et al., 2005; Laight, 1996) that was suggested to apply on clean eyes only (Laight, 1996) and to change regularly (Bates et al., 2004) or when dried up (Laight, 1996). One study used CorneaCare cover (Bates et al., 2004). One study

created a closed chamber system by sterile water soaked gauze and swimming goggles, which would be changed every 12 hours (Sivasankar et al., 2006).

Suctioning technique (1 study)

Parkin et al. (1997) suggested performing tracheal suctioning at the side of bed with eyes covered.

Eye swab for culture (2 studies)

Eye swab for culture was recommended for any signs of eye infection (Laight, 1996; Parkin et al., 1997). Daily conjunctival swab was suggested for patients with respiratory PAER infection (Parkin et al., 1997).

Antibiotics use (2 studies)

Parkin et al. (1997) suggested Gentamicin for eye PAER infection; while Desalu et al. (2008) implemented topical chloramphenicol drops or ointment to patients.

Consultation of medical professionals (3 studies)

Marshall et al. (2008) suggested a timely referral for any signs of OSDs. Laight (1996) suggested informing doctor for any signs of eye infection; while Parkin et al. (1997) recommended an ophthalmologist consultation for eye PAER infection.

Outcome measures

Incidence of OSDs (all 13 studies)

Six studies evaluated the effectiveness of the eye care protocols by the incidence of corneal breakdowns (Cortese et al., 1995; Joyce, 2002; Koroloff et al., 2004; Lenart & Garrity, 2000; Sivasankar et al., 2006; So et al., 2008). Seven studies measured corneal and conjunctival disorders (Bates et al., 2004; Desalu et al., 2008; Ezra et al., 2005; Laight, 1996; Marshall et al., 2008; Parkin et al., 1997; Suresh et al., 2000). Only 3 studies measured the incidence of eye infection (Joyce, 2002; Marshall et al., 2008; Parkin et al., 1997).

The incidence of OSDs ranged from 22% to 55.4% with unstandardized eye care (Desalu et al., 2008; Parkin et al., 1997), eye hygiene (Bates et al., 2004; Ezra et al., 2005; Suresh et al., 2000), or passive lids closure (Lenart & Garrity, 2000). Eye lubricants reduced the incidence to 4% to 32% (Cortese et al., 1995; Ezra et al., 2005; Koroloff et al., 2004; Lenart & Garrity, 2000; Sivasankar et al., 2006; So et al., 2008). Combination of eye hygiene and eye lubricants led to an incidence of 14% (Bates et al., 2004). Eye covers, except Geliperm, reduced the incidence to 0 to 8% (Bates et al., 2004; Cortese et al., 1995; Koroloff et al., 2004; Sivasankar et al., 2006; So et al., 2008). Combination of eye covers and eye lubricants reduced the incidence to 8.7% (Suresh et al., 2000). Therefore, eye covers provided better OS protection than eye lubricants alone. Eye care protocol also significantly reduced the eye PAER infection rate from 26% to 5.1% (Parkin et al., 1997).

Marshall et al. (2008) suggested using readily available measurement tools such as fluorescein stain and cobalt pen torch to evaluate the incidence of OSDs. Nine studies

used fluorescein stain (Bates et al., 2004; Cortese et al., 1995; Desalu et al., 2008; Ezra et al., 2005; Koroloff et al., 2004; Lenart & Garrity, 2000; Sivasankar et al., 2006; So et al., 2008; Suresh et al., 2000). Desalu et al. (2008) used penlight, 2 studies used penlight with blue filter (Cortese et al., 1995; So et al., 2008), while 3 used cobalt blue penlight (Bates et al., 2004; Ezra et al., 2005; Lenart & Garrity, 2000). Three studies used slit lamp (Koroloff et al., 2004; Sivasankar et al., 2006; Suresh et al., 2000), and 2 studies used ophthalmoscope (Desalu et al., 2008; Ezra et al., 2005). Only Laight (1996) used Rose Bengal stain and photography for OSD detection.

Severity of OSDs (4 studies)

Four studies evaluated the severity of OSDs (Ezra et al., 2005; Sivasankar et al., 2006; So et al., 2008; Suresh et al., 2000). The severity is graded 0 to 7 (Ezra et al., 2005; Mercieca et al., 1999; Sivasankar et al., 2006) (see Appendix 9). Routine lid cleansing led to grade 1 to 4 OSDs (Suresh et al., 2000) while eye toilet produced 54% of grade 1 to 3 OSDs (Ezra et al., 2005). Eye lubricants yielded grade 0 to 4 OSDs, 68% to 84% of which graded 0 (Ezra et al., 2005; Sivasankar et al., 2006; So et al., 2008). Eye covers provided better protection, it yielded grade 0 to 2 OSDs, of which 92% graded 0 (Sivasankar et al., 2006). Eye taping and lubricants produced grade 1 OSDs (Suresh et al., 2000). However, Geliperm worsened the severity and produced 80% of grade 2 to 3 OSDs (Ezra et al., 2005).

With reference to the early onset time and high prevalence of OSDs in the ICU patients, early nurse-initiated implementation of evidence-based eye care protocol is necessary to reduce the incidence and severity of OSDs.

Data synthesis

Eye care protocol

Eye assessments

Assessment is important before eye care (Cunningham & Gould, 1998) and is vital for the guidelines development. Although the 4 studies of eye assessment are at lower levels of evidence (Laight, 1996; Marshall et al., 2008; Parkin et al., 1997; Suresh et al., 2000) (evidence levels 1- and 2-, with 25% to 45% of CASP criteria met), their findings are included because eye assessment has not been mentioned in the other papers of higher levels of evidence. The following eye assessments are recommended.

1. Risk factors for incomplete lid closure

Marshall et al. (2008) (evidence level 1-, with 45% of CASP criteria met) recommended the assessment of the risk factors for incomplete lid closure. It is reasonable because incomplete lid closure is the most significant risk factor for OSDs (Bates et al., 2004; Cunningham & Gould, 1998; Dua, 1998; Johnson et al., 2000; Marshall et al., 2008; Parkin & Cook, 2000; Sivasankar et al., 2006). Reduced conscious level, intubation, and metabolic derangement are the biological plausible risks factors for incomplete lid closure and OSDs. As the risk factors are unlikely to have great change or be eliminated in 24 hours, and the onset of OSDs is within 24 to 48 hours (Desalu et al., 2008; Sivasankar et al., 2006; So et al., 2008; Suresh et al., 2000), daily assessment is recommended.

2. Lid closure

Eye care protocols based on lid closure reduced the OSD incidence (Joyce, 2002; Marshall et al., 2008; Parkin et al., 1997; Suresh et al., 2000) and severity (Suresh et al., 2000). All 4 studies emphasized the importance of assessing the completeness of lid closure. As mentioned, the lid closure assessment was suggested to perform daily (Marshall, et al., 2008) or every 8 hours (Suresh et al., 2000) or 2 hours (Laight, 1996; Parkin et al., 1997). Although the study of Marshall et al. (2008) is at the highest evidence level 1- with 45% of CASP criteria met, the early onset time of OSDs, that is 24 to 48 hours (Desalu et al., 2008; Sivasankar et al., 2006; So et al., 2008; Suresh et al., 2000), showed daily assessment is inadequate to prevent OSDs. Eight-hourly lid closure assessment reduced the OSD incidence from 42% to 8.7% and reduced OSD severity from grade 4 to grade 1 (Suresh et al., 2000) (evidence level 2-, with 25% of CASP criteria met). Two studies (Laight, 1996; Parkin et al., 1997) (evidence level 2-, with 28.6% and 31.3% of CASP criteria met respectively) recommended 2-hourly assessment which is neither practical nor necessary. Therefore, 8-hourly assessment using a hand-held torch is recommended (Bates et al., 2004; Suresh et al., 2000).

For patients with incomplete lid closure, Marshall et al. (2008) suggested 2-hourly application of lids cleansing and eye lubricants, and passive or mechanical lid closure; Suresh et al. (2000) applied eye lubricants and taping; Parkin et al. (1997) suggested 2-hourly application of eye ointment and taping; Laight (1996) consulted doctors for prescribing eye ointment, paraffin gauze

dressing, and taping. Three studies showed their eye care protocols reduced the OSD incidence (Marshall et al., 2008; Parkin et al., 1997; Suresh et al., 2000), and 1 study showed a reduced severity of OSDs (Suresh et al., 2000). Therefore, incomplete lid closure indicates a need for eye hygiene, eye lubricants, and eye covers.

3. Corneal dryness

Corneal desiccation predisposes OSD damage and infection (Dua, 1998; McClellan, 1997; Mercieca et al., 1999). Laight (1996) (evidence level 2-, with 28.6% of CASP criteria met) assessed the corneal dullness and sparkles every 2 hours, and applied eye lubricants and taping to dry cornea. Dua (1998) suggested assessing the patients at risk for OSDs every 4 to 6 hours. Four-hourly assessment is recommended together with the routine pupil assessment. Eye covers or eye lubricants will be implemented to dry cornea.

4. Lid cleanliness

Eyes should be kept clean (Cunningham & Gould, 1998). Laight (1996) (evidence level 2-, with 28.6% of CASP criteria met) suggested 2-hourly assessment of lid cleanliness, and the application of sterile water soaked gauze lid cleansing to unclean lids. Four-hourly lid cleanliness assessment together with the routine pupil assessment is adequate and more applicable. Unclean lids require eye hygiene. For patients with eye infection or copious discharge, or respiratory infection with copious sputum especially PAER infection (Hilton et

al., 1983; Hunt, 1991; Hutton & Sexton, 1972; Johnson et al., 2000; Parkin & Cook, 2000), more frequent assessment and eye hygiene are indicated.

5. Signs of eye infection

Parkin et al. (1997) and Laight (1996) (evidence level 2-, with 31.3% and 28.6% of CASP criteria met respectively) provided 2-hourly assessment of the signs of eye infection, such as eye redness or discharge (Laight, 1996), for patients with respiratory PAER infection (Parkin et al., 1997). Parkin et al. (1997) showed a significant reduction in PAER conjunctival infection rate from 0.8% to 0.05%. For any signs of infection, nurses took an eye swab for culture and informed the doctors (Laight, 1996), or sent an urgent Gram stain culture (Parkin et al., 1997). Eye PAER infection indicated an ophthalmologist consultation and Gentamicin prescription (Parkin et al., 1997). Based on the 24-hour onset of OSDs (Desalu et al., 2008; Sivasankar et al., 2006; So et al., 2008; Suresh et al., 2000), at least daily assessment is recommended. More frequent assessment is suggested for patients with respiratory infection with copious sputum, especially PAER infection (Hilton et al., 1983; Hunt, 1991; Hutton & Sexton, 1972; Johnson et al., 2000; Parkin & Cook, 2000). Signs of eye infection indicate eye swab culture, and medical and ophthalmologist consultations. More frequent lid cleansing is indicated as discussed.

6. Signs of OSDs

Two studies suggested a regular assessment of the signs of OSDs (Marshall et al., 2008; Parkin et al., 1997) (evidence level 1-, with 45% of CASP criteria met; evidence level 2-, with 31.3% of CASP criteria met). Marshall et al. (2008) suggested a weekly assessment. Suspected OSDs indicate a timely referral (Marshall et al., 2008). As 65% to 95% of OSDs develop in 24 to 48 hours (Desalu et al., 2008; Sivasankar et al., 2006; So et al., 2008; Suresh et al., 2000), weekly assessment will largely underestimate the true incidence of OSDs, delay treatment, worsen OSDs, and predispose complications. Daily assessment is more logical. Prompt ophthalmology consultation is recommended to prevent ocular complications (Asburst, 1997; Dua, 1998; Hunt, 1991; Johnson et al., 2000; Marshall et al., 2008; Parkin et al., 1997).

Eye care interventions

Eye hygiene

Marshall et al. (2008) (evidence level 1-, with 45% of CASP criteria met) suggested that 2-hourly NS soaked gauze cleansing to patients with incomplete lid closure is an effective practice in preventing OSDs. However, 5 studies did not evaluate the effect of eye hygiene on OSDs (Cortese et al., 1995; Joyce, 2002; Koroloff et al., 2004; Laight, 1996; So et al., 2008), and 2 studies showed eye hygiene is less effective than eye lubricants or eye covers in preventing OSDs (Ezra et al., 2005; Suresh et al., 2000). Nevertheless, eye hygiene is necessary to promote comfort and remove discharge, debris, and microorganisms

(Cunningham & Gould, 1998). Together with the lid cleanliness assessment, 4-hourly eye hygiene is suggested for unclean lids (Laight, 1996). More frequent eye hygiene is preferred for patients with eye infection or copious discharge, or respiratory infection with copious sputum especially PAER infection (Hilton et al., 1983; Hunt, 1991; Hutton & Sexton, 1972; Johnson et al., 2000; Parkin & Cook, 2000). Lid cleansing with sterile gauze in a once-swab-once manner is recommended over eye toilet to reduce the risk of cross infection (Cunningham & Gould, 1998). NS irrigation is not recommended as it predisposes the risk of cross infection, and produced a higher OSD incidence rate in 1 study (Desalu et al., 2008) (evidence level 2-, with 50% of CASP criteria met). All studies have not compared the effectiveness of NS and sterile water on OSD prevention. Lloyd (1990) and Trees & Tomlinson (1990) showed that NS eye drops disrupted the tear lipid layer and increased tears evaporation rate, the use of NS is still controversial until further evidence is available.

Eye covers

Eye hygiene is not sufficient for OSD prevention (Ezra et al., 2005; Suresh et al., 2000). Marshall et al. (2008) (evidence level 1-, with 45% of CASP criteria met) emphasized the importance of maintaining a complete lid closure by means of passive lids closure or mechanical methods. Passive lids closure is less effective than eye lubricants in reducing the incidence of corneal breakdown (Joyce, 2002; Lenart & Garrity, 2000) (evidence level 1++, with 75% of CASP criteria met; evidence level 1-, with 35% of CASP criteria met). On the other

hand, mechanical eye covers significantly reduced the incidence and severity of corneal breakdown when compared with eye lubricants (Sivasankar et al., 2006) (evidence level 1-, with 25% of CASP criteria met). Eye covers, except Geliperm (Bates et al., 2004; Ezra et al., 2005; Joyce, 2002; Laight, 1996) or CorneaCare (Bates et al., 2004), are more effective than eye lubricants, routine care, or no care in reducing OSDs (Cortese et al., 1995; Ezra et al., 2005; Joyce, 2002; Koroloff et al., 2004; Sivasankar et al., 2006; Suresh et al., 2000) (evidence levels 1++ to 2-, with 25% to 75% of CASP criteria met). Eye cover acts as a physical barrier to prevent eye inoculation of respiratory microorganisms during suctioning (Dua, 1998; Hernandez & Mannis, 1997; Hilton et al., 1983; Hunt, 1991; Hutton & Sexton, 1972; Johnson et al., 2000; Ommeslag et al., 1987; Parkin & Cook, 2000; Parkin et al., 1997; So et al., 2008). In addition, using eye covers is more time- and cost-saving and applicable in the ICU (Cortese et al., 1995; Joyce, 2002; Koroloff et al., 2004; So et al., 2008). The use of mechanical eye covers is therefore supported over eye lubricants.

Polyethylene cover is recommended as Joyce (2002) (evidence level 1++, with 75% of CASP criteria met), Koroloff et al. (2004) (evidence level 1+, with 70% of CASP criteria met) and Cortese et al. (1995) (evidence level 1+, with 50% of CASP criteria met) concluded that polyethylene significantly reduced the incidence of corneal breakdowns with the odd ratio of 6.05 to 6.22, when compared with hypromellose or Lacrilube instillations. Polyethylene is suggested to apply from eyebrows to cheekbones (Cortese et al., 1995; Koroloff

et al., 2004; So et al., 2008), with Micropore sealing edge if necessary (Koroloff et al., 2004; So et al., 2008). As daily (Cortese et al., 1995) or 8-hourly (Koroloff et al., 2004) changing of polyethylene offered the same effect on OSD prevention, changing daily or whenever necessary is recommended.

Micropore taping is not suggested because the studies involved are at low evidence level 2- with 25% to 31.3% of CASP criteria met (Laight, 1996; Parkin et al., 1997; Suresh et al., 2000). Moreover, Micropore was used as one of the interventions in the protocols, thus no definite effectiveness in OSD prevention could be evaluated.

Geliperm and CorneaCare are not suggested. Bates et al. (2004) (evidence level 1-, with 38.9% of CASP criteria met), Laight (1996) (evidence level 2-, with 28.6% of CASP criteria met) and Joyce (2002) (evidence level 1++, with 75% of CASP criteria met) showed that the effects of Geliperm or CorneaCare use were similar to that of eye hygiene or lubricants; while Ezra et al. (2005) (evidence level 2-, with 43.8% of CASP criteria met) showed that Geliperm produced higher incidence and severity of OSDs than Lacrilube or simple eye toilet.

Sivasankar et al. (2006) (evidence level 1-, with 25% of CASP criteria met) found that the swimming goggles chamber significantly reduced the incidence and severity of OSDs when compared with eye ointment or taping. However, goggles use is not preferable because of the low evidence level of the study, the unpleasant patient appearance, and possible complications such as lid abrasions and conjunctival or lid edema.

Eye lubricants

All unconscious or heavily sedated patients' eyes should be lubricated (Marshall et al., 2008) (evidence level 1-, with 45% of CASP criteria met) to reduce the risks of corneal dehydration and infection (Cunningham & Gould, 1998; Dua, 1998; Hernandez & Mannis, 1997). Compared with passive closure or lid cleansing, eye lubricants significantly reduced the incidence (Ezra et al., 2005; Joyce, 2002; Lenart & Garrity, 2000; Suresh et al., 2000) and severity of OSDs (Ezra et al., 2005; Suresh et al., 2000). Eye lubricants use is recommended when eye covers are not applicable, for example, in the cases of eye infection or copious eye discharge, or for mildly sedated patients with occasional blink reflex (Suresh et al., 2000). Eye ointment is preferred over eye drops as ointment is physiologically more effective in providing longer-lasting eye moisture and thus it requires less frequent instillation (Lenart & Garrity, 2000). Four-hourly Duratears application (Joyce, 2002; Lenart & Garrity, 2000; So et al., 2008) is the choice. Duratears ointment is more effective than passive closure (Joyce, 2002; Lenart & Garrity, 2000) (evidence level 1++, with 75% of CASP criteria met; evidence level 1-, with 35% of CASP criteria met), and is as effective as polyethylene cover (So et al., 2008) (evidence level 1+, with 66.6% of CASP criteria met) in reducing the incidence of corneal breakdowns. Although in the study of So et al. (2008), the wide calculated 95% CI of the insignificant results might indicate a type II error, both Duratears and polyethylene cover produced a low OSD incidence of 5.3% to 6.8% (So et al., 2008). 1.27-cm Duratears (Lenart

& Garrity, 2000) is suggested to apply to the "V" pocket between eyeball and lower lid (So et al., 2008).

Using hypromellose drops alone is not recommended, as no studies have showed its effectiveness over routine care, and hypromellose increased the OSD incidence by 6 folds when compared with polyethylene cover (Cortese et al., 1995; Joyce, 2002) (evidence levels 1+ and 1++, with 50% and 75% of CASP criteria met respectively).

Using Lacrilube ointment is not preferred as well. Ezra et al. (2005) (evidence level 2-, with 43.8% of CASP criteria met) showed Lacrilube significantly reduced the incidence and severity of OSDs when compared with eye toilet and Geliperm covers. However, Lacrilube use is not supported because Lacrilube produced a high incidence of OSDs (15.4%), and eye toilet (Cunningham & Gould, 1998) and Geliperm (Bates et al., 2004; Ezra et al., 2005; Joyce, 2002; Laight, 1996) are not effective in preventing OSDs.

Two-hourly application of HL combination is also not recommended. Joyce (2002) (evidence level 1++, with 75% of CASP criteria met) showed that HL combination, compared with polyethylene cover, increased the OSD incidence by an odd ratio of 6.22. Koroloff et al. (2004) (evidence level 1+, with 70% of CASP criteria met) showed that HL combination was as effective as polyethylene, and it produced a low OSD incidence (6.7%). However, the wide calculated 95% CI of the insignificant results might indicate a type II error. Moreover, the purpose of the study of Koroloff et al. (2004) was to measure corneal damages; however, they measured corneal ulcerations only. As the

majority of corneal damages are less severe superficial punctuate keratopathy that is grade 1 to 2 OSDs, while corneal ulcerations are the more severe form and the minority group of OSDs (Ezra, Heavly & Coombes, 2005), the low incidence of corneal damage with the use of HL combination (Koroloff et al., 2004) might contribute to the operational definition of OSDs (Ezra, Heavly & Coombes, 2005).

As discussed, eye covers prevent eye inoculation of respiratory microorganisms. During oropharyngeal or open endotracheal suctioning, especially for patients with respiratory PAER infection, covering eyes is recommended (Dua, 1998; Hernandez & Mannis, 1997; Hilton et al., 1983; Hunt, 1991; Hutton & Sexton, 1972; Johnson et al., 2000; Ommeslag et al., 1987; Parkin & Cook, 2000; Parkin et al., 1997; So et al., 2008).

In conclusion, developing an eye care protocol in the ICU setting is necessary to prevent the OSDs and subsequent complications. The selected studies have showed that eye assessments, lid cleansing, polyethylene cover, and Duratears ointment are the main components of the proposed evidence-based protocol. In the next chapter, the translation and application of the protocol will be discussed.

CHAPTER 3 TRANSLATION AND APPLICATION

The previous chapters show a definite urgency to develop an evidence-based eye care protocol for the patients in the target ICU, where the proposed protocol is to be implemented, so as to reduce the incidence and severity of OSDs and subsequent complications. The proposed evidence-based innovation is composed of the assessments of lid closure, lid cleanliness, OS desiccation and signs of OSDs, and 3 eye care interventions including soaked gauze lid cleansing, polyethylene eye covers, and Duratears eye lubricant. In this chapter, the implementation potential of this proposed innovation will be assessed before translating the research findings into an evidence-based eye care protocol.

3.1 IMPLEMENTATION POTENTIAL

The implementation potential will be assessed in terms of target setting, target audience, transferability of the findings, feasibility, and cost-benefit ratio of the innovation (Polit & Beck, 2008).

Target setting

The target setting is a 20-bed general adult ICU of a large teaching public hospital in HK, which serves 10 to 18 patients daily. The common diagnoses are acute coronary syndrome, trauma, post-operative care, heart, respiratory or renal failure, and multi-organ failure. The average ICU LOS is 4 to 7 days.

Target audience

The target audience of the proposed innovation includes all ICU patients who are

- Aged 12 or above
- Mechanically ventilated
- Having altered LOC (GCS 3-12) due to critical condition, or the use of sedatives or neuromuscular blockers
- Having no or limited spontaneous blinking reflexes for an expected period of at least 24 hours
- Having any diagnoses, except the burn or trauma patients, or patients with preexisting eye or face injuries or diseases

Transferability of the findings

The findings are transferable as they fit the target setting and audience. All selected studies were conducted in the ICUs. Seven studies were conducted in large teaching hospitals (Bates et al., 2004; Cortese et al., 1995; Desalu et al., 2008; Koroloff et al., 2004; Lenart & Garrity, 2000; Sivasankar et al., 2006; So et al., 2008), while 5 were conducted in the ICUs of similar specialties, including general (Cortese et al., 1995; Laight, 1996; So et al., 2008), medical (Bates et al., 2004; Sivasankar et al., 2006), surgical, and neurosurgical ICUs (Bates et al., 2004). Except the 3-patient pilot study (Laight, 1996), the ICU capacities were similar, ranging from 10 to 18 (Bates et al., 2004; Cortese et al., 1995; Koroloff et al., 2004; So et al., 2008; Suresh et al., 2000). Although 5 studies did not mention the ICU capacity (Desalu et al., 2008; Ezra et al.,

2005; Lenart & Garrity, 2000; Parkin et al., 1997; Sivasankar et al., 2006), this will not affect the nurses' workload or transferability in the one-to-one care ICU setting.

The studies were mainly conducted in UK and United States (US). Although there is only 1 HK study (So et al., 2008), the cultural difference is not likely to be a factor affecting the eye care innovation. In HK, there are often patients from UK, US, Canada, and Southeast Asia. Moreover, So et al. (2008) has successfully carried out the saline lid cleansing, polyethylene eye covers, and 4-hourly Duratears application in a 16-bed ICU in HK. The findings are therefore transferable to HK setting. Firstly, eye hygiene is not an odd innovation to the target ICU setting, where patient hygiene is highly emphasized. Nurses perform bed bathing to patients daily, and face washing and mouth care 3 times a day. Some nurses also perform lid cleansing to obviously soiled eyes by saline soaked gauze. Secondly, the transparency, easy application, and easy removal of the polyethylene covers save time (Cortese et al., 1995; Koroloff et al., 2004; So et al., 2008), minimize the interruption of frequent pupil assessment in the ICU (Koroloff et al., 2004), and reduce family distress (Cortese et al., 1995) and the risk of skin damage. Lastly, eye lubricant does not interfere the frequent pupil assessment (Lenart & Garrity, 2000), but it is more time-consuming than eye covers. Less frequent application is preferred to allow time for life-sustaining issues. Four-hourly Duratears application, together with the routine 4-hourly pupil assessment in the target ICU under implementation, is less time-consuming (Lenart & Garrity, 2000; So et al., 2008).

The subjects of the studies are similar to the target audience of the proposed innovation. The samples of the studies were all adult ICU patients, at age 15 to 64 (Bates et al., 2004; Cortese et al., 1995; Desalu et al., 2008; Koroloff et al., 2004; Laight,

1996; Lenart & Garrity, 2000; Sivasankar et al., 2006; So et al., 2008; Suresh et al., 2000). They were either comatose (Cortese et al., 1995; Joyce, 2002; Koroloff et al., 2004; Laight, 1996; Marshall et al., 2008; Sivasankar et al., 2006; So et al., 2008; Suresh et al., 2000), semicomatose (Cortese et al., 1995; Joyce, 2002; Marshall et al., 2008; Sivasankar et al., 2006), sedated (Bates et al., 2004; Cortese et al., 1995; Desalu et al., 2008; Joyce, 2002; Koroloff et al., 2004; Lenart & Garrity, 2000; Marshall et al., 2008; Sivasankar et al., 2006; So et al., 2008; Suresh et al., 2000), or paralysed (Cortese et al., 1995; Joyce, 2002; Koroloff et al., 2004; Laight, 1996; Lenart & Garrity, 2000; Marshall et al., 2008; So et al., 2008; Suresh et al., 2000) by similar drugs used in the target setting, such as morphine and midazolam (Cortese et al., 1995), and propofol (Lenart & Garrity, 2000). The patients' GCS ranged from 3 to 10 (Bates et al., 2004; Marshall et al., 2008; Sivasankar et al., 2006; So et al., 2008) with limited (Cortese et al., 1995) or no blinking reflex (Bates et al., 2004; Koroloff et al., 2004; Marshall et al., 2008; Suresh et al., 2000) for at least 24 to 48 hours (Bates et al., 2004; Lenart & Garrity, 2000).

The patients participated in the studies were also similar to the target audience in terms of the LOS, pupil assessment frequency, diagnoses, duration of mechanical ventilation, and ventilator settings. The ICU LOS ranged from 1 to 17 days (Desalu et al., 2008; Ezra et al., 2005; Koroloff et al., 2004; Sivasankar et al., 2006; So et al., 2008), with pupil assessment 10 to 20 times a day (Koroloff et al., 2004; So et al., 2008). The patients were mechanically ventilated (Joyce, 2002; Marshall et al., 2008; Suresh et al., 2000) for at least 24 hours (Bates et al., 2004; Koroloff et al., 2004; Lenart & Garrity, 2000; So et al., 2008) to 28 days (Desalu et al., 2008; Laight, 1996; Parkin et al., 1997),

with similar ventilator modes, PEEP (Laight, 1996), and peak airway pressure settings (So et al., 2008). The patients were medical (Koroloff et al., 2004; Lenart & Garrity, 2000), surgical (Lenart & Garrity, 2000), neurological (Cortese et al., 1995; Suresh et al., 2000), or neurosurgical cases (Koroloff et al., 2004), with similar diagnoses such as respiratory problems (Cortese et al., 1995; Suresh et al., 2000), septic shock (So et al., 2008), post-operative care (Desalu et al., 2008; Suresh et al., 2000), acute renal failure, heart failure (Parkin et al., 1997), multi-organ failure (Desalu et al., 2008), and head injury (Bates et al., 2004; Cortese et al., 1995; Desalu et al., 2008). Studies did not include patients with facial or eye trauma (Bates et al., 2004; Cortese et al., 1995; Ezra et al., 2005; Joyce, 2002; Koroloff et al., 2004; Lenart & Garrity, 2000; So et al., 2008; Suresh et al., 2000).

The proposed innovation fits the prevailing philosophy of care of the target ICU setting. In the view of the low nurse-to-patient ratio in the ICU, the best individualized patient-centre nursing care, nursing autonomy, critical thinking, and evidence-based practice (EBP) are highly emphasized in a top-down approach. Primary nursing has been newly introduced to emphasize the importance of individualized nursing care plan. Primary nurse develops and evaluates the care plan, and is responsible for any adverse patient outcomes such as pressure sore. Moreover, the managers highly appreciate EBP and the room for improvement. The audit core group is responsible for continuous nursing care auditing to ensure nursing care quality. An audit control officer (ACO), who is an ICU nurse, is assigned to monitor the nursing care outcomes through data collection and analysis on topics such as the monthly incidence of methicillin resistant staphylococcus aureus (MRSA) infection, VAP, or pressure sore. The statistics will be

presented in monthly ward meetings, or on the circulars and boards, to alert the nurses and strive for better patient care. Monthly journal clubs with Continuous Nursing Education (CNE) points are held to update the nursing knowledge. Contributions of the nurses in the core groups, such as the pressure sore or audit core groups, will be recognized in the Self Development Report (SDR) and by the Continuous Quality Improvement (CQI) awards at the end of each year. Moreover, 2 RCTs on the topics of VAP and sedation vacation are being conducted by the doctors and nurses in the target ICU. Guidelines and protocol-guided patient care are common as well. The proposed innovation is not a new idea to the target ICU setting. Fortunately, the nurses are mostly bachelor or master degree holders. Nurses follow the evidence-based insulin protocol well when a clear relationship between blood glucose and mortality has been demonstrated. Therefore, nursing EBP is possible with the provision of clear evidence. Lastly, bottom-up communication is not difficult. Communicating the implementation plan is possible if the protocol is working for better patient outcome.

The proposed innovation will benefit a sufficiently large number of patients. At least 50% of the admitted patients are having altered LOC and intubated, with an average LOS of 4 to 7 days, around 250 patients can directly benefit from this innovation each year. Prevention of complications, treatments, or prolonged LOS allows more appropriate resources allocation and benefits other patients indirectly. Lastly, the duration of implementation and evaluation is transferable as it is within the patient's ICU stay. Eye care starts from the ICU admission to the recovery of patient's blinking reflex or development of OSDs, which lasts approximately 1 to 2 weeks or at most 1 to 2 months.

Feasibility

Managerial support plays a key role in actively promoting and supporting the change (Bryar et al., 2003; LaPierre, Ritchey & Newhouse, 2004). There is freedom to carry out the innovation as the ward manager (WM) and nurse specialist highly appreciate the proposed EBP innovation, and have already approved the innovation. In addition to the administrative support, the organizational EBP climate in the target ICU, as discussed, facilitates the research utilization and practice change. Although the communication path to the other decision makers, including the Chief of Service (COS) and Departmental Operational Manager (DOM), has been shortened, their consensus, support, and approval have to be obtained by a priority communication.

Moreover, the WM has invited an interventional study in the target ICU recently. There is freedom to conduct a pilot study by the WM, nurse specialist, the investigator who is in charge of the protocol, and the ACO. Pilot study is useful for a systematic process and outcome evaluations, to identify unexpected implementation obstacles, magnitude of effects, and the need to modify implementation and evaluation (Melnyk & Fineout-Overholt, 2005). Evaluation results will be presented to the users and decision makers in ward meeting, so as to strive for a better success.

One-way top-down approach does not lead to an intervention success; consensus should be gained from all stakeholders (Melnyk & Fineout-Overholt, 2005). There is no consensus among nurses, including the ACO, who are the main stakeholders bearing the greatest source of resistance. The reasons behind are nurses' traditional reluctance to changes, weak evidence support, and increased workload or paperwork. For example, the recent introduction of nursing round, primary nursing, or 8-hourly mouth care led to

huge nurses' resistance because of their increased workload and reluctance to change. Insufficient evidence and nurses' skepticism towards change intensify their resistance (Melnyk & Fineout-Overholt, 2005). In addition, the EBP in the target ICU is dominated by manager's authority and research utilization, with the ignorance of clinical environment and users' preference (Melnyk & Fineout-Overholt, 2005). Nurses often regard themselves as incapable of making decisions and changes (Bryar et al., 2003). Time and good evidence support aid better acceptance, like the success of the insulin protocol discussed before. According to the transtheorectical model, 80% of people are at the precontemplation and contemplation stages (Melnyk & Fineout-Overholt, 2005). Their unawareness of the OSD prevalence and the significance of eye care protocol are the great barriers to a successful implementation. Therefore, the first step to do is to raise nurse's awareness of OSDs and the importance of eye care protocol (Laight, 1995).

Forming an eye care team with registered nurse (RN) members can reduce the hierarchical effect and aid better expression of opinions. The eye care team shows nurses the knowledge of eye care on the boards, and then presents them the literature review and clear evidence on the prevalence of OSDs, and the significance and user-friendliness of the eye care interventions in the journal clubs (Laight, 1995). The communication helps better nursing commitment, compliance, and success of the protocol (Laight, 1995; Melnyk & Fineout-Overholt, 2005; Thurston & King, 2004). Open discussions show a treasure of user's opinions that empowers them to change, reduce skepticism, and enhance compliance (Melnyk & Fineout-Overholt, 2005). A few months will be needed for nurses to digest the information before implementation. It is

important to keep this innovation in an appropriate pace, and prevent it from clashing with other ICU trainings or audits, so as to minimize nurses' indigestion or workload.

A user-friendly protocol is also important to minimize the interference to staff function. For example, eye assessment will be performing with the routine pupil assessment; saline lid cleansing is already dominating in HK ICUs (Chiang et al., 2007); daily application of transparent eye covers saves time and minimizes the interruption of pupil assessment; 4-hourly eye lubricant application is also feasible in one-to-one care.

Briefing and training during work are feasible and highly supported in the target ICU. Examples are the renal replacement therapy training, intubation or resuscitation drills, and the continuous clinical briefing and auditing to nurses. The nurse specialist and the investigator who is in charge of the protocol will provide the briefing and auditing skills to the team, who is responsible for the delivery of the detailed protocol contents to all nurses by the briefing sessions. Questions answering and repeated explanations are expected. The team conducts the knowledge audit to nurses following the briefing sessions. Well contributed team members will be given recognition. The protocol will be circulated among nurses (Laight, 1995) and uploaded to the intranet. A flow chart of the protocol will be attached to each bedside reference book as well.

To ensure a good compliance, intervention checks will be done by the investigator who is in charge of the protocol, DOM, WM, and nurse specialist as usual during ward round. Visible eye covers enhance better nursing compliance and easier monitoring. The primary nursing system reduces the frictions between different case nurses. Compliance can also be monitored by the documentation charts of the eye assessments and eye care interventions. Simple and user-friendly charts, such as box

ticking, would help reduce nurses' workload and resistance to paper work. The reasons of noncompliance will be identified during ward rounds or focus group interview. Adding eye care as a SDR item may help better compliance.

The equipment and measuring tools in the protocol are available, except the fluorescein stain; and human resources are available in the one-to-one nursing care setting. However, the protocol requires skills in the primary outcome measure, that is the identification of OSDs. Ophthalmologists have to be consulted for the provision of a professional skills training to the eye care team, so that the ICU RNs and doctors are able to assess the OSDs, and the ICU doctors are able to consult ophthalmologists as early as possible for the suspected OSD (Cortese et al., 1995; So et al., 2008). Ophthalmologists' resistance may exist because of the burdens of consultation and treatments. Priority communication is required to gain their consensus and support.

The ICU doctors are not likely a resistance as they support EBP and are cooperating well with nurses. For example, doctors are willing to sign in the printed chlorohexidine prescription for mouth care without hesitation. The proposed eye care innovation minimizes doctor's involvement, and the eye drops prescription is unlikely a problem.

The hospital pharmacy department is unlikely a source of friction, as the eye lubricant prescription will not interfere its daily function, and Duratears ointment is available.

Therefore, with the priority communications with the decision makers, eye care team, nurses, and the ophthalmologists, the proposed innovation is feasible. Detailed communication plans with the stakeholders will be discussed in Chapter 4.1.

Cost/ benefit ratio of the innovation

The benefits of the innovation outweigh its costs. A HK survey showed that 82.1% nurses performed lid cleansing, 30.6% used eye lubricant, but only 14.8% applied eye covers (Chiang et al., 2007). As discussed, mechanical eye cover is the most effective eye care in preventing OSDs, while eye hygiene is the least effective measure. Therefore, the common practice in HK is not supported by the literature, but the recommended evidence-based eye care is not carried out in HK. As mentioned in previous chapter, unstandardized care or eye hygiene produced an OSD incidence of 22% to 55.4% (Bates et al., 2004; Desalu et al., 2008; Ezra et al., 2005; Lenart & Garrity, 2000; Parkin et al., 1997; Suresh et al., 2000), and a severity of grade 1 to 4 (Ezra et al., 2005; Suresh et al., 2000) (see Appendix 9). However, 11 studies showed that eye care protocols with eye covers or eye lubricants significantly reduced the incidence and severity of OSDs (Bates et al., 2004; Cortese et al., 1995; Ezra et al., 2005; Joyce, 2002; Koroloff et al., 2004; Lenart & Garrity, 2000; Marshall et al., 2008; Parkin et al., 1997; Sivasankar et al., 2006; So et al., 2008; Suresh et al., 2000). A HK eye care protocol using saline lid cleansing, Duratears, and polyethylene covers reduced the OSD incidence to 5.3% to 6.8% (So et al., 2008). Maintaining current unstandardized practice in the target ICU leaves high prevalent OSDs unrecognized, and leads to preventable eye complications such as corneal perforation and scarring, life-long visual damages, and poor quality of life. Unnecessary eye treatment or surgeries and prolonged ICU stay burden the health care system in terms of financial and human resources. Prolonged ICU stay further harms patients by the complications such as hospital acquired pneumonia, and causes a vicious cycle. On the other hand, lid cleansing, eye covers, or eye lubricant

do no harm to patients. The innovation enhances early prevention, identification, and treatment to prevent the above adverse consequences to patients and health care system.

As discussed, equipment is available except the fluorescein stain. The material costs of the proposed innovation are minimal, compared with the huge health care expenses and invaluable patient's benefits such as the visual acuity or quality of life. The gauze or sterile solution for lid cleansing costs EUR$3.24 per patient (Laight, 1996); while 200-feet polyethylene costs HKD$15 (So et al., 2008) for 6 months in a 14-bed ICU (Cortese et al., 1995; Joyce, 2002). The use of polyethylene covers saves AUD$10000 a year (Koroloff et al., 2004). Moreover, 1 tube of Duratears costs HKD$20 per patient (So et al., 2008). However, 1 day of general ward stay costs at least HKD$3900 per patient (Wong, 2005). One day of ICU stay costs much more for the human resources and advanced technologies. The public hospitals in HK serve 94% of hospital services. However, the patient's fee income is only 2.5% of the operating expenses (Wong, 2005). The great financial burden is further affected by the financial tsunami and aging population, and so early discharge is preferred (Wong, 2005). Therefore the unnecessary eye treatments or prolonged ICU stay cost much more than the minimal costs of the innovation.

The potential nonmaterial costs of implementing the proposed innovation are the potential frictions between nurses, increased workload, stress and anxiety, and thus their overall morale or more sick leaves. Priority communication with the nurses and appropriate implementation timing and pace prevent information indigestion, reduce stress and anxiety, and help acceptance and compliance. It takes time to learn, implement, and evaluate. Communication, education, outcomes presentation, and

recognition or awards may increase better commitment. However, the outcome evaluation and staff recognition should aim at appreciation, rather than imposing stress and anxiety to primary nurses. The primary nurse system improves nurses' sense of responsibility, enhances a better compliance, and aids easier evaluation of the factors or barriers affecting the desired outcomes.

The proposed innovation brings potential nonmaterial benefits to the organization as well. It brings nurses job satisfaction when they understand that a simple lid cleansing or eye cover can protect patients' eye sight in long term and their quality of life. A well-developed protocol is a kind of EBP education and culture development in ICU, rather than research utilization. A contributive evidence-based nursing-guided protocol is a good start to enhance nursing autonomy and their sense of control. It might earn respects from other disciplines, and be a good start of nursing professionalisation.

In conclusion, having considered the implementation potential of the eye care protocol, this innovation is transferable, feasible, and cost-effective in the target clinical setting. In the following section, an evidence-based eye care protocol will be developed for the ICU patients with altered level of consciousness.

3.2 EVIDENCE-BASED EYE CARE PROTOCOL FOR ICU PATIENTS WITH ALTERED LEVEL OF CONSCIOUSNESS

With the sufficient research base of eye care, the next step of the Iowa Model is to develop an evidence-based eye care protocol (Melnyk & Fineout-Overholt, 2005; Polit & Beck, 2008; Titler, 2002) (see Appendix 1).

Target users of the protocol: Nurses in the target ICU under implementation

The objectives of the protocol are to:

- increase nurses' awareness and understanding of the importance of eye care in the prevention of OSDs.
- specify the nursing assessments and interventions in providing evidence-based eye care to the ICU patients who are at risk.
- reduce the incidence and severity of OSDs, and the subsequent long-term eye problems and hospital costs.

Target population of the protocol is:

- the target audience in the target setting as described.

Rating scheme for the strength of the recommendations

According to the assigned levels of evidence of the studies (see Appendices 6A, 6B, and 7), a grade is assigned to each recommendation with reference to the "SIGN 50: A guideline developer's handbook Annex B: key to grades of recommendations" (Scottish Intercollegiate Guidelines Network, 2008b) (see Appendix 10).

Recommendations

As discussed in Chapter 1, the risk factors for OSDs include the use of muscle relaxants or sedative, mechanical ventilation, VAP, conjunctival edema, multiorgan failure, and patients' poor immunity. Incomplete lid closure is the major significant predisposing factor for OSDs (Bates et al., 2004; Cunningham & Gould, 1998; Dua, 1998; Johnson et al., 2000; Marshall et al., 2008; Parkin & Cook, 2000; Sivasankar et al., 2006), as it removes the physical and chemical protections of eye lids, tears and conjunctiva, and leads to a constant OS exposure (Asburst, 1997; Cunningham & Gould, 1998; Dua, 1998; Hilton et al., 1983; Hunt, 1991; Hutton & Sexton, 1972; Johnson et al., 2000; Mercieca et al., 1999; Parkin & Cook, 2000). Constant OS exposure predisposes corneal desiccation, OS damage, and a higher risk of eye inoculation of respiratory pathogens (Coyer et al., 2006; Desalu et al., 2008; Laight, 1996; Mercieca et al., 1999; Parkin et al., 1997). In addition, eye care protocols based on lid closure reduced the OSD incidence (Joyce, 2002; Marshall et al., 2008; Parkin et al., 1997; Suresh et al., 2000) and severity (Suresh et al., 2000). Therefore, the proposed eye care protocol focuses on the patients who are at risk for incomplete lid closure, corneal desiccation, and eyes contaminations.

The eye care protocol consists of the assessment and intervention parts, with the grades of recommendations (**A, B, C,** and **D**) and evidence levels of the supporting evidences (**1++** to **4**) provided. The implementation of the protocol is shown in a flow chart (see Appendix 11).

Assessments

Recommendation 0.0 Assess the risk factors for OSDs 

Assess the risk factors for OSDs regularly (see Recommendations 1.0 to 5.3) on all newly admitted ICU patients regardless of their levels of consciousness. Patients who are at risk will receive the corresponding eye care interventions.

Supporting evidences:

- Assessment should be done before eye care (Cunningham & Gould, 1998) **(4)**.
- Regular and frequent eye inspection is suggested to all ICU patients (Asburst, 1997; Desalu et al., 2008; Dua, 1998; Hunt, 1991; Johnson et al., 2000) **(3, 4)**.
- Addressing risk factors and early prompt interventions enhance OSD prevention (Dua, 1998) **(4)**.

Recommendation 1.0 Assess the risk factors for incomplete lid closure 

Assess the risk factors for incomplete lid closure at least daily. Patients who are at risk will receive the following eye assessments (see Recommendations 2.0 to 5.3). The risk factors include the reduced conscious level and protective eye reflexes, use of sedatives or neuromuscular relaxants, tracheal intubation, use of PEEP of 5 or above, ventilation in prone position, conjunctival edema, and significant metabolic derangement (cardiac or renal failure).

Supporting evidences:

- ICU nurses must assess each patient for the risk factors of incomplete lid closure, including reduced conscious level, tracheal intubation, and significant metabolic derangement (Marshall et al., 2008) **(1-)**.
- Incomplete lid closure is the major significant predisposing factor for OSDs (Bates et al., 2004; Marshall et al., 2008; Sivasankar et al., 2006) **(1-)**.
- Bates et al. (2004) found that all keratopathies occured in patients with incomplete lid closure **(1-)**.
- Eye care protocols based on the completeness of lid closure reduced the OSD incidence (Joyce, 2002; Marshall et al., 2008) **(1++, 1-)** (Parkin et al., 1997; Suresh et al., 2000) **(2-)** and severity (Suresh et al., 2000) **(2-)**.
- The above risk factors for incomplete lid closure are not likely to have great change or be eliminated within 24 hours. In addition, 65% to 95% of OSDs develop in 24 to 48 hours (Sivasankar et al., 2006; So et al.,

2008) **(1-, 1+)** (Desalu et al., 2008; Suresh et al., 2000) **(2-)**. Daily assessment is suggested.

- Muscle relaxant (Sivasankar et al., 2006) **(1-)** and longer duration of sedation (Desalu et al., 2008) **(2-)** are significant predictive factors for OSD incidence.
- Higher incidence of conjunctival edema is related to higher degree of OS exposure (Suresh et al., 2000) **(2-)** and higher risk of OSDs (Dua, 1998; Hilton et al., 1983; Hunt, 1991) **(3, 4)**.
- Frequent eye inspection is suggested for ventilated and unconscious patients (Hunt, 1991) **(4)**. Intubation process creates a sharp intraocular pressure surge (Cunningham & Gould, 1998) **(4)**. Mechanical ventilation, PEEP of 5 or above, and prone ventilation increase intrathoracic and intraocular pressures, reduce venous drainage (Asburst, 1997; Cunningham & Gould, 1998; Desalu et al., 2008; Dua, 1998; Hunt, 1991; Mercieca et al., 1999) **(2-, 4)**, and predispose conjunctival edema.
- Suresh et al. (2000) showed that conjunctival edema developed in 100% of the prone ventilated patients **(2-)**.
- Longer duration of ventilation is related to higher risk of OSDs (Desalu et al., 2008; Hutton & Sexton, 1972) **(2-, 3)**.
- Multiorgan failure is related to higher OSD incidence. Metabolic derangement, especially cardiac or renal failure, predisposes generalized edema and compromises the eye circulation (Desalu et al., 2008; Hernandez & Mannis, 1997) **(2-, 4)**.

Recommendation 2.0 Assess the incomplete lid closure 

Assess the incomplete lid closure at least every 8 hours, using a bright hand-held torch in line with eye lashes.

Supporting evidences:

- Eye care protocols based on the completeness of lid closure reduced the OSD incidence (Joyce, 2002; Marshall et al., 2008) **(1++, 1-)** (Parkin et al., 1997; Suresh et al., 2000) **(2-)** and severity (Suresh et al., 2000) **(2-)**.
- Incomplete lid closure is the major significant predisposing factor for OSDs (Bates et al., 2004; Marshall et al., 2008; Sivasankar et al., 2006) **(1-)**.
- Bates et al. (2004) found that all keratopathies occured in patients with incomplete lid closure **(1-)**.
- Eight-hourly lid closure assessment led to a reduction in OSD incidence from 42% to 8.7%, and also a reduction in severity from grade 4 to grade 1 (Suresh et al., 2000) **(2-)**.
- Assessing lid closure in line with lashes by bright hand-held torch (Bates et al., 2004) **(1-)** prevents unrecognized incomplete lid closure by naked eye observation, especially in the medial portion (Suresh et al., 2000) **(2-)**.

Recommendation 2.1 

Patients who are unable to maintain complete lid closure will receive eye hygiene, eye cover, or eye lubricant (see Recommendations 6.0 to 9.1).

Supporting evidences:

- Eye care protocols based on the completeness of lid closure reduced the OSD incidence (Joyce, 2002; Marshall et al., 2008) **(1++, 1-)** (Parkin et al., 1997; Suresh et al., 2000) **(2-)** and severity (Suresh et al., 2000) **(2-)**.
- For patients who are unable to maintain complete lid closure, it should be maintained by passive or mechanical methods (Marshall et al., 2008) **(1-)**.
- Eyes should be lubricated to reduce the risks of corneal dehydration, ulceration, or infection (Johnson et al., 2000) **(3)** (Cunningham & Gould, 1998; Dua, 1998; Hernandez & Mannis, 1997; Hunt, 1991) **(4)**.
- Patients with incomplete lid closure would receive lid cleansing (Marshall et al., 2008) **(1-)**, eye lubricants (Marshall et al., 2008) **(1-)** (Laight, 1996; Parkin et al., 1997; Suresh et al., 2000) **(2-)**, and eye covers (Marshall et al., 2008) **(1-)** (Laight, 1996; Parkin et al., 1997; Suresh et al., 2000) **(2-)** in the literature**.**

Recommendation 3.0 Assess the ocular surface dryness 

Assess the ocular surface dryness (dullness and absence of sparkles) at least every 4 hours, using a hand-held torch.

Supporting evidences:

- Laight (1996) assessed corneal dullness and sparkles from reflected light regularly **(2-)**.
- OS desiccation predisposes OS abrasion, damage, and infection because:
  - tears lubricate OS, flush out microorganisms, and allow leukocytes passage (Dua, 1998; McClellan, 1997; Mercieca et al., 1999) **(4)**.
  - tears contain IgA (that prevents bacterial attachment, neutralizes toxins and virus), lysozyme (that hydrolyzes bacteria), and lactoferrin (that enhances the function of natural killer cells and deprives essential iron of bacteria) (Dua, 1998; McClellan, 1997; Mercieca et al., 1999) **(4)**.
- Frequent eye inspection every 4 to 6 hours is suggested for patient at risk for OSDs (Dua, 1998) **(4)**. Four-hourly pupil assessment is routinely performed in the target ICU.

Recommendation 3.1 

Dry ocular surface indicates a need of having eye cover or eye lubricant (see Recommendations 7.0 to 9.1).

Supporting evidences:

- Laight (1996) applied eye lubricants and taping to dry cornea **(2-)**.
- Eyes should be closed and lubricated to reduce the risks of corneal dehydration, ulceration, or infection (Johnson et al., 2000) **(3)** (Cunningham & Gould, 1998; Dua, 1998; Hernandez & Mannis, 1997; Hunt, 1991) **(4)**.

Recommendation 4.0 Assess the lid cleanliness 

Assess the lid cleanliness at least every 4 hours. More frequent assessment is required for patients with signs of eye infection or copious eye discharge, or respiratory infection with copious sputum production (that requires frequent suctioning at least 2-hourly), especially PAER infection. Unclean lids indicate a need for eye hygiene (see Recommendations 6.0 to 6.1).

Supporting evidences:

- Laight (1996) assessed the lid cleanliness regularly, and applied sterile water soaked gauze lid cleansing to the unclean lids **(2-)**.
- Eyes should be kept clean to remove debris and promote comfort (Cunningham & Gould, 1998) **(4)**.

- Frequent inspection of eyes in every 4 to 6 hours is suggested for patient at risk for OSDs (Dua, 1998) **(4).** Four-hourly pupil assessment is routinely performed in the target ICU.
- Respiratory infection with copious sputum predisposes eye inoculation of respiratory pathogens and eye infection (Hilton et al., 1983; Hunt, 1991; Johnson et al., 2000; Parkin & Cook, 2000**) (3, 4)**.
- Virulent PAER is a common and the most serious corneal infectious agent (Hutton & Sexton, 1972)**,** which liquefies cornea (Hilton et al., 1983; Hunt, 1991; Johnson et al., 2000)**,** causes ulceration, and perforates eyeball rapidly in 48 hours (Hunt, 1991; Hutton & Sexton, 1972; Ommeslag et al., 1987) **(3, 4)**.

Recommendation 5.0 Assess the signs of OSDs 

Assess the signs of OSDs at least daily, using readily available tools such as fluorescein stain and cobalt blue hand-held torch. Other signs of OSDs include lid swelling, conjunctival swelling with hyperaemia, lid margin crusting, corneal clouding, epithelial loss, redness, or discharge.

Supporting evidences:

- Identify OSDs early by weekly assessment using readily available tools such as fluorescein stain and cobalt blue pen torch (Marshall et al., 2008) **(1-)**.
- 65% to 95% of OSDs develop in 24 to 48 hours (Sivasankar et al., 2006; So et al., 2008) **(1-, 1+)** (Desalu et al., 2008; Suresh et al., 2000) **(2-)**,

and PAER causes rapid eyeball perforation in 48 to 72 hours (Hunt, 1991; Hutton & Sexton, 1972) **(3)** (Ommeslag et al., 1987) **(4)**. Weekly assessment will underestimate the incidence.

- Regular assessment of the signs of OSDs or eye infection (Laight, 1996; Parkin et al., 1997) **(2-)** significantly reduced the PAER eye infection incidence from 0.8% to 0.05% (Parkin et al., 1997) **(2-)**.
- Signs of OSDs are lid swelling, conjunctival hyperaemia, corneal clouding, epithelial loss (Parkin et al., 1997) **(2-)**, corneal haziness, and localized white spots (Dua, 1998) **(4)**.
- Signs of eye infection are redness, discharge (Laight, 1996; Parkin et al., 1997) **(2-),** lid swelling, conjunctival swelling with hyperaemia, and lid margin crusting (Dua, 1998) **(4)**.

Recommendation 5.1 

Assess the signs of OSDs more frequently for patients with respiratory infection, especially those with PAER infection or copious sputum production (that requires at least 2-hourly suctioning).

Supporting evidences:

- Assessing the signs of eye infection for patients with PAER respiratory infection 2-hourly (Laight, 1996; Parkin et al., 1997) **(2-)** significantly reduced the PAER eye infection rate from 0.8% to 0.05% (Parkin et al., 1997) **(2-)**.

- Respiratory infection with copious sputum (that requires suctioning at least 2-hourly) predisposes eye inoculation of respiratory pathogens (Hilton et al., 1983; Hunt, 1991; Johnson et al., 2000; Parkin & Cook, 2000**) (3, 4)**.
- Virulent PAER is the most serious corneal infectious agent (Hutton & Sexton, 1972)**,** which liquefies cornea (Hilton et al., 1983; Hunt, 1991; Johnson et al., 2000) and perforates eyeball rapidly in 48 hours (Hunt, 1991; Hutton & Sexton, 1972; Ommeslag et al., 1987) **(3, 4)**.

Recommendation 5.2 

Signs of OSDs indicate a prompt medical and ophthalmic consultation for early treatment and complications prevention.

Supporting evidences:

- Suspected OSDs indicate a timely referral to prevent complications (Marshall et al., 2008) **(1-)**.
- Nurses informed the doctors for any signs of eye infection in 1 study (Laight, 1996) **(2-).** Parkin et al. (1997) suggested an ophthalmologist consultation for eye PAER infection **(2-)**.
- Early ophthalmologist consultation prevents eye complications (Asburst, 1997; Dua, 1998; Hunt, 1991; Johnson et al., 2000) **(3, 4)**.

Recommendation 5.3 D

Signs of eye infection indicate an eye swab for culture and more frequent eye hygiene (see Recommendations 6.0 to 6.1).

Supporting evidences:

- If there is any sign of eye infection, nurses have to send an eye swab for culture (Laight, 1996) **(2-)** (Asburst, 1997; Johnson et al., 2000) **(3, 4)** or an urgent Gram stain culture (Parkin et al., 1997) **(2-)**.

Eye care interventions

Recommendation 6.0 Eye hygiene C

Perform lid cleansing at least 4-hourly for patients with incomplete lid closure and unclean lids (see Recommendations 2.0 and 4.0). More frequent lid cleansing is indicated for eye infection or copious eye discharge, or respiratory infection with copious sputum (that requires frequent suctioning at least 2-hourly), especially PAER infection.

Supporting evidences:

- Eyes should be kept clean to remove debris and promote comfort (Cunningham & Gould, 1998) **(4)**.
- Eye hygiene has been performed in 9 studies as routine patient care (Cortese et al., 1995; Koroloff et al., 2004; So et al., 2008) **(1+)** (Bates et al., 2004; Marshall et al., 2008) **(1-)** (Desalu et al., 2008; Ezra et al., 2005; Laight, 1996; Suresh et al., 2000) **(2-)**.

- Regular saline soaked gauze cleansing to patients with incomplete lid closure is effective in preventing OSDs (Marshall et al., 2008) **(1-)**.
- Laight (1996) performed lid cleansing to patients with unclean lids (**2-)**.
- Four-hourly pupil assessment is routinely performed in the target ICU.
- Respiratory infection with copious sputum predisposes eye inoculation of respiratory pathogens (Hilton et al., 1983; Hunt, 1991; Johnson et al., 2000; Parkin & Cook, 2000**) (3, 4)**.
- Virulent PAER is the most serious corneal infectious agent (Hutton & Sexton, 1972)**,** which liquefies cornea (Hilton et al., 1983; Hunt, 1991; Johnson et al., 2000) and perforates eyeball rapidly in 48 hours (Hunt, 1991; Hutton & Sexton, 1972; Ommeslag et al., 1987) **(3, 4)**.

Recommendation 6.1 Lid cleansing method C

Lid cleansing with sterile water or normal saline soaked sterile gauze, in once-swab-once manner, is recommended over eye irrigation. However, the use of normal saline is still controversial until further evidence is available. Nurses' hand hygiene is emphasized.

Supporting evidences:

- Five studies used NS soaked sterile gauze for routine lid cleansing (Bates et al., 2004; Marshall et al., 2008) **(1-)** (Koroloff et al., 2004; So et al., 2008) **(1+)** (Suresh et al., 2000) **(2-)**; while 2 studies used sterile water soaked gauze (Laight, 1996; Suresh et al., 2000) **(2-)**.

- NS soaked gauze cleansing is effective in preventing OSDs for the patients with incomplete lid closure (Marshall et al., 2008) **(1-)** and in crusts softening (Laight, 1996) **(4)**.
- None of the studies has compared sterile water and NS on their effectiveness in OSD prevention. NS lid cleansing is a common practice in 5 studies, UK (Cunningham & Gould, 1998) **(4)**, and HK (Chiang et al., 2007) **(3)**.
- However, 2 interventional studies showed that NS disrupted the tears lipid layer and increased the tear evaporation rate for a long period of time (Lloyd, 1990; Trees & Tomlinson, 1990).
- Cross infection of eyes should be avoided by the direction of swabbing and using fresh swab for each eye (Cunningham & Gould, 1998) **(4)**. Handwashing should be done before eye hygiene (Laight, 1996) **(2-)**.
- NS irrigation predisposes a higher risk of cross infection and is related to a higher OSD incidence (Desalu et al., 2008) **(2-)**.

Recommendation 7.0 Eye covers 

For patients with incomplete lid closure and dry ocular surface, eyes should be kept closed by mechanical eye covers (see Recommendations 2.0 and 3.0). Mechanical eye cover is preferred over eye lubricant.

Supporting evidences:

- For patients who are unable to maintain lid closure, a complete lid closure should be maintained by passive eye closure or mechanical methods, so as to prevent OSDs effectively (Marshall et al., 2008) **(1-)**.
- Passive lid closure is less effective than regular eye instillations (Joyce, 2002; Lenart & Garrity, 2000) **(1++, 1-)**, while eye instillation is less effective than mechanical eye covers, in reducing OSD severity (Sivasankar et al., 2006) **(1-)** and incidence (Joyce, 2002) **(1++)** (Cortese et al., 1995; Koroloff et al., 2004) **(1+)** (Sivasankar et al., 2006) **(1-)**.
- Eye care protocols with eye covers reduced the incidence of OSDs from 42% to 8.7% or less (Cortese et al., 1995; Koroloff et al., 2004; So et al., 2008) **(1+)** (Bates et al., 2004; Sivasankar et al., 2006) **(1-)** (Suresh et al., 2000) **(2-)**, and reduced the OSD severity to mainly grade 0 to 1 OSDs (Sivasankar et al., 2006; Suresh et al., 2000) **(1-)**.
- Eye cover acts as a physical barrier to prevent eye inoculation of respiratory microorganisms (So et al., 2008) **(1+)** (Parkin et al., 1997) **(2-)** (Dua, 1998; Hernandez & Mannis, 1997; Hilton et al., 1983; Hunt, 1991; Hutton & Sexton, 1972; Johnson et al., 2000; Ommeslag et al., 1987; Parkin & Cook) **(3, 4)**.

- Eye care protocol with eye covers significantly reduced the incidence of PAER eye infection from 0.8% to 0.05% (Parkin et al., 1997) **(2-)**.

Types of mechanical eye covers

Recommendation 7.1 Polyethylene covers 

Transparent polyethylene covers (Gladwrap) is suggested to apply on clean eyes from eyebrows to cheekbones, with Micropore sealing edge if necessary. Change the polyethylene covers daily or whenever necessary (such as soiled or torn).

Supporting evidences:

- Polyethylene cover significantly reduced the incidence of corneal breakdowns with the odd ratio of 6.05 to 6.22, when compared with regular hypromellose or Lacrilube instillations (Joyce, 2002) **(1++)** (Cortese et al., 1995; Koroloff et al., 2004) **(1+)**.
- Daily application of polyethylene covers significantly reduced the OSD incidence from 26.7% to 3.3%, compared with 2-hourly hypromellose instillation (Cortese et al., 1995) **(1+)**.
- Apply polyethylene from eyebrows to cheekbone (Cortese et al., 1995; Koroloff et al., 2004; So et al., 2008) **(1+)**, with micropore sealing the edges, to ensure adequate moisture in the closed chamber (Koroloff et al., 2004; So et al., 2008) **(1+)**.
- Laight (1996) applied eye covers to clean eyes only **(2-)**.

Recommendation 7.2 Micropore taping 

Micropore taping is NOT recommended until further evidence is available.

Supporting evidences:

- Micropore taping was used as a part of the eye care protocols in the 3 lowest-quality studies. No definite effectiveness of Micropore in OSD prevention could be evaluated (Laight, 1996; Parkin et al., 1997; Suresh et al., 2000) **(2-)**.

Recommendation 7.3 Geliperm and CorneaCare covers 

Geliperm and CorneaCare covers are NOT recommended.

Supporting evidences:

- Geliperm or CorneaCare produced no significant difference on OSD incidence, compared with the application of routine NS eye cleansing and eye lubricants (Bates et al., 2004) **(1-)**.
- Geliperm protocol was showed to be as effective as a standard hypromellose protocol (Joyce, 2002) **(1++)** (Laight, 1996) **(2-)**.
- Geliperm produced the highest severity of OSDs (grade 2 to 3) and the highest OSD incidence (90%) significantly, compared with routine eye toilet (54.2%) and regular Lacrilube instillation (15.4%) (Ezra et al., 2005) **(2-)**.

Recommendation 8.0 Eye lubricant 

Eye lubricant is recommended when eye cover is not applicable, such as the patients with eye infection or copious eye secretion, or occasional spontaneous blink reflex.

Supporting evidences:

- Two-hourly eye lubricant is suggested to prevent OSDs effectively for all unconscious or heavily sedated patients with incomplete lid closure (Marshall et al., 2008) **(1-)**.
- Laight (1996) applied eye covers to clean eyes only **(2-)**.
- Mildly sedated patients with occasional spontaneous blink reflex are at risk of corneal exposure, eye lubricant is recommended over eye covers (Suresh et al., 2000) **(2-)**.
- Compared with passive lid closure, regular instillations of eye lubricant significantly reduced the incidence of OSDs (Joyce, 2002) **(1++)** from 22% to 4% (Lenart & Garrity, 2000) **(1-)**.
- Compared with eye hygiene, the use of eye lubricant reduced the OSD incidence (to 8.7% to 15.4%) and severity (to mainly grade 0 to 1) (Ezra et al., 2005; Suresh et al. 2000) **(2-)**.

Types of eye instillations

Recommendation 8.1 Duratears A

1.27-cm Duratears is suggested to apply to the "V" pocket between eyeball and lower lid every 4 hours.

Supporting evidences:

- Compared with passive closure, 4-hourly application of 1.27-cm Duratears significantly reduced the incidence of OSDs (Joyce, 2002; Lenart & Garrity, 2000) **(1++, 1-)** from 22% to 4% (Lenart & Garrity, 2000) **(1-)**.
- Four-hourly application of 1-cm Duratears is as effective as polyethylene covers, which produced a low OSD incidence of 5.3% to 6.8% (So et al., 2008) **(1+)**.
- Apply Duratears to the "V" pocket between eyeball and lower lid (So et al., 2008) **(1+)**.

Recommendation 8.1 Hypromellose, Lacrilube and HL combination A

Hypromellose, Lacrilube, and HL combination are NOT recommended.

Supporting evidences:

- Hypromellose and HL combination increased the incidence of OSDs by the odd ratios of 6.05 and 6.22 respectively, compared with polyethylene covers (Joyce, 2002) **(1++)**.
- Lacrilube reduced the incidence of OSDs to 15.4%, when compared with the Geliperm and eye toilet (Ezra et al., 2005) **(2-)**. The high OSD

incidence (15.4%), and the ineffectiveness of Geliperm (Joyce, 2002) **(1++)** (Bates et al., 2004) **(1-)** (Ezra et al., ,2005; Laight, 1996) **(2-)** and eye toilet in OSD prevention (Cunningham & Gould, 1998) **(4)** do not support the use of Lacrilube.

- Koroloff et al. (2004) showed an insignificant difference between the effectiveness of HL combination and polyethylene covers in OSD prevention **(1+)**. However, the results have been rejected by Ezra, Healy & Coombes (2005) as Koroloff et al. (2004) only measured the corneal ulceration, which is the minority group and the more severe form of corneal damage. The major group of OSDs, that is superficial punctuate keratopathy, is not measured (Ezra, Healy & Coombes, 2005) **(4)**.

Recommendation 9.0 Cover eyes during suctioning 

Apply eye covers (see Recommendations 7.0 to 7.1) during open tracheal or oropharyngeal suctioning for patients with respiratory infection (especially PAER infection) and copious sputum production (that requires suctioning at least 2-hourly).

Supporting evidences:

- Eye cover acts as a protective barrier for eye infection during oropharyngeal suctioning (So et al., 2008) **(1+)** (Parkin et al., 1997) **(2-)**. Eyes should be closed to reduce the risks of infection (Cunningham & Gould, 1998; Dua, 1998; Hunt, 1991; Johnson et al., 2000) **(3, 4)**.
- Closed suction system reduces the incidence of ocular infection (Johnson et al., 2000) **(3)**.

- Combination of eye covers and eye lubricants reduced the incidence of OSDs to 8.7% (Suresh et al., 2000) **(2-)** and reduced eye infection rate (Parkin et al., 1997) **(2-)**.
- Patch eyes during suctioning (Dua, 1998; Hernandez & Mannis, 1997; Hilton et al., 1983; Hunt, 1991; Johnson et al., 2000) **(3, 4)**.
- Respiratory infection with copious sputum production (requires suctioning at least 2-hourly) is a risk factor for OSDs (Hilton et al., 1983; Hunt, 1991; Johnson et al., 2000; Parkin & Cook, 2000) **(3, 4)**.
- Virulent PAER is the most serious corneal infectious agent (Hutton & Sexton, 1972) which perforates eyeball rapidly in 48 hours (Hunt, 1991; Hutton & Sexton, 1972; Ommeslag et al., 1987) **(3, 4)**.

Recommendation 9.1 Suctioning technique 

Should not withdraw the suction catheter across patient's face after suctioning.

Supporting evidences:

- Appropriate suction techniques prevent inoculation of respiratory pathogens into eyes (Hilton et al., 1983; Ommeslag et al., 1987) **(3)**.
- Should avoid cross infection during suctioning (Cunningham & Gould, 1998) **(4)**.
- Should not withdraw the suction catheter across face after suctioning (Dua, 1998; Hilton et al., 1983; Hunt, 1991; Johnson et al., 2000) **(3, 4)**.

Recommendation 10.0 Prevention or management of conjunctival edema D

To reduce or prevent conjunctival edema, elevate the head of bed, and check for appropriate tightness of airway securing taping.

Supporting evidences:

- Higher incidence of conjunctival edema is related to higher degree of OS exposure and higher risk of OSDs (Suresh et al., 2000) **(2-)** (Dua, 1998; Hilton et al., 1983; Hunt, 1991) **(3, 4)**.
- Elevating head of the bed and an appropriate tightness of airway securing taping encourage jugular venous drainage, prevent the increase in intraocular pressure (Asburst, 1997; Hunt, 1991), and reduce the conjunctival edema (Hunt, 1991) **(4)**.

Recommendation 11.0 Ventilator-associated pneumonia (VAP) prevention D

Prevention of VAP reduces the risk of eye infection. For example, use aseptic technique during open tracheal suctioning, and follow the VAP bundle care protocol as implemented in the target ICU.

Supporting evidences:

- Aseptic technique to airway and the VAP prevention prevent eye inoculation of respiratory pathogens (Hutton & Sexton, 1972) **(3)**.
- VAP bundle care protocol reduces the risk of VAP development (Crocker & Kinnear, 2008; Westwell, 2008). The VAP bundle composes of sedation vacation, elevation of head of the bed to 30 to 45 degrees, deep vein thrombosis and gastric ulcer prophylaxis, appropriate humidification

of inspired gases, the change of ventilator tubing, suctioning of respiratory secretions, and mouth care **(4)**.

CHAPTER 4 IMPLEMENTATION PLAN

In the previous chapter, an evidence-based eye care protocol is developed with sufficient research evidence base. According to the Iowa Model, the next step is to implement the EBP in a pilot unit (Melnyk & Fineout-Overholt, 2005; Polit & Beck, 2008; Titler, 2002) (see Appendix 1). Pilot study is useful for revising the protocol and deciding the appropriateness of a larger-scale implementation. When the pilot supports an adoption of protocol, it proceeds to a larger-scale practice change (Melnyk & Fineout-Overholt, 2005). In this chapter, an implementation plan is developed from the communication, pilot study, and evaluation plans.

4.1 COMMUNICATION PLAN

The implementation plan starts with a well-planned communication plan. Gaining approval and support from the stakeholders is crucial for the organizational implementation and sustenance of the eye care protocol (Bick & Stephens, 2003).

Identification of stakeholders

The communication plan starts with the identification of the stakeholders of the protocol, who need or want to know the change (Hirkpatrick, 2001). They are:

1. decision makers in the taget ICU, including the Chief of Service (COS), Departmental Operational Manager (DOM), ward manager (WM), and nurse specialist
2. eye care team
3. ICU nurses and audit control officer (ACO)
4. ICU doctors
5. hospital ophthalmologists
6. ICU clerical staff
7. ICU health care assistants (HCAs)

The organization structure of the target ICU (see Appendix 12) is provided for reference.

Communication plan with stakeholders

The communication cycle runs in the order of 1 to 7 as described above. According to the Iowa Model, top-down organizational support is important for implementing and sustaining an EBP (Bick & Stephens, 2003; Melnyk & Fineout-Overholt, 2005; Polit & Beck, 2008; Titler, 2002). Managerial support has a key role in promoting change (Bryar et al., 2003; LaPierre et al., 2004). Therefore, the decision makers should be the first in the communication to get in approval and support.

Communication with decision makers in ICU

Decision makers' approval is a good start for a successful EBP. The investigator who is in charge of the proposed protocol has communicated with the WM and nurse specialist in advance (in January 2009) and obtained their approval for the protocol. The communication with the decision makers started when the nurse specialist and the investigator noticed the significance of OSDs in the ICU, and discussed about a need of practice change. Relevant research papers were searched and critiqued, and a research base was synthesized (Melnyk & Fineout-Overholt, 2005). The findings (see Chapters 1 and 2), with the significance of OSDs and a need of change stressed (Laight, 1995), were presented to the nurse specialist and WM. Feedbacks were received, and the implementation potential (Chapter 3.1) was presented to them with the feasibility and cost-benefits of the protocol stressed (Laight, 1995). Finally, they have approved the innovation.

The next step is to communicate with the DOM and COS. A proposal will be prepared for meeting the DOM and COS. The proposal is a summary of the dissertation, focusing on the significance of OSDs in ICU, proposed eye care protocol contents and evidence base, benefits of the protocol (Laight, 1995), program aims and objectives, implementation potential, and the implementation plan with expected barriers and proposed solutions. A tentative budget plan and timetable will be included.

Gaining managerial support and approval in the training, implementation, and evaluation parts of the protocol are important as well. For example, the provision of time and resources, the introduction of eye care protocol into the SDR, and the arrangement

of training workshops, journal club, and ward meetings with CNE points and refreshment offer (Melnyk & Fineout-Overholt, 2005).

Communication with eye care team

An eye care team will be formed to guide the change (Laight, 1995; Melnyk & Fineout-Overholt, 2005; Thurston & King, 2004; Titler, 2002). In order to develop a sense of ownership towards the eye care program (Melnyk & Fineout-Overholt, 2005), the team composes of the nurse specialist, 1 Advance Practice Nurse (APN), the investigator who is in charge of the protocol, 2 to 3 RNs, and 1 to 2 doctors in the target ICU. The managerial level, including COS, DOM, and WM, appoints the team members and supervises the team. The nursing members are responsible for communicating with the non-medical stakeholders, skill training, briefing and auditing, troubleshooting and being a role model for the nurses, and guiding the implementation and evaluation of the protocol. On the other hand, the medical members are responsible for communicating with the ICU doctors and the hospital ophthalmologists, and supervising the ICU doctors in the protocol implementation and medical issues such as medications prescription and side effects monitoring.

A package of preparation for the eye care team, as follow, is important to start and sustain a successful change (Melnyk & Fineout-Overholt, 2005).

Training workshops

Evidence increases the stakeholders' acceptance of the protocol (Laight, 1995; Madsen et al., 2005), therefore education is essential to enhance their awareness, knowledge, attitudes, and behaviours. Interactive education is more effective than passive one. Three training workshops, each lasts for 1.5 to 2 hours, will be delivered to the eye care team (Richens, Garrett, Rycroft-Malone & Morrell, 2004) in the tea room or any appropriate places. The aims of the workshops are to educate the purpose and importance of eye care, to show the protocol contents, to train the specific implementation and evaluation skills, to show the charts and audit tool, and to inform their clear roles and responsibilities (Melnyk & Fineout-Overholt, 2005). Date and time will be selected with the decision makers and eye care team to ensure that all members are able to attend, and to avoid clashing the protocol with other issues in the unit (Hirkpatrick, 2001; Melnyk & Fineout-Overholt, 2005). Approved official release is preferred.

The first workshop aims at educating the eye care team on the OSDs and eye care program. Oral communication allows feedback and discussion, increases interest and persuasion, and saves reading time (Hirkpatrick, 2001). On the other hand, written communication provides future reference and shows complex flow of protocol with step-by-step procedure (Hirkpatrick, 2001). Therefore, an education package (Beck & Johnson, 2008; Richens et al., 2004) will be prepared to ensure all team members understand the innovation well before educating other stakeholders. The education package is a summary of:

- introduction of OSDs and the risk factors
- significance of OSDs and eye care
- need of practice change
- research evidence base and critical appraisal
- proposed evidence-based eye care protocol
- pilot study and evaluation plans
- target patients, feasibility, and cost-benefits of the protocol
- literature supporting the family acceptance towards polyethylene covers
- roles and responsibilities of the team members (Hirkpatrick, 2001; Melnyk & Fineout-Overholt, 2005)

The second workshop involves the hospital ophthalmologists providing the team a group skill training (Hirkpatrick, 2001) on how to evaluate the incidence of corneal abrasion using sodium fluorescein stain test.

The third workshop provides the details of the implementation and evaluation of the protocol, with an implementation and evaluation guide and a list of frequently asked questions provided (Bick & Stephens, 2003; Polit & Beck, 2008). The guide includes:

- details of the protocol contents and rules of application
- a flow chart of the eye care protocol (see Appendix 11)
- eye care documentation charts (see Appendix 14)
- appropriate way to assess family acceptance towards polyethylene covers
- appropriate way to obtain a family consent for a pilot study, with consent form and explanatory letter attached

- briefing and auditing skills
- audit plan (Cooper, 2004) and audit tool (Bick & Stephens, 2003) with agreed standard criteria for a good practice (see Appendices 13A and 13B)
- details of the evaluation plan

According to the Iowa Model, reward and recognition program are important to give recognition to staff members who implement the EBP (Melnyk & Fineout-Overholt, 2005; Polit & Beck, 2008; Titler, 2002). To enhance better team contribution, with the managerial approval, the team will be given SDR recognition and public recognition like the CQI reward, or be invited to present or share experiences in ward meetings.

Communication with ICU nurses

The Iowa Model emphasizes that EBP must involve every level of the organization (Melnyk & Fineout-Overholt, 2005; Polit & Beck, 2008; Titler, 2002). As evidence-based changes are instituted by front-line staff rather than the high-level management (Titler, 2002), top-down passive dissemination is ineffective to change practice (Melnyk & Fineout-Overholt, 2005). The communication plan should therefore involve the front-line staff as below.

Nurses are the main users and resistors of the protocol. Their acceptance and compliance directly affect the success of the protocol implementation and sustenance. Three main EBP barriers are research quality, organizational support, and the nurses' attitudes (Polit & Beck, 2008). The former two have been tackled, the main problem is

the nurses. Studies show that the main barrier in eye care protocol implementation is poor nursing compliance (Dawson, 2005; Laight, 1996; Suresh et al., 2000). Together with nurses' resistance to change and their inadequate understanding on research and EBP (Polit & Beck, 2008), nurses are the main stakeholders to be communicated.

Poster and board

Insufficient awareness and understanding towards the need of evidence-based eye care protocol can be a source of resistance and poor compliance (Dawson, 2005; Laight, 1995; Melnyk & Fineout-Overholt, 2005). According to the transtheoretical model, raising awareness helps nurses' transition from precontemplation stage to behavioral change (Melnyk & Fineout-Overholt, 2005). Existing research raises nurses' awareness of the OSDs in ICU (Dawson, 2005; Laight, 1995; Melnyk & Fineout-Overholt, 2005; Richens et al., 2004). The physiology of OSDs, common types of eye care, and existing evidence base of eye care will be displayed on posters and boards in the unit, to increase the staff members' awareness and interest towards OSDs and eye care (Laight, 1996), and the attendance of the journal club (Dawson, 2005).

Journal club

Multifaceted interventions and education program are important for a successful protocol implementation and EBP change (Bick & Stephens, 2003; Dawson, 2005;

Melnyk & Fineout-Overholt, 2005; Richens et al., 2004; Thurston & King, 2004). Presentation and discussion are typical media addressing professional issues (Laight, 1995). Therefore, 2 to 3 months after the poster and board display, an 1-hour interactive education session will be held by the eye care team through a journal club in tea room (Bick & Stephens, 2003; Laight, 1995; Melnyk & Fineout-Overholt, 2005). With the managerial approval, official time release, CNE points, and refreshment are preferred (Hirkpatrick, 2001; Melnyk & Fineout-Overholt, 2005).

Journal club develops partnership between eye care team and stakeholders (Richens et al., 2004), provides nurses with the knowledge about what to do (Laight, 1995), enhances nurses' acceptance of the protocol (Hirkpatrick, 2001; Laight, 1995; Madsen et al., 2005), reduces their skepticism towards the change (Melnyk & Fineout-Overholt, 2005), and clearly informs the nurses about their roles in the implementation and evaluation. The journal club highlights the incidence of OSDs and the importance of eye care in ICU (Dawson, 2005), introduces the evidence-based eye care protocol using sound evidence, and stresses the clinical relevance and effectiveness, patient benefits, and family acceptance towards the eye care (Bryar et al., 2003; Cortese et al., 1995; Dawson, 2005; Hirkpatrick, 2001; Laight, 1995; Melnyk & Fineout-Overholt, 2005; Richens et al., 2004). Highlighting patient's benefits also promotes work satisfaction and nursing autonomy (Hirkpatrick, 2001). The journal club information will be uploaded to the ICU intranet for reference (Richens et al., 2004).

Briefing and training

One week after the journal club, the eye care team will start briefing and training the nurses one-by-one on the audit tool criteria of good practice, fluorescein stain test skill, skills in obtaining consent in pilot study, documentation charting, and their roles in assisting the data collection for the protocol evaluation (Cooper, 2004; Melnyk & Fineout-Overholt, 2005). The audit tool (see Appendices 13A and 13B), consent form, and documentation charts (see Appendix 14) will be posted onto the board. Nurses' achievement will be audited in the evaluation.

Reading materials and charts

ICU nurses are often occupied in the life-sustaining measures. Simple and easy-to-follow eye care protocol reduces workload and enhances acceptance (Hirkpatrick, 2001), compliance (Dawson, 2005) and EBP (Richens et al., 2004). Readily available documentation charts in the admission package will be prepared by clerical staff (Beck & Johnson, 2008). A protocol flowchart (see Appendix 11) and the severity grading for OSDs (see Appendix 9) will be included in the bedside reference for quick reference (Laight, 1995; Madsen et al., 2005; Melnyk & Fineout-Overholt, 2005; Richens et al., 2004). A resource manual, containing a summary of the eye care dissertation, documentation charts, audit tool, and the protocol implementation and evaluation reports, will be available in the nursing station to orient new nurses. It will be updated with the

new evidence half-yearly (Beck & Johnson, 2008; Bick & Stephens, 2003; Madsen et al., 2005).

Two-way communication and recognition for the well-contributed staff

Nurses often regard themselves as incapable of making decisions and changes (Bryar et al., 2003). This thought is a barrier of EBP. Communication is a two-way understanding rather than telling, and empathy is a component to change (Hirkpatrick, 2001). Two-way communication and users' rational suggestions should be welcomed to promote a positive attitude towards open discussion and reflective thinking, to clarify misconception, to identify barriers, and to promote ownership, acceptance, and euthusiatism towards the change (Bick & Stephens, 2003; Hirkpatrick, 2001; Laight, 1995; Melnyk & Fineout-Overholt, 2005; Thurston & King, 2004; Tiwari, Avery & Lai, 2003). The protocol will be circulated, read and signed, with a comment form attached (Laight, 1995). Misconceptions of the protocol will be presented on the board (Laight, 1995) and in ward meetings.

Given the education and support, critical care nurses should be able to make objective decisions to promote positive outcomes and better care quality for patients (Beck & Johnnson, 2008). Communication plan therefore increases the supportive forces to change and makes the new protocol as a norm. Staff recognition helps freezing the norm and therefore reduces the nurses' resistance to change (Laight, 1995). The

nurses will be given recognitions of their contributions like the eye care team (Hirkpatrick, 2001).

Communication with Audit Control Officer (ACO)

ACO is a RN, who is responsible for data collection and survey in the target ICU. She will receive the communication plan for nurses. Besides, she is responsible for collecting the documentation charts of eye care in the ACO box at the nursing station, of which she should be informed.

Communication with ICU doctors

The medical eye care team members are responsible for seeking cooperation from the medical colleagues in ICU. ICU doctors are responsible for prescribing fluorescein stain, Duratears eye ointment and eye treatment for OSDs, diagnosing suspected OSDs, and consulting the ophthalmologists when indicated. The team will explain to the ICU doctors about the approved evidence-based eye care protocol, the importance and significance of OSDs and eye care, and their roles in the protocol implementation, in their usual daily meeting, with a question and answer session. A lack of doctors' cooperation is a barrier of EBP (Bryar et al., 2003; LaPierre et al., 2004), and evidence enhances their acceptance and cooperation (Madsen et al., 2005).

Communication with hospital ophthalmologists

The hospital ophthalmologists' support and cooperation should be obtained. Roles of the ophthalmologist are to provide skill training to the eye care team, to assess suspected OSDs upon consultation, and to diagnose OSDs and provide treatment. Besides discussing the roles, the eye care team doctors will explain to the opthalmologists the proposed eye care protocol, and stress the significance of OSDs and eye care, and patient benefits. To enhance cooperation, the communication emphasizes that ophthalmologists' help in skill training enhances early identification and treatment of OSDs, and reduces the unnecessary ophthalmologist consultation. Ophthalmologists' professional opinions on assessments, interventions, or medications are welcomed.

Communication with ICU clerical staff

The eye care team will clearly inform the clerical staff about their roles in helping the paperwork for training, implementation, and evaluation. The clerks have to prepare the audit tool (see Appendix 13A and 13B), documentation charts (see Appendix 14) in admission packages, protocol flow chart (see Appendix 11) and OSD severity grading chart (see Appendix 9) in the bedside reference, resource manual, poster and board, education packages and implementation and evaluation guide for the eye care team, consent forms and explanatory letter for pilot study, and the drug prescription form with printed "Duratears" and "sodium fluorescein stain" (Beck & Johnson, 2008).

Communication with ICU health care assistants (HCAs)

To sustain a new norm and enhance better acceptance (Laight, 1995), continuous supply of the eye care materials is necessary. The eye care team will provide the HCAs a list of eye care materials required in each patient bedside trolley in their handbooks. They are responsible for checking the stock weekly and inform the nurse-in-charge when nearly out of stock.

4.2 PILOT STUDY PLAN

The communication with all stakeholders and the nurses' skills training on eye care require approximately 3 months. After that, according to the Iowa Model, the change of practice will start with a pilot study on a smaller group of clinicians and patients (Melnyk & Fineout-Overholt, 2005; Polit & Beck, 2008; Titler, 2002) (see Appendix 1). It is a trial run to test the feasibility of the protocol and to heighten the stakeholders' awareness of the significance of OSDs and eye care before a larger-scale implementation (Laight, 1996).

Target setting and target population

The target setting and target population for the pilot study are the same as that of the proposed eye care protocol as described.

Study design and sampling plan

An after-only quasi-experimental study design with nonequivalent control group will be used (Polit & Beck, 2008). The target ICU composes of two 10-bed wards C and D. Fifteen newly admitted eligible cases will be recruited in each ward (Dawson, 2005; Madsen et al., 2005). Ward C clients are the intervention group receiving the eye care protocol, while ward D clients are the nonequivalent control group receiving the usual care. As 2 to 5 patients are eligible daily, and their average ICU LOS is 4 to 7 days, the sampling takes 3 to 4 months.

Ethical considerations

The pilot study is subjected to ethical approval by the Hospital Ethics Committee (Laight, 1996; Polit & Beck, 2008; So et al., 2008). The committee objectively assesses the clients' risk and benefits (Polit & Beck, 2008), and safeguards their rights, privacy, and wellbeing (Mckenzie, Neiger & Smeltzer, 2005; Polit & Beck, 2008).

In view of the physical and mental vulnerability of ICU patients, family consent should be obtained for the pilot study participation (Polit & Beck, 2008). Case nurse will deliver the Chinese- or English-version consent form and study explanatory letter with explanations to the primary family member, who is the first contact next-of-kin. The consent is obtained upon admission, at different time from patient condition discussion (Laight, 1996). The explanatory letter describes the study goals, objectives, data collection plan, risks and benefits, voluntary participation, right to refuse or withdraw, and the anonymity and confidentiality (Polit & Beck, 2008). The nurses' consent

obtaining skills are trained through role playing during the briefing session (Laight, 1996).

Moreover, the anonymity of patients is preserved in data collection and evaluation record (Cooper, 2004; Mckenzie et al., 2005).

Objectives

The objectives of the pilot study are:

(1) to establish the baseline data on the incidence and severity of OSDs (Mckenzie et al., 2005).

(2) to test the feasibility of the protocol by trying out the protocol contents and outcome measurements (Polit & Beck, 2008).

(3) to assess the nursing compliance to the protocol, and family acceptance towards the appearance of polyethylene eye covers.

(4) to estimate the budget of a larger-scale implementation (Polit & Beck, 2008).

(5) to identify the problems of the study, and improve the larger-scale implementation (Mckenzie et al., 2005; Polit & Beck, 2008) according to the pilot results (Polit & Beck, 2008).

Outcomes to be measured

The objectives guide the outcome data measurement. According to the Iowa Model, outcome data are collected from patients, family, staff, and cost (Madsen et al., 2005; Melnyk & Fineout-Overholt, 2005; Polit & Beck, 2008; Titler, 2002) (see Appendix 1). The outcomes for the pilot study are:

- incidence and severity of OSDs in the intervention and control groups
- nursing compliance to the protocol
- family acceptance towards the polyethylene covers
- cost associates with the protocol implementation
- unanticipated problems associate with the protocol implementation and evaluation

The significance of the identified outcomes will be elaborated in Chapter 4.3.

Data collection and analysis plan

The identified outcomes will be collected at the end of the pilot study in cross-sectional manner.

There is no measurement on the baseline incidence and severity of OSDs in the target ICU. As OSDs detection requires fluorescein stain instillation, obtaining the baseline incidence and severity of OSDs under usual care is not feasible before gaining

the decision makers' approval of the eye care program. Therefore, the pilot firstly aims at establishing the baseline data. The pilot also examines the magnitude of effect of the eye care protocol, in percentages, by comparing the incidence and severity of OSDs between the intervention and control groups, so as to show the protocol effectiveness, and to provide convincing evidence that a larger-scale implementation is well worth the effort (Dawson, 2005; Madsen et al., 2005; Melnyk & Fineout-Overholt, 2005).

Nursing compliance is important for ensuring the intervention fidelity (Melnyk & Fineout-Overholt, 2005; Polit & Beck, 2008) and a successful protocol implementation and outcome evaluation (Kinsman, 2004). Measured compliance is useful for guiding a better briefing and audit approach, and thus a better compliance in the larger-scale implementation.

Moreover, cost measurement is useful for budget planning. The family acceptance and their comments towards the polyethylene covers guide the eye care team the ways to promote better family feelings.

The pilot aims at trying out the outcome measurement, therefore, the data collection and analysis plans on the incidence and severity of OSDs, nursing compliance, cost measurement, and family acceptance are more or less the same in both pilot and full implementation. Problems encountered will be used for the protocol revision. However, due to the small pilot sample size, insignificant difference in the incidence and severity of OSDs between the intervention and control groups can be a Type II error (Polit & Beck, 2008). The percentage of the incidence and severity of OSDs in two groups will also be compared with the existing literature so as to show the effectiveness of protocol.

The detailed plans of data measurement, collection, and analysis will be discussed in Chapter 4.3.

Unanticipated problems during the pilot study are expected, such as the problems of time, materials supply, documentation, or misunderstandings (Laight, 1995, 1996). Expression of barriers, opinions, and weaknesses and strengths of the protocol (Polit & Beck, 2008) is encouraged during ward meetings and daily ward rounds. An 1-hour semistructured focus group meeting with 6 to 12 volunteer stakeholders will be held at the end of the pilot study by the nurse specialist, eye care team doctors, and the investigator who is in charge of the protocol. Meeting in tea room enhances a richer, deeper, and open expression of feedbacks and experiences (Polit & Beck, 2008). It will be audiotaped, with the preservation of the participants' anonymity (Polit & Beck, 2008).

Evaluation of the pilot study results

According to the Iowa Model, evaluation of the pilot study guides the decision of the protocol adoption (Melnyk & Fineout-Overholt, 2005; Polit & Beck, 2008; Titler, 2002) (see Appendix 1). The data analysis and evaluation of the pilot study take approximately 6 months. A formative evaluation (Mckenzie et al., 2005) of the identified outcomes will be conducted in the same way as the full implementation, which will be discussed in Chapter 4.3. Ongoing communication between stakeholders enhances protocol feasibility and acceptance (Hirkpatrick, 2001; Rosswurm & Larrabee, 1999). The eye care team presents the pilot study results, successful stories and experience, and unanticipated problems on the board and in the monthly nursing ward

meetings. Sharing encourages further discussion and planning (Laight, 1995), appraises staff effort, and promotes a sense of achievement (Cooper, 2004). The eye care team doctors are responsible for informing the ICU doctors and hospital ophthalmologists about the protocol progress and results. A formal written report will be prepared for the managerial level, including the COS, DOM, and WM, to determine whether to adopt, revise, modify, or reject the eye care protocol. After the modification of protocol, if necessary, another pilot test maybe required before a full implementation (Mckenzie et al., 2005).

4.3 EVALUATION PLAN

When the pilot study results support the eye care protocol implementation, the next step of the Iowa Model is to implement the eye care protocol in a larger scale (Melnyk & Fineout-Overholt, 2005; Polit & Beck, 2008; Titler, 2002) (see Appendix 1). Before a larger-scale implementation, a systematic summative evaluation plan should be developed (Madsen et al., 2005; Mckenzie et al., 2005; Melnyk & Fineout-Overholt, 2005; Thurston & King, 2004).

Purposes of evaluation

Evaluation is important for any protocol implementation. Evaluation assesses the degree of goals and objectives achievement, which guides the protocol improvement and modification, in order to enhance the protocol feasibility. Evaluation also provides scientific bases to quantify stakeholders' effort, and to show the stakeholders their accountability and the value of protocol, so as to sustain the changes (Dawson, 2005;

Mckenzie et al., 2005; Melnyk & Fineout-Overholt, 2005).

Outcomes to be achieved

The outcomes are determined according to the objectives of the eye care protocol in Chapter 3.2, which determine the effectiveness of the protocol. As discussed, outcome data are collected from patients, family, staff, and cost (Melnyk & Fineout-Overholt, 2005; Titler, 2002). Among the different types of OSDs, the primary outcome is the incidence of corneal abrasion or ulcerations, while the secondary outcomes include the patient, nurses, and system outcomes. They are prioritized according to their importance as follow:

- nurses' skills and compliance in assessment, implementation, and evaluation parts of the eye care protocol
- incidence of other OSDs, including conjunctival abrasion and ulceration, and corneal or conjunctival infection
- severity of OSDs
- family acceptance towards the appearance of polyethylene eye covers
- cost-effectiveness analysis (Polit & Beck, 2008) of the eye care protocol

Significance of the outcomes

Incidence and severity of OSDs

As discussed in Chapter 3.2, the major aim of the eye care protocol is to reduce the incidence and severity of OSDs. As the protocol is developed based on the 13 reviewed studies, and all the studies evaluated the effectiveness of eye care on the

incidence of corneal abrasions or ulcerations, the protocol is more likely to be effective in reducing corneal breakdowns. Therefore, the incidence of corneal abrasion or ulceration is the primary outcome of the evaluation plan for determining the effectiveness of protocol.

On the other hand, only 2 to 4 studies evaluated the incidence of eye infection (Joyce, 2002; Marshall et al., 2008; Parkin et al., 1997) and conjunctival disorders (Desalu et al., 2008; Suresh et al., 2000), or severity of OSDs (Ezra et al., 2005; Sivasankar et al., 2006; So et al., 2008; Suresh et al., 2000). Therefore they are the secondary outcomes.

Nursing skills and compliance

The patient outcomes are affected by the interpersonal care (Rosswurm & Larrabee, 1999). The main barrier in eye care protocol implementation is poor nursing adherence to the guidelines (Dawson, 2005; Laight, 1996; Suresh et al., 2000). Manipulation check or intervention fidelity (Melnyk & Fineout-Overholt, 2005) should be done by evaluating nurses' skills and compliance. When there is poor nursing compliance, the effectiveness of protocol can be affected by both nursing compliance and protocol contents; while if there is adequate nursing compliance, ineffective eye care indicates a problem of the protocol (Kinsman, 2004).

Cost-effectiveness analysis

When the pilot study shows that the protocol is effective in reducing the incidence of corneal abrasion or ulceration, that is the primary outcome, cost-

effectiveness analysis is proposed in the full implementation. Cost-effectiveness analysis estimates what it costs to produce impacts on the outcomes that cannot be easily valued in dollars (Polit & Beck, 2008). The outcomes include the benefits of patients and health care system, such as a better quality of life, shorter length of hospital stay, or prevention of eye treatment or hospital acquired complications. The analysis shows the value of the program, that is the stakeholders' interest (Laight, 1995, 1996; Melnyk & Fineout-Overholt, 2005; Polit & Beck, 2008; Rosswurm & Larrabee, 1999).

Family acceptance towards polyethylene covers

As discussed, the sedated or paralysed critically ill patients are vulnerable and unable to express their opinions towards eye care. Family feelings and acceptance towards polyethylene cover should not be ignored.

Plan of measurement and data collection

This is an internal evaluation conducted by the eye care team members. As discussed in Chapter 4.1, their roles, responsibilities, and specific skills in the evaluation will be taught during the training workshops, so as to enhance the interrater reliability and validity (Mckenzie et al., 2005; Polit & Beck, 2008). The evaluation will be done half-yearly since the implementation (Polit & Beck, 2008), which can be modified according to the availability of the target sample size. The analysis process of the evaluation lasts for approximately 6 months. As the full implementation of eye care protocol applies to all eligible ICU patients, no family consent is required.

Incidence and severity of OSDs

A study showed that regular OSD screening by ICU staff would facilitate earlier identification and treatment of OSDs (McHugh, Alexander, Kalhoro & Ionides, 2008). Therefore, the case nurses, who are trained by the ophthalmologist-trained eye care team, are responsible for the daily assessment of the incidence of corneal abrasions and ulcerations. In addition to the symptoms detection, a biophysiologic measure (Polit & Beck, 2008), that is the sodium fluorescein stain test with cobalt blue penlight (So et al., 2008), is used. Sodium fluorescein is a premier vital dye extensively used for the detection of corneal ulcers and abrasions since 1888 (Korb, Herman, Finnemore, Exford & Blackie, 2008; Vorvick, 2007; Ward, 2008; Wikipedia, 2009). Corneal defects and cell degeneration or death disrupt the intercellular tight junctions, and allow the fluorescein stain to diffuse into the underlying epithelium or stroma and produce staining (Kim, 2000). The stain is an aromatic organic molecule that absorbs light with wavelength of 490 nm, and emits brilliant green fluorescence light that can be visualized under a cobalt blue light (Kim, 2000; Ward, 2008). As a study showed that ICU doctors produced a reasonable sensitivity of 77.8% and specificity of 96.7% in detecting OSDs, when compared with ophthalmologists (McHugh et al., 2008), the suspected OSDs will be confirmed by the ICU doctors or hospital ophthalmologists.

The evaluation of individual patient outcome is a short-term measurement during patient's ICU LOS. The eye care completes when the patient regains consciousness or develops OSD (Bates et al., 2004; Cortese et al., 1995; Koroloff et al., 2004; Sivasankar et al., 2006; So et al., 2008). Patients who are transferred out or die without regaining consciousness are regarded as drop-out cases. When the ICU doctors or hospital

ophthalmologists diagnose an OSD, the case nurses document its incidence and severity according to the diagnosis on the eye care documentation charts (see Appendix 14). The case nurses then photocopy the documentation charts and put them into the ACO collection box upon patient discharge from ICU. The collected charts will be analyzed half-yearly since the implementation (Polit & Beck, 2008), or prolonged until there is sufficient sample size.

Patient's demographics and possible confounders will be collected in the eye care documentation charts (see Appendix 14) for data analysis. The confounders include the ICU LOS, GCS, peak airway pressure, ventilator settings, sedation or muscle relaxant used, septic shock, degree of conjunctival edema, Acute Physiology And Chronic Health Evaluation II (APACHE II) score, and pupil assessment frequency (So et al., 2008).

Nursing skills and compliance

Nurses' achievement of the skills required in the assessment, implementation, and evaluation of the protocol, and the average nursing compliance to the protocol will be evaluated by nursing audit (Melnyk & Fineout-Overholt, 2005). Nursing audit is necessary for any issue that consumes resources or affects patient outcomes (Nolan & Scott, 1993). It is an effective and valuable tool to evaluate guidelines, to ensure an EBP (Gould, 2008), and to measure and improve the practice and quality of care against an agreed standard (Cooper, 2004; Richens et al., 2004). Although audit compliance does not have necessary relationship with the actual standard of care (Nolan & Scott, 1993), audit improves teamwork and interprofessional communication (Cooper, 2004; Gould,

2008), increases professional satisfaction and knowledge (Cooper, 2004; Gould, 2008), enhances a clearer understanding of a new protocol, and most importantly ensures a more appropriate use of resources and time (Cooper, 2004). Daily audits improve compliance by increasing nurses' awareness and ensuring their adherence to protocol (Charrier et al., 2008; Westwell, 2008).

A valid audit tool with well-established measurable and objective criteria determines a good practice (Bick & Stephens, 2003; Charrier et al., 2008; Cooper, 2004; Gould, 2008; Madsen et al., 2005; Nolan & Scott, 1993). It is developed, with the eye care team, using the evidence-based recommendations of the protocol in Chapter 3.2 (see Appendices 13A and 13B) (Bick & Stephens, 2003; Cooper, 2004; Kinsman, 2004; Richens et al., 2004). As discussed in Chapter 4.1, the eye care team briefs each of the nurses about the standard of care based on the standardized criteria of the audit tool (see Appendices 13A and 13B). After briefing all nurses, in approximately 2 months, the team conducts a one-to-one initial nursing audit (Bick & Stephens, 2003; Cooper, 2004) to ensure each nurse has obtained the understandings and skills before a full-scale implementation.

Knowledge does not necessarily lead to compliance. Therefore, it is necessary to conduct intermittent audits during the implementation period to ensure a practice change (Westwell, 2008) and adherence to the protocol, by means of chart audits and daily ward rounds (Dawson, 2005; Madsen et al., 2005; Melnyk & Fineout-Overholt, 2005; Rosswurm & Larrabee, 1999). Chart audits (Bick & Stephens, 2003; Dawson, 2005; Madsen et al., 2005; Rosswurm & Larrabee, 1999) will be conducted half-yearly since the larger-scale implementation, using the documentation charts (see Appendix 14)

collected in the ACO box. The DOM, WM, nurse specialist, and the investigator who is in charge of the protocol will perform daily random ward rounds as usual to observe the eye care practice in the unit. The audit frequency will be reduced with an improving compliance (Westwell, 2008). Nurses' feedbacks, experiences, and the expression of problems related to noncompliance are encouraged during the ward rounds and ward meetings (Beck & Johnson, 2008; Bick & Stephens, 2003; Cooper, 2004; Gould, 2008).

Cost-effectiveness analysis

Only the material costs required to produce the primary outcome (Polit & Beck, 2008) in the 6-month implementation will be recorded by the eye care team, with the assistance of clerical staff. The material costs include the costs of the paperwork, like the documentation and audit charts; the costs of the eye care materials, such as fluorescein stain, cobalt blue penlights, gauzes and sterile solution, Duratears, and polyethylene covers (Mckenzie et al., 2005); and the training costs, like the cost for the inviting ophthalmologists, and the staff cost per hour spending on training.

Family acceptance towards polyethylene eye covers

A successful EBP is a combination of evidence, clinical expertise, and patient's preference (Melnyk & Fineout-Overholt, 2005). The family's preference should not be ignored for the sedated or paralysed patients. Cortese et al. (1995) showed families developed favorable perceptions towards the use of transparent polyethylene cover after explanation. Upon application, the case nurses explain the purpose and importance of eye care to the patient's family so as to reduce their psychological distress and promote

family acceptance towards the polyethylene eye covers.

As family acceptance is related to opinion, feelings, and psychological characteristics, structured direct questioning is proposed (Polit & Beck, 2008). The case nurse asks the primary next-of-kin's opinions after applying the eye cover. A standardized yes-no question is printed on the eye care documentation chart (see Appendix 14) that will be collected in the ACO box finally. A space is provided after the choice of "no" for comments. The proposed question is:

"As part of the eye care for your_____ (husband/ wife/ father/ mother, brother, sister, son, daughter etc.), his/her eyes have to be covered by a polyethylene cover. Do you find this acceptable?"

Nature of clients to be involved

The clients involved in the target setting are the same as the target population of the eye care protocol as discussed.

Number of clients to be involved

The number of clients involved is calculated on the primary outcome. The full-scale implementation is a one group design with all clients receiving the eye care protocol. The incidence of corneal abrasion or ulceration will be analyzed in cross-sectional manner half-yearly, or in an extended time interval according to the availability of participants. The evaluation objective is to determine if the incidence of corneal abrasion or ulceration is changed since the implementation of eye care protocol. The incidence of corneal abrasions or ulcerations during the implementation period will

be compared with the baseline incidence of corneal disorders under usual care in the pilot study.

The usual eye care in the target ICU is mainly no care. Only a few nurses occasionally provide gauze cover, NS soaked gauze lid cleansing, or chloramphenicol or methylcellulose instillations. Literature showed that the incidence of corneal abrasion or ulceration was 22% to 42% with such care (Bates et al., 2004; Cortese et al., 1995; Desalu et al., 2008; Laight, 1996; Lenart & Garrity, 2000). By observation, the incidence of corneal disorders is about 40% in the target ICU. To be conservative, the null value is taken as 0.4.

Evidence showed that polyethylene covers or Duratears produced 0 to 6.8% corneal disorders, and reduced the incidence by 6 times compared with methylcellulose (Cortese et al., 1995; Joyce, 2002; Koroloff et al., 2004; Lenart & Garrity, 2000; So et al., 2008). Literature also showed that eye care protocols having eye assessment produced an incidence of 8.7% (Suresh et al., 2000) and 33% (Parkin et al., 1997). To be conservative, an actual value of 0.2 is taken. The null and actual values may be modified after the pilot study.

The incidence of corneal disorders will be analyzed by a 2-tailed z-test, and the test for one proportion is used for sample size calculation. Exact method, a level of significance (alpha) of 0.05 and a power of 80% are taken. The sample size required is at least 45 patients (Lenth, 2006). Because of the critical patient condition, taking an attrition rate of 10% to 20%, at least 55 patients will be recruited. The sampling takes 6 to 9 months.

Data analysis

Incidence and severity of OSDs

The incidence and severity of OSDs during the implementation period will be compared with that in the usual care group of the pilot study. A two-tailed z-test for testing one proportion will be used to evaluate the change, in proportion, in the incidence of the OSDs; while a two-tailed independent t-test will be used to examine the change in the severity of OSDs, that is graded 0 to 7 (see Appendix 9), since the implementation of eye care protocol. The incidence and severity of OSDs will be analyzed with demographics, possible confounders, and nursing compliance.

Nursing skills and compliance

The average compliance rate, in percentage, of each standardized criteria will be calculated. The specific noncomplied item will be analyzed with the agreed standard and the reasons of noncompliance (Bick & Stephens, 2003; Charrier et al., 2008; Cooper, 2004; Gould, 2008).

Cost-effectiveness analysis

Cost-effectiveness analysis is to estimate the costs to produce the impacts on the primary outcome, that is the prevention of corneal damage and subsequent complications (Polit & Beck, 2008). It will be performed by comparing the achievement of the primary outcome with the resource costs associate with the eye care protocol for each patient.

Family acceptance towards the appearance of patients receiving eye care

The percentage of families who do not object to the application of polyethylene covers will be calculated together with their comments.

Basis on which the eye care protocol will be considered as effective

The main objectives of the eye care protocol are to reduce the incidence and severity of OSDs, among which, the primary outcome determining the effectiveness of the eye care protocol is the incidence of corneal abrasion or ulceration. However, without an adequate nursing compliance, the primary outcome fails to show the effectiveness of the protocol (Kinsman, 2004). Therefore, the eye care protocol is considered as effective according to the following bases, which are listed from the top to least prioritization. The protocol is effective when:

1. the incidence of corneal abrasion or ulceration is less than 10%. Literature showed that the incidence of corneal disorders was approximately 0 to 8.7% in the eye care protocol having eye assessment and using Duratears or polyethylene covers (Cortese et al., 1995; Joyce, 2002; Koroloff et al., 2004; Lenart & Garrity, 2000; So et al., 2008; Suresh et al., 2000).
2. there is a statistically significant reduction in the incidence of corneal abrasion or ulceration since the implementation of eye care protocol. Studies showed that the use of Duratears or polyethylene covers produced a statistically significant reduction in the incidence of corneal disorders (Cortese et al., 1995; Joyce, 2002; Lenart & Garrity, 2000).
3. all nurses obtain the required skills and 100% of them comply to the criteria in

the initial audit before the implementation. Nurses should obtain the skills and understandings before implementation.

4. the average nursing compliance rate to each standardized criteria of the protocol is at least 60% during implementation. Without eye care training to nurses, Dawson (2005) showed only 25.5% documented eye assessment, and 55.3% documented the eye care interventions. With the eye care team's efforts in training, a higher compliance is expected. Usually, in the target ICU, the compliance rate to each criterion of any audit is above 70%. Compliance of 60% is a conservative estimation. Audit should not be rushed, it takes time to prepare, evaluate, and act on the results (Cooper, 2004). Better compliance is expected by keeping the stakeholders informed about the audit results and protocol effectiveness (Cooper, 2004; Dawson, 2005).
5. there is a reduction trend in the incidence of conjunctival disorders and eye infection, and severity of OSDs since the implementation of the eye care protocol. Although only a few studies evaluated the incidence of eye infection (Joyce, 2002; Marshall et al., 2008; Parkin et al., 1997), and some evaluated the incidence of conjunctival disorders (Desalu et al., 2008; Suresh et al., 2000) and the severity of OSDs without significant testing (Ezra et al., 2005; Sivasankar et al., 2006; So et al., 2008; Suresh et al., 2000), they did demonstrate a reduction trend. In view of the insufficient evidence base, it is difficult to specify a fixed percentage of reduction.
6. at least 50% of the patients' primary next-of-kin do not object to the use of polyethylene covers. By observation, 80% of the families in the target ICU do

not ask about the use of gauze eye cover. Fifty percent is a conservative estimation.

Measures to sustain the change of practice

According to the Iowa Model, the evaluation results will be disseminated to the stakeholders (Melnyk & Fineout-Overholt, 2005; Polit & Beck, 2008; Titler, 2002) (see Appendix 1). The results will be reported to the COS, DOM, WM, and the eye care team in written form, for deciding whether to adapt, modify, or reject the protocol (Madsen et al., 2005; Polit & Beck, 2008; Rosswurm & Larrabee, 1999). Ongoing communication and education to other stakeholders about the outcomes are also important to enhance stakeholders' confidence, positive attitude, and euthusiatism in the feasibility and effectiveness of change (Dawson, 2005; Rosswurm & Larrabee, 1999), and therefore their acceptance towards a new protocol (Hirkpatrick, 2001; Rosswurm & Larrabee, 1999). Monthly ward meeting held by the eye care team is a formal route of information dissemination, discussion, and planning (Laight, 1995). Patient outcomes, nursing audit results and recommendations (Bick & Stephens, 2003; Cooper, 2004; Westwell, 2008), and the successful stories and obstacles such as problems of protocol content and insufficient facilitation, will be shared and discussed openly with the stakeholders. According to the stakeholders' agreements, the team modifies the protocol to achieve a better compliance (Bick & Stephens, 2003; Cooper, 2004; Gould, 2008; Kinsman, 2004; Nolan & Scott, 1993). If there is poor nursing compliance, audit will be repeated as an audit cycle to lead a gradual improvement in nursing compliance and thus patient outcome (Dawson, 2005; Gould, 2008). Reward or reinforcement with incentives will be

used to appreciate stakeholders' efforts (Dawson, 2005). Moreover, an intermittent review of the newly emerging evidence will be conducted half-yearly by the investigator in charge of the protocol (Polit & Beck, 2008; Westwell, 2008).

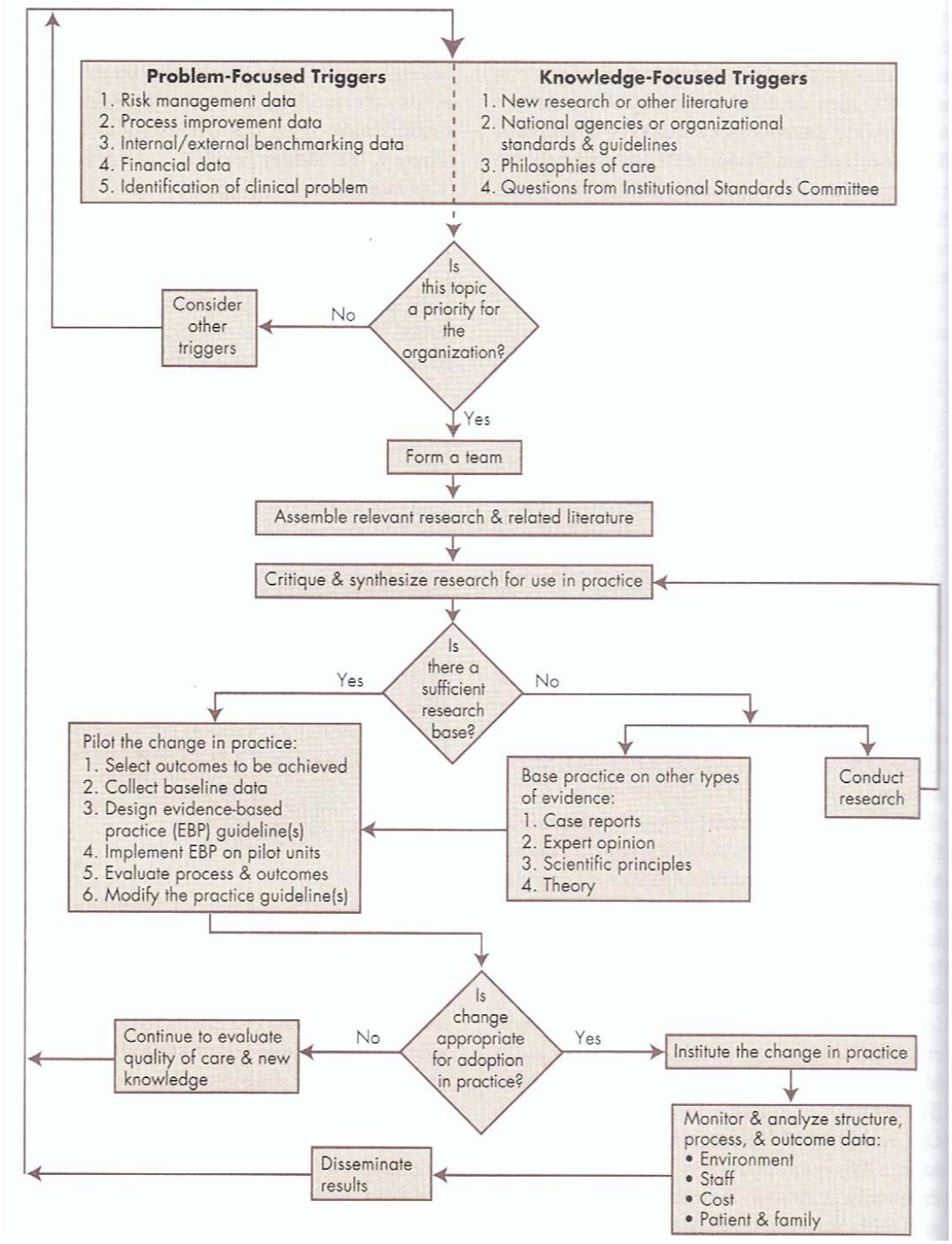
CHAPTER 5 CONCLUSION

In view of the high prevalence of OSDs occurring in the ICU patients with altered LOC, a systematic and critical review of the related research have been conducted. Using the sufficient evidence base, an eye care protocol, with satisfactory grades of recommendations, has been developed. It is the second evidence-based eye care protocol, after Marshall et al (2008), in the world. The protocol contains the assessments of lids and OS, and the applications of soaked gauze lid cleansing, polyethylene eye covers, Duratears eye ointment, medical referral, suctioning technique, conjunctival edema management, and VAP prevention. With the well-designed implementation and evaluation plans of the protocol, the dissemination of the protocol in the target ICU setting is likely to reduce the incidence and severity of OSDs, especially the corneal damages, to prevent the subsequent eye complications, to preserve patient's quality of life, and to lessen the healthcare burdens. The eye care protocol is also potentially beneficial to the sedated, paralysed, or comatose patients in any other ICU settings.

GLOSSARY

APACHE II score	An ICU scoring system: it measures the severity of disease of adults (aged 15 or above) in ICU. The point score is calculated from the points for cardiovascular, respiratory, renal, gastrointestinal, hematological, septic, metabolic, and neurological status during the first 24 hours after admission. The score is interpreted with patient's preadmission health status. Higher score implies a more severe disease and a higher risk of death
CorneaCare	An adhesive polyurethane membrane with a clear non-adhesive window for eye inspection
Duratears	An eye ointment: it contains white petrolatum, anhydrous liquid lanolin, and mineral oil
Geliperm	A high-water-content hydrogel sheet: a dressing material that contains agar, a gellable polysaccharide, and polyacrylamide. It provides a moist environment, and is permeable to water vapour, gases, and small protein molecules, but impermeable to bacteria
hypromellose/ methylcellulose	An artificial tear substitute: it stabilizes and thickens the precorneal tear film, decreases the viscosity of tear film, prolongs corneal contact time, and extends tear film breakup time. It promotes corneal hydration, and lubricates and protects eyes
Lacrilube	An eye ointment: it contains white paraffin, mineral oil, nonionic lanolin derivatives, and chlorbutol. It stabilizes tear film and remains in tears longer than eye drops, but is not easily removed by lacrimal drainage system
polyethylene	A transparent film: it reduces tear evaporation and protects from air current and bacteria

APPENDIX 1 IOWA MOEL (Polit & Beck, 2008; Titler, 2002)



APPENDIX 2 SEARCHING ENGINES

CLINICAL GUIDELINE SEARCH (till Jan 2008)

National guidelines clearinghouse

- by keywords: eye care: 0 out of 253
- by disease → eye diseases (43)→corneal disease (3) → keratitis (1) → eye infection (4) → all irrelevant

CMA infobase

- by keywords: eye care or eyecare or exposure keratitis or keratopathy : 0
- by specialty → Critical care: 0 out of 9

Health service/technology assessment text

- by keywords: intensive care or critical care and eye: 0

Guidelines advisory guidelines:

- by topic: no relevant topic

Scottish Intercollegiate Guidelines Network (SIGN)

- by topic: no relevant topic

National Insitute for Clinical Excellence (NICE):

- by topic→ eye : 0 relevant

New Zealand Guideline Group:

- by topic→ preventive medicine: 0 relevant

Joanna Briggs Institute:

- by keywords: eye care: 1 systematic review of eye care in ICU

ELECTRONIC ENGINES

Cochrane library (1999-2008) (Number in parenthesis: number of relevant articles)

- By topic: eye→keratitis: 0
- By A-Z: C, E, K: 0
- By keywords: eye care, intensive care, prevention of eye disease, nursing care of eye: 0
- Search history: 6 relevant studies were identified

ID	Search	Hits
#1	(eye care or eyecare or eye disease prevention or nursing care or prevention management):ti,ab,kw and (intensive care or critical care or critically ill patient):ti,ab,kw and (sedated or paralyzed or paralysed or unconscious or semiconscious or comatose or semicomatose or muscle relaxants or neuromuscular blocking agent or sedation or sedatives):ti,ab,kw or (mechanical ventilation or tracheal suctioning):ti,ab,kw and (Corneal exposure or corneal injury or corneal perforation or Corneal abrasions or eye infection or corneal infection or exposure keratitis or exposure keratopathy or microbial keratitis or ocular surface disease or Lagophthalmos or chemosis or conjunctival edema or oedema or conjunctival disease):ti,ab,kw	36 (5)
#2	(eye care or eyecare or eye disease prevention or nursing care or prevention management):ti,ab,kw and (intensive care or critical care or critically ill patient):ti,ab,kw or (sedated or paralyzed or paralysed or unconscious or semiconscious or comatose or semicomatose or muscle relaxants or neuromuscular blocking agent or sedation or sedatives):ti,ab,kw or (mechanical ventilation or tracheal suctioning):ti,ab,kw or (Corneal exposure or corneal injury or corneal perforation or Corneal abrasions or eye infection or corneal infection or exposure keratitis or exposure keratopathy or microbial keratitis or ocular surface disease or Lagophthalmos or chemosis or conjunctival edema or oedema or conjunctival disease):ti,ab,kw	7068
#3	(eye care or eyecare or eye disease prevention or nursing care or prevention management):ti,ab,kw and (intensive care or critical care or critically ill patient):ti,ab,kw or (sedated or paralyzed or paralysed or unconscious or semiconscious or comatose or semicomatose or muscle relaxants or neuromuscular blocking agent or sedation or sedatives):ti,ab,kw or (mechanical ventilation or tracheal suctioning):ti,ab,kw and (Corneal exposure or corneal injury or corneal perforation or Corneal abrasions or eye infection or corneal infection or exposure keratitis or exposure keratopathy or microbial keratitis or ocular surface disease or Lagophthalmos or chemosis or conjunctival edema or oedema or	3437 (1)

conjunctival disease):ti,ab,kw

Medline (Ovid SP) with MeSH, explode (1950-2008): 35 relevant studies

# ▲	Searches	Results
1	(eye care or eyecare or eye disease prevention or nursing care or prevention management).mp. [mp=title, original title, abstract, name of substance word, subject heading word]	41708
2	(intensive care or critical care or critically ill patient).mp. [mp=title, original title, abstract, name of substance word, subject heading word]	90766
3	(sedated or paralyzed or paralysed or unconscious or semiconscious or comatose or semicomatose or muscle relaxants or neuromuscular blocking agent or sedation or sedatives).mp. [mp=title, original title, abstract, name of substance word, subject heading word]	26081
4	(mechanical ventilation or tracheal suctioning).mp. [mp=title, original title, abstract, name of substance word, subject heading word]	16408
5	(Corneal exposure or corneal injury or corneal perforation or Corneal abrasions or eye infection or corneal infection or exposure keratitis or exposure keratopathy or microbial keratitis or ocular surface disease or Lagophthalmos or chemosis or conjunctival edema or oedema or conjunctival disease).mp. [mp=title, original title, abstract, name of substance word, subject heading word]	19527
6	1 and 2 and 3 and 4 and 5	1 (1)
7	1 and 2	1861
8	1 and 2 and 5	11 (10)
9	2 and 5	376
10	3 and 5	59 (8)
11	1 and 5	71 (5)
12	1 and 3 and 2	19 (7)
13	4 and 5	147
14	13 and 2	35 (4)
	no more in other combinations	

CINAHL (Ovid SP) with MeSH (1982-2008): 17 relevant studies found

# ▲	Searches	Results
1	(eye care or eyecare or eye disease prevention or nursing care or prevention management).mp. [mp=title, subject heading word, abstract, instrumentation]	23728
2	(intensive care or critical care or critically ill patient).mp. [mp=title, subject heading word, abstract, instrumentation]	32970
3	(sedated or paralyzed or paralysed or unconscious or semiconscious or comatose or semicomatose or muscle relaxants or neuromuscular blocking agent or sedation or sedatives).mp. [mp=title, subject heading word, abstract, instrumentation]	1797
4	(mechanical ventilation or tracheal suctioning).mp. [mp=title, subject heading word, abstract, instrumentation]	2903
5	(Corneal exposure or corneal injury or corneal perforation or Corneal abrasions or eye infection or corneal infection or exposure keratitis or exposure keratopathy or microbial keratitis or ocular surface disease or Lagophthalmos or chemosis or conjunctival edema or oedema or conjunctival disease).mp. [mp=title, subject heading word, abstract, instrumentation]	600
6	1 and 2 and 3 and 4 and 5	1 (1)
7	1 and 2	1397
8	1 and 3 and 2	12 (5)
9	2 and 5	33 (4)
10	1 and 2 and 5	4 (3)
11	1 and 5	7 (3)
12	4 and 5	7 (1)
	no more relevant studies in other combinations	

Pubmed (1950-2008): 17 relevant studies

#6	Search **eye care for intensive care unit patient**	12:04:31	196 (15)
#10	Search **intensive care or critical care, eye care or eyecare, unconscious or semiconscious or comatose or semicomatose, exposure keratopathy or keratits or corneal abrasion**	11:57:02	130317
#9	Search **intensive care or critical care , unconscious or semiconscious or comatose or semicomatose, exposure keratopathy or keratits or corneal abrasion**	11:56:36	130074
#8	Search **intensive care, exposure keratopathy or keratits or corneal abrasion**	11:55:08	355
#3	Search **eye care, intensive care, exposure keratopathy**	11:53:32	2 (2)
#7	Search **eye care, intensive care unit**	11:52:35	241
#5	Search **eye care for intensive care patient**	11:52:06	355
#4	Search **intensive care, exposure keratopathy or keratitis**	11:51:44	16781
#2	Search **eye care, intensive care**	11:50:37	560
#1	Search **eye care**	11:50:19	11010

APPENDIX 3 KEYWORDS USED

4 GROUPS OF KEYWORDS USED

1. Interventions:

- eye care/ eyecare/ eye disease prevention/ nursing care/ prevention management

2. Settings:

- intensive care/ critical care/ critically ill patient

3. Patients:

- sedated/ paralysed/ paralysed/ unconscious/ semiconscious/ comatose/ semicomatose/ sedation/ sedatives/ muscle relaxants/ neuromuscular blocking agent
- mechanical ventilation/ tracheal suctioning

4. Outcomes:

- Corneal exposure/ corneal injury/ corneal perforation/ corneal abrasion/ eye infection/ corneal infection/ exposure keratitis/ exposure keratopathy/ microbial keratitis/ ocular surface disease/ lagophthalmos/ chemosis/ conjunctival edema/ oedema/ conjunctival disease

APPENDIX 4 TABLES OF EVIDENCE AND TABLES OF CRITICAL APPRAISAL

TABLE OF EVIDENCE 1 (Clinical guideline)

Bibliographic citation	Study type	Evidence level	Number& types of studies [1]	Number of patients	Patient characteristics	Interventions	Comparisons	Outcome measures	Length of follow up	Recommendations (Grading[2])
Marshall, A.P., Elliott, R., Rolls, K., Schacht, S., & Boyle, M. (2008)	Clinical guideline	1-	- 5 RCTs -1 before & after study -2 prospective studies with retrospective chart review	<u>RCTs:</u> mean/study: 64.2 <u>Non-RCTs:</u> mean/study: 65.7	- ICU patients - Comatose/ semicomatose - GCS<10 - Receiving NMB - Reduced/ no blink reflex - Mechanical ventilated	<u>RCTs</u> (1) Geliperm/ CorneaCare taping (Bates et al., 2004) (2) Polyethylene covers (Cortese et al., 1995) (3) Duratears (Lenart & Garrity, 2000) (4) Polyethylene covers (Koroloff et al., 2004) (5) Swimming googles + sterile water soaked gauze (Sivasankar et al., 2006) <u>Before & after study</u> (6) Revised eye care guidelines (Parkin et al., 1997) <u>Prospective + retrospective studies</u> (7) Nil (investigate relationship between suctioning & eye infection) (Hilton et al., 1983) (8) Taping to persistent corneal erosions (Imanaka et al., 1997)	(1) QD NS lid cleansing + lubricants ≥ BD (2)Methylcellulose (3) Passive lid closure (4) HL combination (5) Lubricants + taping (6) Unstandardized care (7) Nil (8) Nil	Incidence of : a) corneal abrasions/ ulcerations b) keratopathy/ keratitis c) eye infection	Not mention	1) ICU nurses must assess each patient for the risk factors of incomplete lid closure: reduced conscious level, tracheal intubation, and significant metabolic derangement (D). 2) QD assessment of patient's ability to maintain lid closure (D). 3) Observe for OSDs (at microepithelial level) at least weekly, using practical methods readily available e.g. fluorescein stain and cobalt blue pen torch (D). 4) Timely referral for any suspected OSDs (D). <u>Effective practices in preventing OSDs</u> 1) Complete lid closure should be maintained in patients having incomplete lid closure (D). 2) If lid closure cannot be maintained passively, use mechanical methods (C). 3) All unconscious/heavily sedated patients who cannot achieve lid closure independently should receive q2h eye care with NS soaked gauze lid cleansing and eye lubricants (C).
Main result(s) & special remarks	Despite the guideline was developed from a small number of studies and low levels of evidence, the recommendations v … by peers and ophthalmologic experts. The guideline has a potential to positively affect the patient outcomes by encouraging clinicians to assess and monitor for OSDs and to prov … e preventive interventions. [1] English published studies only [2] National Health and Medical Research Council (NHMRC) grade of recommendati…									

TABLE OF CRITICAL APPRAISAL 1 (CASP appraisal tool for systematic review)

1. Clearly-focused question	Yes	
2. Include right type of studies	Yes	Included RCTs, interventional, and observational studies
3. Try to identify all relevant studies	No	- Electronic databases: Cochrane library, Medline (1966-2001), CINAHL (1982-2001), and Pubmed - Internet search: google scholar - Hand searching of reference list/ bibliographies - Restriction on English language: possible bias (may have excluded some sources of information) - Keywords use: • Insufficient: has not included keywords like eye infection, eye care, corneal abrasions, or chemosis • Used different combinations of keywords in different database: possible bias - No dissertations search/ hand searching of relevant or unpublished studies, conference proceedings, or personal expert contacts for possible unpublished studies - The searched results showed it is not likely a thorough search
4.Assess quality of included studies	Yes (0.5)	- By predetermined inclusion protocol (NHMRC selection criteria) - Each paper was reviewed by at least 2 Guideline Development Network members independently. Papers were assessed by NHMRC Taxonomy for level of evidence. Consensus of group members assigned the papers NHMRC grade of recommendation: minimize bias and improve reliability - Critical appraisal checklist: NOT mentioned (deduct 0.5 mark)
5.Reasonable combination of the results of studies	Can't tell	- No combination rule has been stated - Results of each study are clearly displayed - Similar population, intervention & outcome measures among the studies, except the 2 prospective studies with retrospective chart review - Reasonable recommendations
6. Presentation of main result(s)	Satisfactory	- Clear tables of evidence (summary of papers reviewed) for easy reveal - NHMRC Taxonomy for level of evidence and Grading system of recommendations are clear - Presented the level of evidence for each study and clear grade for each recommendation clearly - Also presented the reasons for non-inclusion of studies
7. Precision of result(s)	Poor	No 95% CI was reported in individual study; only 2 studies reported p-values
8. Applicable to local population	Yes	
9. Consider all important outcomes	Can't tell	The included studies have low levels of evidence, and the recommendations are having low grades of C and D.
10. Policy or practice should change as a result of the evidence of this review	Can't tell	The included studies have low levels of evidence, and the recommendations are having low grades of C and D.
% of criteria fulfilled	45% (4.5/10)	

TABLE OF EVIDENCE 2 (systematic review)

Bibliographic citation	Study type	Evidence level	Number & types of studies[1]	Number of patients	Patient characteristics	Interventions	Comparisons	Outcome measures	Length of follow up	Effect size
Joyce, N. (2002)	Systematic review	1++	- 3 RCTs -1 controlled trial -1 un-controlled trial -1 before & after study	<u>RCTs:</u> mean/study: 73.3 <u>Non-RCTs:</u> mean/study: 15	ICU patients All ages Unconscious / sedated/ paralysed Mechanical ventilated No facial burns/ eye trauma	<u>RCTs</u> (1) Methylcellulose (Cortese et al., 1995) (2) Duratears (Lenart & Garrity, 2000) (3) HL combination (Koroloff et al., 2004) <u>Non-RCTs</u> (4) Geliperm protocol (Laight, 1996) (5) Protocol (lubricants/ Micropore taping) based on lid closure (Suresh et al., 2000) (6) Revised eyecare guidelines (Parkin et al., 1997)	(1) Polyethylene covers (2) Passive lid closure (3) Polyethylene covers (4) Hypromellose protocol (5) Routine care: NS/ sterile water lid cleansing (6) unstandardized care	Incidence of : a) corneal abrasions b) eye infection	<u>RCTs:</u> 48h-1week <u>Non-RCTs:</u> 24h- 28 days	**a) Incidence of corneal abrasions** <u>RCTs</u> (1) Polyethylene covers significantly reduced the incidence, compared with regular instillation of methylcellulose drops (OR 6.05 95% CI 1.48 to 24.66) or HL combination (OR 6.22, 95% CI 1.97 to 19.63). (2) Duratears ointment significantly reduced the incidence, compared with passive lid closure (OR 0.2, 95% CI 0.05 to 0.76)[2]. <u>Non-RCTs</u> (3) Insignificant different in the incidence between the Geliperm & hypromellose protocols. (4) Protocol based on lid closure reduced the incidence. **b) Incidence of eye infection** Eyecare guidelines significantly reduced the conjunctival PAER isolation rate.
Main result(s) & special remarks	Polyethylene cover is the optimum intervention for reducing the incidence of corneal abrasions, and it costs less. - Polyethylene film costs $1 (AUD)/ roll/ 6 months for a 14-bed ICU, saving $10 000 (AUD)/ year. [1] English published studies only [2] Wrong data about the incidence and sample size in each intervention group, thus leading to the wrong OR and 95% CI : conclusion is correct.									

TABLE OF CRITICAL APPRAISAL 2 (CASP appraisal tool for systematic review)

1. Clearly-focused question	Yes	
2. Include right type of studies	Yes	Included RCTs and interventional studies
3. Try to identify all relevant studies	No (0.5)	- Restriction on English language (due to limited time & resources to translate): possible bias (may have excluded some sources of information) - Keywords use: • Insufficient: has not included keywords like eye infection, eye care, corneal abrasions, or chemosis • Used different combinations of keywords in different database: possible bias - 0.5 mark is given because the studies searched are extensive and thorough, by means of a variety of searching strategies: • Reference list, bibliographies • Dissertations (1861+) • Electronic databases: Cochrane library, Medline (1966-2001), CINAHL (1982-2001), Expanded Academic ASAP international edition, and Current contents (Ovid) • Hand searching: ▪ Relevant/ unpublished studies ▪ Conference proceedings: Australian & New Zealand Annual Scientific Meetings on Intensive Care ▪ Heart and lungs: Journals of Acute & Critical Care (1995-2001), Critical Care Nurse (1990-2000), Dimensions of Critical Care (1987-2001) • Contacted researchers by emails
4.Assess quality of included studies	Yes	- by predetermined inclusion protocol - studies were assessed by 2 reviewers: minimize bias, improve reliability - Critical appraisal checklist were showed: focusing randomization, performance bias, outcome measurement, and attrition
5.Reasonable combination of the results of studies	Yes	- By qualitative decision: results of each study were clearly showed; studies have similar populations, interventions & outcomes for combination - Used Review Manager software for evaluating homogeneity a、 Acceptable variation: used quantitative meta-analysis b、 Great variation: examined the causes of differences, and used qualitative overview if significant heterogeneity
6. Presentation of main result(s)	Fair (0.5)	- OR and 95% CIs were presented. Sizes of OR are meaningful. - One of the conclusions: Duratears significantly reduced the incidence, compared with passive lid closure (OR 0.2, 95% CI 0.05 to 0.76) → WRONG calculation of sample size & incidence rate in each intervention group (n=50 for each group is wrongly calculated as n=25) → wrong OR/ 95% CI. However, the conclusion is correct.
7. Precision of result(s)	Poor	Wide 95% CIs (less clinical importance)
8. Applicable to local population	Yes	
9. Consider all important outcomes	Yes	
10. Policy or practice should change as a result of the evidence of this review	Can't tell (0.5)	Wrong calculation of OR and 95% CI for the comparison of Durat instillation and passive eye closure. However, the conclusion is still correct.
% of criteria fulfilled	75% (7.5/10)	

TABLE OF EVIDENCE 3 (RCT)

Bibliographic citation	Study type	Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Outcome measures	Tool	Length of follow up	Effect size
Cortese, D., Capp, L., & McKinley, S. (1995)	RCT	1+	96[1] in a 14-bed general ICU of a large metropolitan teaching hospital in Australia	- Age: 15-84 - Limited/no blinking reflex, due to the use of sedation (mainly morphine & midazolam), coma/ semicoma - Diagnosis: mainly Resp, HI, and Neuro - no preexisting corneal/ lid injury/ inflammation	n=30 Polyethylene covers (Gladwrap): - Extend beyond orbits & eyebrows, & tape to face - Change daily/ prn + Routine NS eye toilet q2h	n=30 Methylcellulose drops (Methopt Forte) q2h + Routine NS eye toilet q2h	Incidence of corneal epithelial breakdown	Fluorescein drops + penlight with blue filter[2]	Started from enrollment, reassessed daily at set time[2] until corneal breakdown developed / blink reflex returned. Ranging from 48h- 1week.	Polyethylene covers significantly ($p<0.05$) reduced the incidence of corneal breakdown to 3.3%, compared with 26.7% in methylcellulose group.
Main result(s) & special remarks	1. Incidence of corneal breakdown with eyecare protocol: 3.3% to 26.7%. 2. Polyethylene film: is more effective than methylcellulose in preventing corneal breakdown, using moisturizing drops alone is not recommended. • Application: simple, easy, and time-saving. • Cost-effective: polyethylene film costs AUS$ 1/roll/6 months; Methylcellulose drops costs AUS$1.8/patient/week. • Relatives' favorable perception of the polyethylene film (because of its transparency) after explanation of the indications. [1] excluded 18 patients in each group (a total of 36) in analysis, as patients died, regained blink reflex, and developed corneal breakdown or dry eyes within 48 hours of recruitment, transferred out to another hospital, or due to incorrect documentation [2] assessed by doctors, diagnosis was confirmed by ophthalmologist									

TABLE OF CRITICAL APPRAISAL 3 (CASP appraisal tool for RCT)

1. Clearly-focused question	Yes	
2. Appropriate to carry out a RCT	Yes	

3. Appropriate allocation to intervention and control groups	Can't tell (0.5) (?unbiased/ true R)	• Randomized 96 patients after affirming their eligibility
		• Unclear R schedule; No training to nurses responsible for recruitment; Inadequate allocation (sealed envelopes)
		• 0.5 mark is given because the equalization effect of R (2 groups are comparable) was reported:
		  • Insignificant difference between 2 groups on the possible confounders e.g. gender, medical problems, causes of the absence of blink reflex, choice of sedatives or muscle relaxant, and lid closure ($p > 0.05$)
		  • However, the effects of the other measured potential confounders (age, motor response to pain, frequency of pupil assessment) on the corneal breakdown were not mentioned→ inadequate confounders control

4. Blinding (performance/ observer bias)	No	• Patient: blinding is not important (as outcome cannot be altered by patients) • Nurse (blinding is impossible)→ no intervention checks for compliance→possible performance bias → affect outcome • Data collector: possible to blind (e.g. remove polyethylene upon assessment) → obvious intervention may contribute to observer bias→ objective assessment tool and ophthalmologist's diagnosis reduce the risk of bias
5. All participants were accounted for conclusion	No (acceptable & omitted)	36 patients (40%) were excluded in the analysis due to patients' ineligibility, with no ITT. Acceptable because: • patients excluded were similarly distributed. Equalization effect of R did not change after the exclusion (n=60): No significant difference in possible confounders between 2 groups (groups are still comparable) • more patients in methylcellulose group developed corneal breakdown and dry eye within 48 hours, exclusion may underestimate the incidence of corneal breakdown→However, main results of the study would be the same
6. Participants were followed up and data collected in the same way	Can't tell	Data collection: same tool & interval (QD at set time); doctors and ophthalmologist are appropriate for diagnosing corneal breakdown However: • For nurses: no intervention check/ skill training (possible performance bias); No pupil assessment frequency (manual blink) was reported • Unclear eye care protocol e.g. unclear dosage of eye drops, actual frequency of changing polyethylene covers
7. Sufficient sample size	Can't tell	No sample size calculation was mentioned
8. Presentation of main result(s)	acceptable (0.5)	• Good use of tables; no duplication of text and tables; used percentage for categorical variables; appropriate significant testing methods; meaningful effect size • Have not reported: mean/SD for continuous data; risk indexes; significance testing for the reasons of exclusion & possible confounders (age, motor response to pain, frequency of pupil assessment)
9. Precision of result(s)	Fair (0.5)	• Reported only p-value, with no 95% CI→calculated 95% CI 6.3% to 40.5% → acceptable clinical significance • Tool: objective and appropriate, valid (but penlight is less sensitive than slit lamp in detecting microepithelial corneal defects). No sensitivity/ specificity was reported. Data collector (ophthalmologist): appropriate qualification • Statistical tests: appropriate; Confounding control: partly controlled
10. Applicability of results	Yes	Morphine & midazolam are commonly used in the target ICU. Polyethylene c…able.
% of criteria fulfilled	50% (4.5/9)	

TABLE OF EVIDENCE 4 (RCT)

Bibliographic citation	Study type	Evidence level	Number of patients	Patient characteristics [1]	Intervention	Comparison	Outcome measures	Tool	Length of follow up	Effect size
Lenart, S.B. & Garrity, J.A. (2000)	RCT	1-	50 in the ICUs of a large teaching hospital in America	- Adult: 54% > age 50 - Gender: 60% male - Diagnosis: medical, surgical - Intubated - Loss of blinking reflex for ≥ 48h, due to the use of NMB and/or propofol - no preexisting eye disease, lid abnormalities, or facial trauma	<u>One eye (n=50):</u> Duratears ointment 1.27cm q4h	<u>Contralateral eye of same patient (n=50):</u> Passive eyelid closure prn	Incidence of corneal breakdown	<u>Sodium fluorescence test:</u> Fluor-I-Strips + Dacriose irrigating solution + cobalt-blue penlight [2]	48h	Instillation of Duratears ointment significantly reduced the incidence of corneal breakdown to 4%, compared with 22% in the passive closure group (p= 0.004).
Main result(s) & special remarks	1. Incidence of the corneal breakdown on admission (no eye care): 28%. 2. Eye care protocol led to a lower incidence of corneal breakdown: 4%. 3. Applying Duratears ointment every 4 hours significantly reduced, but not eliminated, the incidence of corneal abrasions by 18% (Calculated 95% CI 5.3% to 30.7%) in intubated patients who were receiving NMB or propofol. - Duratears: easy to apply, not time-consuming, clinically- & cost-effective, not interfere with pupil examinations. [1] wrong statistical test (McNemar test) was used to evaluate the insignificant effects of incomplete lid closure, age, and diagnosis on the incidence of corneal abrasions→possible confounders [2] assessed by unknown data collector									

TABLE OF CRITICAL APPRAISAL 4 (CASP appraisal tool for RCT)

1. Clearly-focused question	Yes	
2. Appropriate to carry out a RCT	Yes	
3. Appropriate allocation to intervention and control groups	Can't tell (? unbiased / true R)	• Randomized after affirming patients' eligibility • No method/ schedule of R/ allocation concealment were mentioned→? selection bias on left/right eye • Intervention and control groups are the contralateral eyes of the same patients (not included a control group): background characteristics between groups are matched and the same
4. Blinding (performance/ observer bias)	No	• Nurses (impossible to blind) → primary investigator reviewed the protocol with the case nurses in each shift, with no intervention checks → possible performance bias →affect outcome • Data collector (possible & preferable to blind)→ possible observer bias → objective fluorescence test but unknown qualification of assessors → unable to reduce the possible bias
5. All participants were accounted for conclusion	Can't tell 0.5	• Include all 50 participants (100 eyes) in analysis • However, the study has not mentioned about intervention check: possible confusion about the 2 interventions on same patient→ might deliver the eye care intervention to the contralateral control eye
6. Participants were followed up and data collected in the same way	Can't tell	• Primary investigator reviewed the standardized protocol in each shift with the case nurses; clear dosage of eye ointment; same follow up time (but too short) • Unknown data collector(s) • Have not delivered education or skill training to nurses on eye care • Have not reported: frequency of passive closure or pupil examinations; intervention check (possible performance bias/ confusion about 2 interventions on same patient)
7. Sufficient sample size	Can't tell	No sample size calculation was mentioned
8. Presentation of main result(s)	Poor	• Descriptive statistics: simply presented numbers, used percentage for categorical variables e.g. gender • Have not reported the mean or median for continuous variable, or risk indexes • Inconsistent number of patients was reported in the table and text (about the relationship between risk factors in development of corneal abrasions) • Inappropriate McNemar test was used for testing the relationship between the risk factors (incomplete lid closure, age, gender, and diagnosis) and corneal abrasion (Fisher's exact test is preferred)→ possible confounders • Have wrongly interpreted the effect of patient's diagnosis on corneal abrasions as significant (Fisher's exact test p=0.09)
9. Precision of result(s)	Poor	• Provided only p-value, with no 95% CI → Calculated 95% CI: 5.3 % to 30.7% → acceptable clinical significance • Unknown data collector • Tool: objective and appropriate, valid (but penlight is less sensitive than slit lamp), no sensitivity/ specificity was reported • Length of follow up: 48 hours → too short, may underestimate the incidence of corneal breakdown • Wrong statistical test was used for the significant factors → possible confounders
10. Applicability of results	Yes	Propofol/ NMB are commonly used drugs in the mecha ated patients in the target ICU. Duratears is applicable.
% of criteria fulfilled	35% (3.5/10)	

TABLE OF EVIDENCE 5 (RCT)

Bibliographic citation	Study type	Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Outcome measures	Tool	Length of follow up	Effect size
Koroloff, N., Boots, R., Lipman, J., Thomas, P., Rickard, C. & Coyer, F. (2004)	RCT	1+	110 in a 18-bed ICU of the Royal Bristane Hospital (university-affiliated tertiary referral hospital) in Australia	- Mean age (all >18): 50.1-55.1[1] - Gender: 51.7-66% Male[1] - Mechanical ventilated - Unconscious - Blinks: < 5 times/ h - Mean APACHE II: 21.1- 22.2[1] - Mean hours on sedation: 89.7-117.3[1] - Muscle relaxant>2 h: 26.7-44%[1] - Median pupil check/day: 10.5-19 [1] - Diagnosis: mainly medical, neurosurgery[1] - Median ICU LOS: 11-12.5 days [1] - Incomplete lid closure: 5-7 cases[1] - No preexisting eye condition	n=60 HL combination q2h - 2 drops hypromellose - 1-cm strip Lacrilube - to lower eyelid + Standard eye cleansing q2h (NS+ sterile gauze)	n=50 Polyethylene (Cling Wrap) - eyebrow to cheekbone -3M healthcare Micropore seals edges -Change each shift/soiled/ torn + Standard eye cleansing q2h	Incidence of corneal ulceration	Fluorescein drops + slit lamp[2]	Started from enrollment, reassessed daily[2] until patients regained spontaneous eye opening, died, developed corneal ulcer/ eye infection, or discharged. Median hours on study: 104.5-126.5[1]	Incidences of the corneal ulceration in the HL group (6.7%) and polyethylene group (0%) were insignificantly different (p=0.12). [Cal 95% CI: 0.4% to 13%]
Main result(s) & special remarks	1. Eye care protocol produced a low incidence of corneal ulcerations: 0-6.7%. 2. In the view of demanding ICU work, polyethylene cover is preferred over q2h instillation of HL combination because of its easy application and removal, transparency for frequent pupil assessment, time-saving, and cost-effectiveness (estimated to save AUD$10000/year). [1] insignificantly different between 2 intervention groups [2] assessed by 2 ophthalmologist-trained intensivists, available interrater reliability checks									

TABLE OF CRITICAL APPRAISAL 5 (CASP appraisal tool for RCT)

1. Clearly-focused question		Yes
2. Appropriate to carry out a RCT		Yes
3. Appropriate allocation to intervention and control groups	Can't tell (0.5)	• Randomized after affirming patients' eligibility • Inadequate details about R schedule: used computer-generated random number but no details about how to use the random numbers and whether the schedule was adhered strictly; No details about allocation concealment • 0.5 mark is given because of the reported equalization effect of R: insignificant difference in confounders between 2 groups (except the reasons of completion)
4. Blinding (performance/ observer bias)	No	• Nurse (impossible to blind) → no nursing compliance/ intervention check → possible performance bias may affect outcome • 2 intensivists (data collectors): possible & preferable to blind e.g. remove polyethylene upon assessment → objective assessment tool and interrater reliability reduce possible observer bias
5. All participants were accounted for conclusion	Yes	Include all 110 participants in analysis
6. Participants were followed up and data collected in the same way	Can't tell (0.5)	• Data collection: same time interval, collected in same way (same tool), appropriate data collectors' qualifications, available interrater reliability • Insignificant difference in pupil assessment frequency between groups • No nurses' skill training on eye care/ no intervention checks for compliance and skills were recorded→possible performance bias • No analysis on the reasons of study completion • change polyethylene prn: not measured about compliance or actual frequency
7. Sufficient sample size	Yes	Appropriate sample size calculation was reported
8. Presentation of main result(s)	Fair (0.5)	• Good use of table, no duplication of text and tables; used percentage for continuous variables; used mean (SD)/median (IQR) for categorical variables • Detailed demographics and confounders comparisons between groups: showed insignificant differences (except the reasons of study completion) • No significance testing was specified in tables 1 and 3; No descriptive statistics was specified for each diagnostic category in table 2, and therefore the presented numbers are difficult to understand. • Not presented risk indexes • Inappropriate to use Fisher's Exact test for continuous dependent variable; Normality of variables does not mean the normal distribution of the residuals, checking residuals is advised to show the validity of the use of student's t-test • There are 2 wrong conclusions: 1) Both interventions are effective: Insignificant result showed the similar effects of 2 interventions, either both effective or ineffective in reducing the incidence of corneal ulcerations 2) Earlier onset time and higher risk of corneal ulceration in burn population: p=0.18→insignificant difference between burn and non-burn patients
9. Precision of result(s)	Fair (0.5)	• Tool: objective, valid, and appropriate (slit lamp is more sensitive than penlight). No sensitivity/ specificity was reported. • 2 intensivists (data collectors): appropriate, available interrater checks • Confounding control: satisfactory • Unclear statistical tests for each tables • Provided only p-values, with no 95% CI: Calculated 95% CI: 0.4% to 13% is wide → I[illegible]sult is possible a Type II error due to inadequate sample size, unchecked intervention compliance, poor data quality, or unnecessary nonparamet[illegible]ombination: a trend of higher incidence)
10. Applicability of results		Yes
% of criteria fulfilled	70% (7/10)	

TABLE OF EVIDENCE 6 (RCT)

Bibliographic citation	Study type	Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Outcome measures	Tool	Length of follow up	Effect size [4]
Bates, J., Dwyer, R., O'Toole, L., Kevin, L., O'Hegarty, N., & Logan, P. (2004)	RCT	1-	31 [1] in a mixed 10-bed medical/ surgical ICU & a 10-bed neurosurgical ICU of a university teaching hospital in Ireland	- Age: 17-76 - Mechanical ventilated - sedated with GCS <8 & no blink reflex for >24h - APACHE II: 16-21 - Diagnosis: mainly HI - No facial trauma/ corneal abnormalities	<u>One eye</u> 1) (n=14) Geliperm - change regularly OR 2) (n=14) CorneaCare taping	<u>Contralateral eye of same patient</u> (n=28) Standard care QD lid cleansing (NS + sterile gauze) + ocular ointments ≥ BD	1) Incidence of superficial keratopathy (punctuated/ macroepithelial defects)	Fluorescein stain + cobalt blue filtered light [2]	Started from enrollment, reassessed daily [2] until the return of blink reflex. Ranging from 2-8 days.	<u>1) Incidence of superficial keratopathy</u> Overall incidence: 23% [3] (all unilateral). Incidences in the CorneaCare group (0%) and Standard Care group (14%) were insignificantly different (p=0.18). [Cal 95% CI 1.1% to 26.9%] Incidences in the Geliperm group (7%) and Standard Care group (14%) were insignificantly different (p=0.52). [Cal 95% CI -11.5% to 25.5%] Incidences in the eye cover groups (3.6%) and Standard Care group (14%) were insignificantly different (p=0.18). [Cal 95% CI -4% to 25.4%]
Main result(s) & special remarks	1. Incidence of the superficial keratopathy with standard care: 14%; lower incidence with eye covers: 0-7% → insignificant differences between groups maybe related to the small sample size, background demographics/ confounders, poor nursing compliance/ performance bias, insensitive penlight assessment, or unqualified data collector (Type II error). 2. Calculated 95% CI for CorneaCare versus Standard care: 1.1% to 26.9% → a trend showing CorneaCare reduced the incidence of keratopathy. 3. Eye covers: No periobital skin irritation or damage, or bacterial conjunctivitis, even though frequent pupil assessment. [1] excluded 3 patients (2 have superficial keratopathies at initial examination, 1 died within 48h of enrollment) [2] assessed by unknown data collector (with observer blinded: temporary removal of eye covers before assessment) [3] wrong calculation: should be 5/28 (17.8%) [4] incomplete lid closure (assessed by hand-held torch): best indicator of keratopathy (p=0.01), all keratopathies occurr with incomplete lid closure→ a possible confounder if it was significantly different between groups									

TABLE OF CRITICAL APPRAISAL 6 (CASP appraisal tool for RCT)

1. Clearly-focused question	Yes	
2. Appropriate to carry out a RCT	Yes	
3. Appropriate allocation to intervention and control groups	Can't tell (?unbiased /true R)	• Randomized left and right eyes after affirming patients' eligibility • No detailed R/ allocation methods/ R schedule were mentioned; Inadequate allocation concealment (sealed envelopes) • Standard care and eye covers on contralateral eyes of same patients: no separate control group • Unknown equalization effect of R: No comparison on the possible confounders e.g. demographics, diagnosis, LOS, sedation score etc. → can't tell if R was successful, confounders may annoy the results
4. Blinding (performance/ observer bias)	Yes (observer) (0.5)	• Nurse (impossible to blind)→no nursing compliance/ intervention check (possible performance bias) • Reported observer blinding
5. All participants were accounted for conclusion	No (acceptable & omit)	• Excluded 3 subjects due to preexisting keratopathies or death within 48 hours (included 28 patients in analysis) o acceptable to exclude ineligible cases o randomized after exclusion of ineligible cases, having no ITT is reasonable
6. Participants were followed up and data collected in the same way	Can't tell	• Unclear protocol was presented: o no application rule/changing frequency/compliance for the use of Geliperm/ CorneaCare o Standard care: have not specified the kind of eye ointment and dosage, not measured the actual frequency of eye ointment application (compliance) • No nurse training on eye care, no intervention/compliance checks: possible performance bias, or wrong interventions to contralateral eyes • Data collection: performed in same time interval, and assessed by unknown data collectors • Different pupil assessment frequency
7. Sufficient sample size	No	• Appropriate sample size calculation o Power of 0.75: inadequate sample size for the power of 0.8 o Should it be 26 patients per group? (if yes, it is a seriously inadequate sample)
8. Presentation of main result(s)	Poor	• Used mean/median for continuous variables; appropriate Fisher's exact test for the incidence of keratopathy (Has Fisher's exact test been used for incomplete lid closure?) • Lack of useful table; no percentage was used for categorical variables; no risk indexes • Wrongly calculated the overall incidence: have counted the 3 excluded patients into data analysis (should be 5/28) • Have not mentioned the possible confounders e.g. demographics, APACHE II score in groups
9. Precision of result(s)	Poor	• Provided only p-value, with no 95% CI → wide calculated 95% CI → insignificant result maybe due to inadequate sample size, sampling bias, unchecked intervention compliance, confounders, unknown data collector, or insensitive lamp (Type II error) • Tool: objective and appropriate, valid (penlight is less sensitive than slit lamp), no sensitivity/ specificity was reported • Unknown data collector: query on the measurement bias/ qualification; no confounding control; appropriate significance testings
10. Applicability of results	Yes	
% of criteria fulfilled	38.9% (3.5/9)	

TABLE OF EVIDENCE 7 (RCT)

Bibliographic citation	Study type	Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Outcome measures	Tool	Length of follow up	Effect size [3]
Sivasankar, S., Jasper, S., Simon, S., Jacob, P., John, G. & Raju, R. (2006)	RCT	1-	146 [1] in a medical ICU of a large teaching hospital in South India	- Sedated/ semiconscious: GCS≤10 - ICU LOS >24h - Mean Age: 39.2-42.3 - Chemosis: 26-28% grade 1 - Incomplete lid closure: 30%, grade 0-3 OS exposure (no exposure to lower half OS exposure) (mainly grade 0) - No primary ocular diseases	n=63 Closed Chamber swimming goggles + sterile water soaked gauze q12h	n=61 Open Chamber ocular lubricants + securing tape	Exposure keratopathy (corneal epithelial breakdown): a) overall incidence & onset time b) intervention effectiveness c) severity	slit lamp +1% Fluorescein drops [2]	Started within 24h of admission, reassessed daily[2] until patient regained spontaneous eye opening, died, discharged, or developed corneal lesions.	a) Overall incidence of corneal breakdown: 21%, with 80- 95% developed ≤48h. b) Closed Chamber significantly (p=0.001) reduced the incidence of corneal breakdown to 8%, compared with 32% in the Open Chamber group. c) Degree of keratopathy was more severe in Open Chamber group (grade 0-4: 1 require tarsorrhaphy) than Closed Chamber group (grade 0-2)[4].
Main result(s) & special remarks	1. Incidence of exposure keratopathy with eye care: 8-32%. 2. Closed chamber method significantly reduced the incidence & severity of exposure keratopathy, & reduced keratitis from 100% to 27.5% for those with incomplete lid closure (p=0.001). 3. Complications: Open chamber group: 12% lid & conjunctival abrasions; Closed chamber group: 6.5% lid edema. [1] excluded 22 subjects in analysis because: age<18, ICU LOS< 24h, and the presence of primary ocular diseases [2] assessed by ophthalmologist [3] incomplete lid closure (p=0.001) & muscle relaxants (p=0.025) are significant predictive factors for developing e: pathy→ possible confounders if they were significantly different between groups [4] no significance testing									

TABLE OF CRITICAL APPRAISAL 7 (CASP appraisal tool for RCT)

1. Clearly-focused question	Yes	
2. Appropriate to carry out a RCT	Yes	
3. Appropriate allocation to intervention and control groups	Can't tell (?unbiased/ true R)	• Randomized all admitted patients with GCS ≤10→ have no details about R/ allocation methods • Have not reported the equalization effect of R: no comparisons on the measured possible confounders between groups e.g. age, demographics, LOS, intraocular pressure, or papillary reaction a. If there are differences between groups in the use of muscle relaxants or incomplete lid closure (significant factor for keratopathy)→ may affect the outcome
4. Blinding (performance/ observer bias)	No (impossible)	• nurse (impossible to blind): no intervention check/ nursing compliance measure → possible performance bias • observer (ophthalmologist) (impossible to blind): obvious intervention (easy to differentiate the Closed Chamber group even if nurses remove the goggles before data collection), however, objective assessment tool reduces possible observer bias
5. All participants were accounted for conclusion	No	• Randomized 146 patients on admission, then excluded 22 in analysis (due to: age<18,<24h in ICU, initial eye disease): reasonable to exclude ineligible cases with no ITT • The exclusion made the equalization effect of R and the groups comparability doubtful
6. Participants were followed up and data collected in the same way	Can't tell	• Unclear protocol: not provided the type/dosage of eye ointment, type of taping/ application rule, frequency of changing eye covers (possible performance bias) • No intervention checks/ nursing compliance/ skill training on eye care to nurses • Not mentioned different pupil assessment frequency • Data collector (Ophthalmologist) is appropriate; Performed reassessment at same time interval
7. Sufficient sample size	Can't tell	No sample size calculation has been mentioned
8. Presentation of main result(s)	Fair	• Not systematic, difficult to understand • Used percentages for categorical variables, and mean for continuous data (no SD); No risk indexes • Tables: have not specified statistical tests/ p-values, no duplication of text • Appropriate Chi square test (Fisher's exact test is more preferable); but have not provided all p-values e.g. severity of OSDs, chemosis • Not discussed about measured confounders, severity of keratopathy, or OS exposure • Not showed the number of excluded patients for each reason/analysis • Wrong calculation of chemosis rate in Open Chamber group: 22% (should be 26%) → still insignificantly different between groups
9. Precision of result(s)	Fair 0.5	• Provided only p-value , with no 95% CI → calculated 95% CI for the incidence of exposure keratopathy: 14.7% to 33.3% (clinically significant) • Tool: objective and appropriate, valid (slit lamp is more sensitive than penlight), no sensitivity/ specificity was mentioned → minimize measurement bias of assessors • Data collector with appropriate qualification; Appropriate statistical test; No confounding control
10. Applicability of results	Can't tell (doubtful)	• inadequate information about the sample; lack of confounders contro ity study • in view of the appearance and the induced complications of the gogg umber, it may not be applicable in the target ICU, or may be distressing to the relatives or nurse managers
% of criteria fulfilled	25% (2.5/10)	

TABLE OF EVIDENCE 8 (RCT)

Bibliographic citation	Study type	Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Outcome measures	Tool	Length of follow up	Effect size
So, H.M., Lee, C.C.H., Leung, A.K.H., Lim, J.M.J.A., Chan, C.S.C., & Yan, W.W. (2008)	RCT	1+	120[1] in a 16-bed general ICU of a large teaching hospital in HK (Pamela Youde Nethersole Eastern Hospital)	- Mean Age (>18): 59-62 [2] - Gender: 59%-65% male [2] - Mean ICU LOS (days): 11.7-16.8[2] - Septic shock: 45%-56% [2, 3] - Comatose/ sedated with impaired/ no blink reflex • mean APACHE II: 26-27[2] • median GCS: 3 [2] • mean days of sedation: 3.6-4.3[2] • muscle relaxants use: 6.8-7% [2,3] - Mechanical ventilated for >24h with mean PEEP of 8.6-9.3 [2] , peak airway pressure of 28.5-28.8 [2] - Median pupil exam/day: 21[2,3] - Chemosis: 49-65% [2,3] - Incomplete eye closure: 15.3-17.5%[2,3] - No previous eye surgery, preexisting eye trauma, corneal abrasions, or eye infection, or not receiving eye medication	n=59 Polyethylene covers (Gladwrap) - apply from eyebrow to cheekbone - Adhesive tape to secure edges - change daily/ when soiled + Standard NS cleansing to eyelids & surrounding skin q4h	n=57 Duratears - q4h 1-cm - apply to "V" pocket between eyeball & lower lid + Standard NS cleansing to eyelids & surrounding skin q4h	Corneal abrasions a) incidence b) severity c) onset time	Fluorescein stain FLUOSTRIP + blue penlight [4]	Reassessed QD for 1 week, then weekly [4] until patients regained blinking reflex, developed positive fluorescein stain or eye infection, or died. Mean days of study: 6.1-6.88 [2]	a) Incidences of corneal abrasions in polyethylene group (6.8%) and Duratears group (5.3%) were insignificantly different (p=0.519). [Cal 95% CI: -7.2% to 10.2%] b) Severity: 42.9% superficial epithelial cells loss, with 1 eye infection in Duratears group c) Early onset time: 26-146h[2]
Main result(s) & special remarks	1. Eye care protocol produced low incidence and severity of corneal abrasions: 5.3%-6.8% (epithelial loss), with onset time of 26-146h. 2. Incidences of corneal abrasions were insignificantly different between 2 groups (wide calculated 95% CI): suggested inadequate sample size to support the equivalent effectiveness of 2 interventions. However, it is not economically beneficial to detect a statistical significance (requires 2375 patients and huge resources). 3. Conclusion: polyethylene cover is preferred over Duratears ointment because: i、 Cost-effective (200 feet of polyethylene film: HK$15; 1 tube of Duratears: HK$20), easy & earlier application, convenience, & non-involvement of prescription. ii、 Suggested possible protective barrier for eye infection during OP suctioning. [1] excluded 4 patients in analysis because they died ≤24h after commencement of the study [2] no significant difference between the intervention and comparison groups [3] insignificant predisposing factors for corneal abrasions (maybe due to small sample size or low incidence of corneal al [4] assessed by eye care team (ICU doctors & nurses) who were trained by ophthalmologist & nurse specialist; Reconfirm asion with ICU doctor before consulting ophthalmologist									

TABLE OF CRITICAL APPRAISAL 8 (CASP appraisal tool for RCT)

1. Clearly-focused question	Yes	
2. Appropriate to carry out a RCT	Yes	
3. Appropriate allocation to intervention and control groups	Can't tell 0.5	• Randomized patients after affirming their eligibility • True R: computerized with R schedule provided (i.e. computer program which consisted of 20 blocks of 6 randomized combinations of polyethylene cover or Duratears) • Inadequate allocation concealment: sealed envelopes • Equalization effect of R (after exclusion of ineligible cases): showed no significant difference between 2 groups in demographics and possible confounders (less possible selection bias), especially pupil assessment, ventilator settings, and septic shock→ adequate measures of possible confounders
4. Blinding (performance/ observer bias)	No	• Nurses (impossible to blind): no intervention check for nursing compliance → possible performance bias • Data collector (eye care team) (possible to blind): objective assessment tool minimizes possible observer bias or variable interrater reliability
5. All participants were accounted for conclusion	No(acceptable & omit)	• Excluded 4 cases (3.3%) in analysis due to deaths within 24h, no ITT o equalization effect of R has not been altered in the analysis of the remaining 116 participants
6. Participants were followed up and data collected in the same way	Can't tell 0.5	• Clear protocol (although no specified type of taping, or not measured changing frequency of polyethylene) • Pupil assessment frequency was measured: it is insignificantly different between groups & has insignificant effect on corneal abrasions (maybe due to low incidence rate) • Date collection: same time interval; different trained data collectors (have not mentioned interrater reliability) • No intervention/ performance checks or skill training on eye care for nurses→ possible performance bias
7. Sufficient sample size	Yes	Appropriate approach for sample size calculation: 49 per group
8. Presentation of main result(s)	Satisfactory	• Used mean (SD)/median (IQR) for continuous variables; frequency/ percentage for categorical variables • Appropriate statistical testings (not specified each testing in tables); Effective table use with no duplication of tables and texts, consistent • Comparisons only illustrated that the 2 interventions produced similar incidences of corneal abrasions, rather than showing their effectiveness in preventing corneal damage. However, it is acceptable to use the existing studies to show that the rate of corneal abrasions is much higher when no eye care has been done.
9. Precision of result(s)	Fair	• Provided only p-values, with no 95% CI →Calculated 95% CI: -7.2% to 10.2% wide → inadequate sample size to support the insignificant result • Tool: objective, appropriate physiobiological measure (penlight is less sensitive than slit lamp), no sensitivity/ specificity was mentioned • Data collector (trained eye care team): appropriate qualification, no interrater reliability has been assured • Confounding control: yes (thorough) • May be a Type II error for insignificant results related to e.g. unc ention compliance, poor data quality
10. Applicability of results	Yes	A study in HK
% of criteria fulfilled	66.6% (6/9)	

TABLE OF EVIDENCE 9 (Pilot controlled trial)

Bibliographic citation	Study type	Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Outcome measures	Tool	Length of follow up	Effect size
Laight, S.E. (1996)	Pilot controlled trial	2-	6 in a 3-bed general ICU of a National Health Service Trust Hospital in UK	- Age: 64-75 - Gender: 83% female - Mechanical ventilated for 2-7 days: SIMV mode + PEEP - Unconscious: paralysed to rousable with movement/ suction - Dry eyes[1]: all patients (0-60% of normal tears production)	<u>One eye (n=6)</u> **Geliperm protocol** **1) Ax lid cleanliness q2h:** **(a)** clean→ Geliperm (cover whole eye) **(b)** unclean→ wash hands →sterile water soaked gauze cleansing **2) Ax Geliperm q2h** → change if dry up **3) Ax signs of infection q2h** (redness, discharge)→ swab culture, inform doctor → remove patient from trial	<u>Contralateral eye of same patient (n=6)</u> **Standard eyecare** **1) 3M transpore taping** (splint method) **2) hypromellose:** wash hands, re-Ax q2h **3) q2h Ax cornea dryness** **(a)** dry (dull, no sparkle) → hypromellose (to lower lid)→ re-Ax q1h → (i) dry: inform doctor for prescribing Lacrilube, retaping, paraffin gauze dressing (ii) moist: repeat (2) **(b)** moist: hypromellose→ re-Ax q4h → (i) moist: hypromellose, re-Ax q6h (ii) dry: repeat (2) **4) Ax eye closure q2h** **(a)** open: inform doctor for prescription **(b)** closed: repeat (2&3) **5) Ax lid cleanliness q2h** **(a)** clean: repeat (2&3) **(b)** unclean: sterile water soaked gauze cleansing **6) Ax signs of infection q2h**→ swab culture, inform doctor	Eye surface abrasion	Rose Bengal staining test [2] + photography [3]	Started from admission, monitored q2h, and a total of 24h.	No significant difference (p=0.05) in the incidences of eye surface abrasion between Geliperm group (1/6) and standard eye care groups (2/6)[4]. [Mann-Whitney U test] [5]
Main result(s) & special remarks	1. All subjects have dry eyes →at risk of OSDs → need eye care. 2. Cost per patient: Lid cleansing: EUR0.27-3.24; hypromellose EUR 0-2.24; Geliperm EUR 4.3-8.6 (Standard care is more cost-effective). [1] Schirmer test (sensitivity 82.4%): trained under the direction of optician on volunteer subjects [2] sensitivity 95.2% [3] trained by medical photographer on ICU patients, performed by researcher, under academic & professional supervis inical facilitator and management structure [4] have not presented the outcome measure, only photography was presented [5] inappropriate significant testing for paired subjects (for independent samples only) [not use Wilcoxon signed rank t due to small sample size]									

TABLE OF CRITICAL APPRAISAL 9 (CASP appraisal tool for RCT)

1. Clearly-focused question	Yes	
2. Appropriate to carry out a RCT	NA	Clinical trial is appropriate
3. Appropriate allocation to intervention and control groups	NA	• Not mentioned the method of allocation • Performed both Geliperm and standard care on the same patient (no separate control group) → possible selection bias on left/right eye → matched eyes are comparable groups in terms of demographics & confounders
4. Blinding (performance/ observer bias)	No	• Nurses (impossible to blind): intervention checks showed a poor nursing compliance to the eye care protocol (possible performance bias to old fashion) • Data collector (single researcher) (possible to blind): researcher is at risk of biasing his/ her intended result → objective assessment tool and academic/ professional supervision minimize the risk of observer bias • Numbered slides blind analysis (validated by associated researcher): achieved only 50% correlation
5. All participants were accounted for conclusion	Yes	Intervention checks minimize the risk of possible confusion in giving interventions to the contralateral eyes
6. Participants were followed up and data collected in the same way	Can't tell	• No briefing/ training to nurses on the protocol • Poor nurse compliance (due to possible performance bias to old fashion/ demanding ICU work) to (1) lid cleansing: 1-12 times/day (2) hypromellose protocol • Clear Geliperm application rule: actual frequency of Geliperm change: 2-4/day (appropriate as manufacturer recommended) • Unclear protocol: e.g. splint method, hypromellose dosage, changing frequency of 3M taping, tools for assessing lid closure • Not mentioned frequency of pupil assessment • Data collection: single researcher (under supervision): same follow up period; Variable application & rinsing of Rose Bengal staining test; Schirmer test used under unusual conditions, technical variations in photography
7. Sufficient sample size	NA (omit)	No sample size calculation, acceptable for pilot study
8. Presentation of main result(s)	Poor	• No clear data for the incidence of OSDs (Rose staining), no interpretation on incidence/severity, no effect size • Mentioned about chemosis but not presented the result • Mann-Whitney U test (for 2 independent samples) is inappropriate for paired subjects (used because sample size is too small to apply Wilcoxon signed rank test)
9. Precision of result(s)	Poor	• Provided only p-value, with no effect size/ 95% CI, unable to evaluate the precision of insignificant result; 24-hour follow-up is too short for the development of OSDs→ would underestimate the incidence • Tool: objective, reliable in ophthalmology field; Sensitivity: Schirmer 82.4%; Rose staining 95.2% o Schimer test: Varied eye opening, variable application and rinsing, technical photography variation o Data collector: although trained by optician & medical photographer→ variable application of Rose staining test & variable photography quality for each patient (possible bias to intended result) • Insignificant result might be a Type II error → related to short follow-u ll sample size, inappropriate significance testing, observer/performance bias, poor nurse compliance, or poor data quality
10. Applicability of results	Can't tell	Great risk of type II error, insufficient details of study result/ patient's chara diagnosis, possible confounders for OSDs
% of criteria fulfilled	28.6% (2/7)	

TABLE OF EVIDENCE 10 (Controlled trial)

Bibliographic citation	Study type	Evidence level	Number of patients	Patient characteristics [1]	Interventions	Comparison	Outcome measures	Tool[2]	Length of follow up	Effect size
Ezra, D.G., Lewis, G., Healy, M., & Coombes, A. (2005)	Controlled trial	2-	47 in a ICU of Royal London Hospital in UK	- ICU LOS ≥ 3 days - No primary orbital injury	(1) Lacrilube (n=13) (2) Geliperm (n=10)	(3) Simple eye toilet (n=24)	1. Incidence of OSDs (exposure keratopathy) 2. Severity of OSDs (grade 0-6)	fluorescein + cobalt blue light + indirect ophthalmoscope	Assessed weekly[2] until patients developed OSDs.	<u>1. Incidence of exposure keratopathy</u> - overall incidence: 51%. Lacrilube significantly reduced the incidence to 15.4%, compared with 54.2% in the simple eye toilet group (p=0.04), or 90% in Geliperm group (p=0.001). <u>2. OSD Severity [3] (Lacrilube vs Geliperm vs simple eye toilet)</u> **Grade 0** 84% vs 10% vs 46% **Grade 1** 0% vs 10% vs 16.7% **Grade 2** 7.7% vs 40% vs 25% **Grade 3** 7.7% vs 40% vs 12.5%
Main result(s) & special remarks	1. Lacrilube reduced both incidence (p=0.04) and severity (no significance testing) of OSDs over simple eye toilet or Geliperm cover. 2. Geliperm covers provided higher incidence (p=0.001) and severity (especially grade 2-3) (no significance testing) of OSDs than Lacrilube. 3. Conclusion: Lacrilube is a better prophylactic measure for preventing OSDs than basic eye care or Geliperm (OSDs predispose eye infection). [1] sedation score(p=0.45), ICU LOS(p=0.09), degree of chemosis(0.056), or palpebral aperture (p=0.41) were not si[illegible]fferent between groups [2] performed assessments in ophthalmology ward rounds [3] no significance testing between groups									

TABLE OF CRITICAL APPRAISAL 10 (CASP appraisal tool for RCT)

1. Clearly-focused question	Yes	
2. Appropriate to carry out a RCT	NA	Clinical trial is appropriate
3. Appropriate allocation to intervention and control groups	NA	• Allocated by case nurses • Presented possible confounders: sedation score (p=0.45), LOS (p=0.09), degree of chemosis (p=0.056), and palpebral aperture diameter(p=0.41): insignificantly different between groups • Not presented patients' demographics e.g. age, gender, medical history; inadequate confounders control e.g. LOS, ventilator settings →possible selection bias, compromise generalizability
4. Blinding (performance/ observer bias)	No	• Nurses (impossible to blind): no intervention/nursing compliance check:possible performance bias • Data collector (possible to blind): objective assessment tool reduces possible observer bias
5. All participants were accounted for conclusion	Yes	
6. Participants were followed up and data collected in the same way	Can't tell	• No training on eye care/ intervention check for nurses (possible performance bias) • Unclear protocol: no details about each intervention→ e.g. solution/frequency for eye toilet, frequency/ dosage of Lacrilube, taping rule/ changing frequency of Geliperm → possible performance bias • Not mentioned pupil assessment frequency • Same assessment time interval (not presented range of follow-up period) • Assessed OSDs in ophthalmology ward round: have not specified the assessor, might be the ophthalmologist, single or multiple observer (if multiple, have not mentioned about interrater reliability) → possible observer bias
7. Sufficient sample size	Can't tell	No sample size calculation was mentioned
8. Presentation of main result(s)	Fair	• Too simplified presentations, no much details; Lack of tables: no duplication in text • Used frequency and percentages for categorical variable, incidence/severity of OSDs; Not used mean (SD)/median (IQR) for continuous variables e.g. measured possible confounders (only provided p-values); No risk indexes • Appropriate significant testing; but no significance testing for some possible confounders/ demographics/ severity of OSDs
9. Precision of result(s)	Fair 0.5	• Provided only p-values, with no 95% CI→ Calculated 95% CI (acceptable clinical significance): o Lacrilube vs simple eye toilet: 10.8% to 66.8%; Lacrilube vs Geliperm: 47.6% to 102% • Data collection: have not specified data collector (unknown qualifications)→not assured inter-rater reliability; follow-up weekly was too long (may underestimate incidence/severity) • Tool (ophthalmoscope): objective, valid, and appropriate, not provided sensitivity/specificity • confounding control: partly
10. Applicability of results	Can't tell	acceptable intervention & clinical significa nformation about study population; doubtful about possible confounding effect/perform g follow-up period
% of criteria fulfilled	43.8% (3.5/8)	

TABLE OF EVIDENCE 11 (Uncontrolled trial)

Bibliographic citation	Study type	Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Outcome measures	Tool[3]	Length of follow up	Effect size
Suresh, P., Mercieca, E., Morton, A., & Tullo , A.B. (2000).	Un-controlled trial	2-	34[1] in a 10-bed ICU of Manchester Royal Infirmary in UK	- Age:21-78 - male53% - Intubated 97% -NG feeding87% - Diagnosis: mainly Resp, ICH, post-op -Chemosis[2,4]: 60% - Unconscious/ anesthetized to moderate sedated - muscle relaxant use: 47% - no spontaneous eye opening -no facial/eye injury, no RTA victim with poor prognosis	<u>Eye care management algorithm (n=30[1]):</u> - Ax lid closure q8h → **(1)lids closed (n=18):** no treatment **(2) conjunctiva exposed (n=6):** eye lubricants q4h **(3) cornea exposed (n=4)** or **(4) prone ventilated (n=2):** horizontal Micropore taping + q4h eye lubricants	<u>Routine care (n=26)</u> *Historical control of a previous study in the same ICU (Mercieca, Suresh, Morton & Tullo, 1999)* - lid cleansing by NS/ sterile water soaked gauze q2-6h	1. Corneal/ conjunctival abrasions: incidences & onset 2. OSDs severity	1) Hand-held torch (Ax lid position) 2) 1% fluorescein drops + slit lamp (Ax OSDs)	Started ≤5 days of admission, reassessed twice per week[3] until patients recovered from weaning sedation, or regained spontaneous eye opening. Ranging from 3- 28 days (mean 7.8).	1) Eyecare algorithm reduced the incidence of corneal or conjunctival abrasions to 8.7%[5], compared with 42% in routine care[4], with an early onset time of 24h-1week. 2) Eyecare algorithm reduced the severity of corneal or conjunctival abrasions, in which all cases were grade 1. Whereas in routine care, OSDs ranged from grade 1 (63.6%) to grade 4 (27.3%)[4].
Main result(s) & special remarks	1. Incidence of OSDs with eye care algorithm 8.7%; routine eye care 42%. 2. Conclusion: Regular Ax of lid position and eye care algorithm are effective in reducing the incidence and severity of corneal abrasions in a population with prevalent chemosis (especially those in prone ventilation). 3. Suggestions: (1) Add a protective barrier between micropore and skin if skin irritation. (2) Temporary suturing (infeasible for pupil assessment) if taping is inadequate to maintain lid closure, or in severe chemosis. (3) Use eye lubricants only for those with occasional blinks. (4) Ophthalmologist consultation for suspected eye infection. [1] excluded 4 subjects because of incorrect eye care protocol implementation, and excluded 7 in analysis (three in group [illegible]s 2&3) due to wrong eyelid Ax & inappropriate eye care interventions (found in intervention checks)→all excluded cases developed OSDs [2] higher incidence of chemosis is related to higher degree of OS exposure: found 100% chemosis in prone ventilation [3] assessed by unknown single observer [4] no significance testing on the incidence/severity of OSDs [5] 1 case (had received high flow oxygen in High Dependency Unit the day before ICU admission) developed OSD ≤ 24 [illegible]admission→ Actual prevalence would be<8.7%									

TABLE OF CRITICAL APPRAISAL 11 (CASP appraisal tool for RCT)

1. Clearly-focused question	Yes	
2. Appropriate to carry out a RCT	NA	Clinical trial is appropriate
3. Appropriate allocation to intervention and control groups	NA	• Allocation: by nurses according to the completeness of eyelid closure • Presented demographics/ possible confounders: not evaluated their effects on OSDs→ possible selection bias, compromise generalizability
4. Blinding (performance/ observer bias)	No 0.5	• Nurses (impossible to blind): available intervention check to ensure nursing compliance and exclude cases in analysis • Data collector (single observer) (possible to blind): objective assessment tool minimizes possible observer bias
5. All participants were accounted for conclusion	No	• Excluded 4 subjects initially due to incorrect intervention delivery; excluded 7 subjects further in analysis due to poor nursing compliance/ wrong interventions (reasonable exclusion) → all excluded subjects developed OSDs → exclusion may underestimate incidence; No ITT; no change in group assignment for the excluded subjects
6. Participants were followed up and data collected in the same way	Can't tell	• No training on eye care to nurses (wrong intervention assignment did exist); Unclear protocol: not specified types/ dosage of eye lubricants • Available intervention checks (reduced performance bias) • Not mentioned pupil assessment frequency • Unknown data collector (unknown qualifications): possible observer bias • Not set time for first & subsequent follow-up for different patients: Assessing patients within 5 days of admission then twice per week would be too long→underestimated incidence
7. Sufficient sample size	Can't tell	Not mentioned sample size calculation
8. Presentation of main result(s)	Fair 0.5	• Clear; used mean (no SD) for continuous variable; used frequency/percentage for categorical variable • lack of tables use, no duplication in text; Not performed significant testing for incidence/ severity of OSDs
9. Precision of result(s)	Poor	• no p-value/ statistical testing: calculated 95% CI: 11.3% to 55.3% (acceptable clinical significance) • unknown single data collector: unknown qualification and possible observer bias • tool: torch assessment is objective, valid and appropriate; slit lamp is sensitive, objective, valid and appropriate tool. No sen[illegible]ficity was provided • confounding control: no significa[illegible]
10. Applicability of results	Can't tell	No significance testing of the results
% of criteria fulfilled	25% (2/8)	

TABLE OF EVIDENCE 12 (retrospective before and after study)

Bibliographic citation	Study type	Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Outcome measures[1]	Length of follow up[2]	Effect size [3]
Parkin, B., Turner, A., Moore, E. & Cook, S. (1997)	Before and after comparison study (Retro-spective)	2-	Total 9 Period 1: 5 Period 2: 4 In the ICUs in UK	- Critical condition: 66.7% survived - Prolong ventilation: ≥5-28 days -Diagnosis: mainly ARF, heart failure	**Eye care guidelines for unconscious patients** adopted in 1991 (Period2): 1) no eye infection: q2h eye care 2) regularly inspect lid swelling, conjunctival hyperaemia, corneal clouding, and epithelial loss 3) corneal exposure: q2h eye ointment 4) risk of corneal exposure: adhesive taping 5) tracheal suctioning: at the side of bed, cover eyes 6) ETA PAER: QD conjunctival swabs, urgent Gram stain if signs of eye infection 7) eye culture PAER: start Gentamicin, consult ophthalmic opinion	**Unstandardized care** (Period1) - some used Geliperm cover	1) overall incidence of OSDs (period 2) 2) overall incidence of eye infection (type, origin) (period 2) 3) Effectiveness of eye care guidelines for unconscious patients in reducing eye infection (comparing Period 1 & 2)	Period 1: 1988-1991 Period 2: 1991-1995	1) Overall incidence of OSDs: 22% corneal ulcers, 11% epithelial defect. 2) Overall incidence of eye infection: 83.3-100% (PAER, respiratory/ wound origin). 3) Revised eyecare guidelines significantly reduced the positive conjunctival PAER isolate rate from 0.8% to 0.05% ($p<0.001$), the proportion of patients who required conjunctival swabs from 3% to 0.97 % ($p<0.001$), and the PAER isolation rate from 26% to 5.1% ($p=0.015$).
General comments	1. Eye infection and OSDs were common. Eye infections were mainly PAER from respiratory (OP colonization)/ wound origin, leading to severe ocular consequences (visual impairment)→ 67% were corneal scar, 66.7% required penetrating keratoplasty for corneal perforation; all 6 surviving patients had impaired visual acuity. 2. Eye care guidelines significantly reduced the rate of PAER eye infection. [1] assessed by unknown assessor/tool [2] unknown length of follow-up for each patient, unknown criteria of study comp [3] Longer hospital LOS (period 2) significantly reduced the incidence of eye infection ($p=0.029$); whereas the backgro lation rate was insignificantly related to eye infection rate ($p=0.5$)								

TABLE OF CRITICAL APPRAISAL 12 (CASP appraisal tool for RCT)

1. Clearly-focused question	Yes	
2. Appropriate to carry out a RCT	NA	
3. Appropriate allocation to intervention and control groups	NA	• allocated patients by the time of enrollment; No comparisons on the demographics/diagnosis between groups→ preexisting difference/ potential confounders (e.g. suction technique/hand hygiene, lid closure, chemosis, organ failure) might affect the outcome
4. Blinding (performance/ observer bias)	No	• nurses (impossible to blind): possible performance bias/ poor compliance • assessor (possible to blind): unknown identity: possible observer bias
5. All participants were accounted for conclusion	Yes	
6. Participants were followed up and data collected in the same way	Can't tell	• No intervention check/ training on eye care/ nursing compliance monitoring: performance bias • Insufficient details about eye care guidelines: e.g. eye ointment type/dosage, type of eye taping, frequency/dosage of Gentamicin, frequency of inspecting lid swelling/OSDs, meaning of "risk of corneal exposure" (how to measure, with what tool), methods to cover eyes during suction • what the unstandardized care in Period 1 included • not mentioned pupil assessment frequency • unknown data collector for OSDs (unknown qualification); not specified length follow-up/ data collection time interval, unknown assessment tool for signs of OSDs and lid closure (was the measurement subjective/ objective?) • only eye swab/ETA culture were objective and valid measurements
7. Sufficient sample size	Can't tell	No sample size calculation was mentioned
8. Presentation of main result(s)	Poor 0.5	• Not systematic, poor and abstract; Unclear text, need repeated reading to understand • not presented/ analyzed demographics; no risk indexes • good use of tables: clear, no duplication with text • used percentage for categorical variable • appropriate significance testing: effect size and p-values are available
9. Precision of result(s)	Poor	• provided p-values, with no 95% CI→ very wide calculated 95% CI → might be related to the small sample size (poor clinical significance) o positive conjunctival PAER isolate rate: -8.2% to 9.7% o proportion of patients who required conjunctival swabs: -22.3 to 26.33% o PAER isolation rate: -36.7% to 78.9% • Statistical test: appropriate • Tool for assessing OSDs & assess[illegible] • Confounding control: very small [illegible]
10. Applicability of results	Can't tell	• Insufficient details of patients; In[illegible]ediatric/burn cases • Weak causality: doubtful applicat[illegible]
% of criteria fulfilled	31.3% (2.5/8)	

TABLE OF EVIDENCE 13 (Prospective observational cohort study)

Bibliographic citation	Study type	Evidence level	Number of patients	Patient characteristics	Interventions	Outcome measures	Tool[3]	Length of follow up	Effect size
Desalu, I., Akinsola, F., Adekola, O., Akinbami, O., Kushimo, O., & Adefule-Ositelu, A. (2008)	Prospective, observational cohort study	2-	56 in a ICU of a Nigerian teaching hospital in Sub-Saharan	- Unconscious - Mean age: 36.55 [1] -Gender: 75% Male[1] - Diagnosis: Mainly HI, post-op - Incomplete lid closure: 40%-51.6%[1] - Mean days of sedation: 1.8-4.06[2] - Mean days of ventilation: 1.62-4.55[2] - Mean days of muscle relaxants use: 1.8-2.91[1] - Mean days of ICU LOS: 5.4-7.26[1] - Organ failure: 44%-71%[2]	No definite eye care protocol: (1) Chloramphenicol drops/ ointment q2h (2) NS irrigation q2h (3) both (1) & (2)	1) Incidence of OSDs and onset time 2) Eyecare and OSDs	pen-torch+ ophthalmoscope + fluorescein staining	Not mentioned	<u>1) Incidence of OSDs:</u> 55.4% [77.4% conjunctival disorders; 6.5% corneal disorders; 16.1% both corneal & conjunctival disorders] → 67.5% developed ≤ 2days. <u>2) Eye care and OSDs</u> 67.8% patients have received eye care. 87.1% of patients who developed OSDs had received eye care, whereas only 44% in non-OSD group (significantly different) (p=0.001). [Cal 95% CI: 25.5% to 60.7%] 32.1% patients have received NS irrigation. 77.8% of patients who developed OSDs had received NS irrigation, compared with 22.2% in non-OSD group (significantly different) (p=0.02). [Cal 95% CI 6.3% to 51.7%] Application of Chloramphenicol drops/ ointment, or combination of chloramphenicol and NS irrigation were insignificantly related to incidence of OSDs (p=0.437; p=0.389).
Main result(s) & special remarks	1. High incidence of OSDs with unstandardized eye care: 55.4% (mainly conjunctival disorders), with an early onset time of less than 2 days. 2. Eye care was delivered to more patients in OSD group than non-OSD group, with mainly NS irrigation. The association of NS irrigation and higher incidence of OSDs make it difficult to identify the cause-effect relationship of eye care and OSDs. It might be af confounding effects (as OSDs are predisposed by the days of sedation and ventilation, and organ failures). A standardized evidenced-based guideline to reduce OSDs. [1]insignificant differences between OSD & non-OSD groups [2] significant differences between OSD & non-OSD grou by unknown assessor								

TABLE OF CRITICAL APPRAISAL 13 (CASP appraisal tool for cohort study)

1. Clearly-focused question	Yes	
2. Appropriate to carry out a cohort study	Yes	Clinical trial is more preferable
3. Cohort was recruited in an acceptable way	Can't tell	• Recruited all admitted unconscious patients • No significant difference between OSD and non-OSD groups in age and gender; no significant testing on diagnosis→ possible selection bias, affect generalizability
4. Exposure was accurately measured to minimize bias	Can't tell 0.5	• subjective assessment e.g. lid position: unknown assessor/ tool: unknown qualification/skill training, not mentioned about interrater reliability • Other information: from objective documentation review
5. Outcome was accurately measured to minimize bias	Can't tell	• Tool for OSD assessment: objective & valid (pen-torch is less sensitive than slit lamp), not mentioned sensitivity/ specificity • unknown assessor: not mentioned about interrater reliability, assessor blinding, or skill in performing fluorescein stain test
6. A) Authors identified all important confounding factors	No	e.g. ventilator setting, chemosis, manual blinking (pupil assessment), sedation score/ GCS
B) authors have taken account of confounding factors in design and analysis	Yes	Days of sedation/ ventilation and organ failure are significant confounders
7. A) Follow up of subjects was complete enough	Yes	Daily assessment is appropriate (unlikely to miss cases)
B) Follow up of subjects was long enough	Can't tell	Not mentioned length of follow-up or criteria for study completion
8. Main result(s) of study, presentation	Fair 0.5	• Presentation: used precentage, number, mean (SD), effect size, and p-values; no risk indexes • Weak causal relationship between eye care & OSDs (there are also a number of significant confounders affecting the OSD development) a. OSDs were predisposed by the days of sedation and ventilation, and organ failures (not affected by lid position, muscle relaxant, ICU LOS, temperature, or humidity)
9. Precision of result(s)	Fair	Provided only p-values, with no 95% CI → wide calculated 95% CI (acceptable clinical significance) • Eye care in OSD vs non-OSD groups: 25.5% to 60.7% • NS irrigation in OSD vs non-OSD groups: 6.3% to 51.7%
10. Believe the results	Can't tell	• Unknown assessor; No analysis on diagnosis; Not measured other possible confounders; Unclear follow-up period; Fair precision • Weak causal relationship between eye care and OSD incidence (could be related to the biological plausible confounders of OSDs) • More eye care/ NS irrigation maybe the care of OSDs, rather than the cause of OSDs
11. Results can be applied to local population	Can't tell	• High humidity (around 90%) in Nig • Weak causal relationship between e)SDs
12. Results fit with other available evidence	Yes	Eye hygiene is less effective than eye dr in reducing incidence/ severity of OSDs
% of criteria fulfilled	50% (6/12)	

APPENDIX 5

APPENDIX 5A CASP APPRAISAL TOOL FOR SYSTEMATIC REVIEWS (Public Health Resources Unit, National Health Service, 2007)

Screening Questions

1. Did the review ask a clearly-focused question? □Yes □Can't tell □No

Consider if the question is 'focused' in terms of:
– the population studied
– the intervention given or exposure
– the outcomes considered

2. Did the review include the right type of study? □Yes □Can't tell □No

Consider if the included studies:
– address the review's question
– have an appropriate study design

Is it worth continuing?

Detailed Questions

3. Did the reviewers try to identify all relevant studies? □Yes □Can't tell □No

Consider:
– which bibliographic databases were used
– if there was follow-up from reference lists
– if there was personal contact with experts
– if the reviewers searched for unpublished studies
– if the reviewers searched for non-English-language studies

4. Did the reviewers assess the quality of the included studies? □Yes □Can't tell □No

Consider:
– if a clear, pre-determined strategy was used to determine which studies were included. Look for:
– a scoring system
– more than one assessor

5. If the results of the studies have been combined, was it reasonable to do so? □Yes □Can't tell □No

Consider whether:
– the results of each study are clearly displayed
– the results were similar from study to study (look for tests of heterogeneity)
– the reasons for any variations in results are discussed

6. How are the results presented and what is the main result?

Consider:
– how the results are expressed (e.g. odds ratio, relative risk, etc.)
– how large this size of result is and how meaningful it is
– how you would sum up the bottom-line result of the review in one sentence

7. How precise are these results?

Consider:
– if a confidence interval were reported. Would your decision about whether or not to use this intervention be the same at the upper confidence limit as at the lower confidence limit?
– if a p-value is reported where confidence intervals are unavailable

8. Can the results be applied to the local population? □Yes □Can't tell □No

Consider whether:
– the population sample covered by the review could be different from your population in ways that would produce different results
– your local setting differs much from that of the review
– you can provide the same intervention in your setting

9. Were all important outcomes considered? □Yes □Can't tell □No

Consider outcomes from the point of view of the:
– individual
– policy makers and professionals
– family/carers
– wider community

10. Should policy or practice change as a result of the evidence contained in this review? □Yes □Can't tell □No

Consider:
– whether any benefit reported outweighs any harm and/or cost. If this information is not reported can it be filled in from elsewhere?

APPENDIX 5B CASP APPRAISAL TOOL FOR

RCTs (Public Health Resources Unit, National Health Service, 2007)

Screening Questions

1. Did the study ask a clearly-focused question? □Yes □Can't tell □No

Consider if the question is 'focused' in terms of:
– the population studied
– the intervention given
– the outcomes considered

2. Was this a randomised controlled trial (RCT) and was it appropriately so? □Yes □Can't tell □No

Consider:
– why this study was carried out as an RCT
– if this was the right research approach for the question being asked

Is it worth continuing?

Detailed Questions

3. Were participants appropriately allocated to intervention and control groups? □Yes □Can't tell □No

Consider:
– how participants were allocated to intervention and control groups. Was the process truly random?
– whether the method of allocation was described. Was a method used to balance the randomization, e.g. stratification?
– how the randomization schedule was generated and how a participant was allocated to a study group
– if the groups were well balanced. Are any differences between the groups at entry to the trial reported?
– if there were differences reported that might have explained any outcome(s) (confounding)

4. Were participants, staff and study personnel 'blind' to participants' study group? □Yes □Can't tell □No

Consider:
– the fact that blinding is not always possible
– if every effort was made to achieve blinding
– if you think it matters in this study
– the fact that we are looking for 'observer bias'

5. Were all of the participants who entered the trial accounted for at its conclusion? □Yes □Can't tell □No

Consider:
– if any intervention-group participants got a control-group option or vice versa
– if all participants were followed up in each study group (was there loss-to-follow-up?)
– if all the participants' outcomes were analysed by the groups to which they were originally allocated (intention-to-treat analysis)
– what additional information would you liked to have seen to make you feel better about this

6. Were the participants in all groups followed up and data collected in the same way? □Yes □Can't tell □No

Consider:
– if, for example, they were reviewed at the same time intervals and if they received the same amount of attention from researchers and health workers. Any differences may introduce performance bias.

7. Did the study have enough participants to minimise the play of chance? □Yes □Can't tell □No

Consider:
– if there is a power calculation. This will estimate how many participants are needed to be reasonably sure of finding something important (if it really exists and for a given level of uncertainty about the final result).

8. How are the results presented and what is the main result?

Consider:
– if, for example, the results are presented as a proportion of people experiencing an outcome, such as risks, or as a measurement, such as mean or median differences, or as survival curves and hazards
– how large this size of result is and how meaningful it is
– how you would sum up the bottom-line result of the trial in one sentence

9. How precise are these results?

Consider:
– if the result is precise enough to make a decision
– if a confidence interval were reported. Would your decision about whether or not to use this intervention be the same at the upper confidence limit as at the lower confidence limit?
– if a p-value is reported where confidence intervals are unavailable

10. Were all important outcomes considered so the results can be applied? □Yes □Can't tell □No

Consider whether:
– the people included in the trail could be different from your population in ways that would produce different results
– your local setting differs much from that of the trial
– you can provide the same treatment in your setting

Consider outcomes from the point of view of the:
– individual
– policy maker and professionals
– family/carers
– wider community

Consider whether:
– any benefit reported outweighs any harm and/or cost. If this information is not reported can it be filled in from elsewhere?
– policy or practice should change as a result of the evidence contained in this trial

APPENDIX 5C CASP APPRAISAL TOOL FOR COHORT STUDIES (Public Health Resources Unit, National Health Service, 2007)

A/ Are the results of the study valid?

Screening Questions

1 Did the study address a clearly focused issue? □Yes □Can't tell □No

HINT: A question can be focused in terms of:
- the population studied
- the risk factors studied
- the outcomes considered
- is it clear whether the study tried to detect a beneficial or harmful effect?

2 Did the authors use an appropriate method to answer their question? □Yes □Can't tell □No

HINT: Consider
- Is a cohort study a good way of answering the question under the circumstances?
-Did it address the study question?

Is it worth continuing?

Detailed Questions

3 Was the cohort recruited in an acceptable way? □Yes □Can't tell □No

HINT: We are looking for selection bias which might compromise the generalisability of the findings:
- Was the cohort representative of a defined population?
- Was there something special about the cohort?
- Was everybody included who should have been included?

4. Was the exposure accurately measured to minimize bias? □Yes □Can't tell □No

HINT: We are looking for measurement or classification bias:
- Did they use subjective or objective measurements?
- Do the measures truly reflect what you want them to (have they been validated)?
- Were all the subjects classified into exposure groups using the same procedure?

5. Was the outcome accurately measured to minimize bias? □Yes □Can't tell □No

HINT: We are looking for measurement or classification bias:
- Did they use subjective or objective measurements?
- Do the measures truly reflect what you want them to (have they been validated)?
- Has a reliable system been established for detecting all the cases (for measuring disease occurrence)?
- Were the measurement methods similar in the different groups?
- Were the subjects and/or the outcome assessor blinded to exposure (does this matter)?

6. A. Have the authors identified all important confounding factors?
List the ones you think might be important, that the authors missed. □Yes □Can't tell □No

B. Have they taken account of the confounding factors in the design and/or analysis? □Yes □Can't tell □No
List:

HINT:
- Look for restriction in design, and techniques eg modelling, stratified-, regression-, or sensitivity analysis to correct, control or adjust for confounding factors

7. A. Was the follow up of subjects complete enough? □Yes □Can't tell □No
B. Was the follow up of subjects long enough? □Yes □Can't tell □No

HINT:
- The good or bad effects should have had long enough to reveal themselves
-The persons that are lost to follow-up may have different outcomes than those available for assessment
- In an open or dynamic cohort, was there anything special about the outcome of the people leaving, or the exposure of the people entering the cohort?

B/ What are the results?

8. What are the results of this study?

HINT:
- What are the bottom line results?
- Have they reported the rate or the proportion between the exposed/unexposed, the ratio/the rate difference?
- How strong is the association between exposure and outcome (RR,)?
- What is the absolute risk reduction (ARR)?

9. How precise are the results?
How precise is the estimate of the risk?

HINT:
- Size of the confidence intervals

10. Do you believe the results? □Yes □Can't tell □No

HINT:
- Big effect is hard to ignore!
- Can it be due to bias, chance or confounding?
- Are the design and methods of this study sufficiently flawed to make the results unreliable?
- Consider Bradford Hills criteria (eg time sequence, dose-response gradient, biological plausibility, consistency).

Is it worth continuing?

C/ Will the results help me locally?

11. Can the results be applied to the local population? □Yes □Can't tell □No

HINT: Consider whether
- The subjects covered in the study could be sufficiently different from your population to cause concern.
- Your local setting is likely to differ much from that of the study
- Can you quantify the local benefits and harms?

12. Do the results of this study fit with other available evidence? □Yes □Can't tell □No

One observational study rarely provides sufficiently robust evidence to recommend changes to clinical practice or within health policy decision making. However, for certain questions observational studies provide the only evidence. Recommendations from observational studies are always stronger when supported by other evidence.

APPENDIX 5D CASP APPRAISAL TOOL FOR CASE CONTROL STUDIES (Public Health Resources Unit, National Health Service, 2007)

A/ Are the results of the study valid?

Screening Questions

1. Did the study address a clearly focused issue? □Yes □Can't tell □No

A question can be focused in terms of:
- *– the population studied*
- *– the risk factors studied*
- *– whether the study tried to detect a beneficial or harmful effect?*

2. Did the authors use an appropriate method to answer their question? □Yes □Can't tell □No

Consider:
- *– is a case control study an appropriate way of answering the question under the circumstances? (is the outcome rare or harmful?)*
- *– did it address the study question?*

Is it worth continuing?

Detailed Questions

3. Were the cases recruited in an acceptable way? □Yes □Can't tell □No

HINT: We are looking for selection bias which might compromise the validity of the findings:
- *– Are the cases defined precisely?*
- *– Were the cases representative of a defined population (geographically and/or temporally)?*
- *– Was there an established reliable system for selecting all the cases?*
- *– Are they incident or prevalent?*
- *– Is there something special about the cases?*
- *– Is the time frame of the study relevant to the disease/exposure?*
- *– Was there a sufficient number of cases selected? Was there a power calculation?*

4. Were the controls selected in an acceptable way? □Yes □Can't tell □No

HINT: We are looking for selection bias which might compromise the generalisability of the findings:

- *– Were the controls representative of a defined population (geographically and/or temporally)?*
- *– Was there something special about the controls?*
- *– Was the non-response high? Could non-respondents be different in any way?*
- *– Are they matched, population based or randomly selected?*
- *– Was there a sufficient number of controls selected?*

5. Was the exposure accurately measured to minimise bias? □Yes □Can't tell □No

HINT: We are looking for measurement, recall or classification bias:

- *– Was the exposure clearly defined and accurately measured?*
- *– Did the authors use subjective or objective measurements?*
- *– Do the measures truly reflect what they are supposed to measure? (have they been validated?)*
- *– Were the measurement methods similar in cases and controls?*
- *– Did the study incorporate blinding where feasible?*
- *– Is the temporal relation correct? (does the exposure of interest precede the outcome?)*

6. A. What confounding factors have the authors accounted for?
List the other ones you think might be important, that the authors missed *(genetic, environmental and socio-economic)*

B. Have the authors taken account of the potential confounding factors in the design and/or in their analysis? □Yes □Can't tell □No

HINT: Look for restriction in design, and techniques, e.g. modeling, stratified-, regression-, or sensitivity analysis to correct, control or adjust for confounding factors.

B/ What are the results?

7. What are the results of this study?

Consider:

- *– What are the bottom line results?*
- *– Is the analysis appropriate to the design?*
- *– How strong is the association between exposure and outcome (look at the odds ratio)?*
- *– Are the results adjusted for confounding and might confounding still explain the association?*
- *– Has adjustment made a big difference to the OR ??*

8. How precise are the results?
How precise is the estimate of risk?

Consider:

- *– Size of the P-value*
- *– Size of the confidence intervals*
- *– Have the authors considered all the important variables?*
- *– How was the effect of subjects refusing to participate evaluated?*

9. Do you believe the results? □Yes □No

Consider:

- *– Big effect is hard to ignore!*
- *– Can it be due to chance, bias or confounding?*
- *– Are the design and methods of this study sufficiently flawed to make the results unreliable?*
- *– Consider Bradford Hills criteria (e.g. time sequence, dose-response gradient, strength, biological plausibility)*

Is it worth continuing?

C/ Will the results help me locally?

10. Can the results be applied to the local population? □Yes □Can't tell □No

Consider whether:

- *– The subjects covered in the study could be sufficiently different from your population to cause concern.*
- *– Your local setting is likely to differ much from that of the study.*
- *– Can you estimate the local benefits and harms?*

11. Do the results of this study fit with other available evidence? □Yes □Can't tell □No

HINT: Consider all the available evidence from RCTs, systematic reviews, cohort studies and case-control studies as well for consistency.

One observational study rarely provides sufficiently robust evidence to recommend changes to clinical practice or within health policy decision making.
However, for certain questions observational studies provide the only evidence.
Recommendations from observational studies are always stronger when supported by other evidence.

APPENDIX 6

APPENDIX 6A METHODOLOGICAL QUALITY CODING SYSTEM (Scottish Intercollegiate Guidelines Network, 2008)

++	**All or most** of the criteria have been fulfilled. Where they have not been fulfilled the conclusions of the study or review are thought very unlikely to alter.
+	**Some** of the criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are thought unlikely to alter the conclusions.
-	**Few or no** criteria fulfilled. The conclusions of the study are thought likely or very likely to alter.

APPENDIX 6B LEVEL OF EVIDENCE (Scottish Intercollegiate Guidelines Network, 2008)

1++	High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+	Well conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias
1-	Meta-analyses, systematic reviews, or RCTs with a high risk of bias
2++	High quality systematic reviews of case control or cohort studies High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
2+	Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
2-	Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
3	Non-analytic studies e.g. case reports, case series
4	Expert opinion

APPENDIX 7 SUMMARY OF LEVELS OF EVIDENCE

Bibliographic citation	Study type	Level of evidence	% of criteria fulfilled
Marshall et al., 2008	Clinical guideline	1-	45%
Joyce, 2002	Systematic review	1++	75%
Cortese et al., 1995	RCT	1+	50%
Lenart & Garrity, 2000		1-	35%
Koroloff et al., 2004		1+	70%
Bates et al., 2004		1-	38.9%
Sivasankar et al., 2006		1-	25%
So et al., 2008		1+	66.6%
Laight, 1996	Controlled trial	2-	28.6%
Ezra et al., 2005		2-	43.8%
Suresh et al., 2000	Uncontrolled trial	2-	25%
Desalu et al., 2008	Cohort observational study (prospective)	2-	50%
Parkin et al., 1997	Before and after interventional study (retrospective)	2-	31.3%

APPENDIX 8 SUMMARY OF QUALITY ASSESSMENT

APPENDIX 8A CLINICAL GUIDELINES & SYSTEMATIC REVIEW (CASP appraisal tool for systematic review)

	Marshall et al., 2008	Joyce, 2002
1. Clearly-focused question	Yes	Yes
2. Include right type of studies	Yes	Yes
3. Try to identify all relevant studies	No	No 0.5
4.Assess quality of included studies	Yes 0.5	Yes
5.Reasonable combination of the results of studies	Can't tell	Yes
6. Presentation of main result(s)	Satisfactory	Fair
7. Precision of result(s)	Poor	Poor
8. Applicable to local population	Yes	Yes
9. Consider all important outcomes	Can't tell	Yes
10. Policy or practice should change as a result of the evidence of this review	Can't tell	Can't tell
Level of evidence (% of criteria fulfilled)	1- (45%)	1++ (75%)

APPENDIX 8B RCTs (CASP appraisal tool for RCTs)

	Cortese et al., 1995	Lenart & Garrity, 2000	Koroloff et al., 2004	Bates et al., 2004	Sivasankar et al., 2006	So et al., 2008
1. Clearly-focused question	Yes	Yes	Yes	Yes	Yes	Yes
2. Appropriate to carry out a RCT	Yes	Yes	Yes	Yes	Yes	Yes
3. Appropriate allocation to intervention and control groups	Can't tell 0.5	Can't tell	Can't tell 0.5	Can't tell	Can't tell	Can't tell 0.5
4. Blinding (performance/ observer bias)	No	No	No	Yes (observer blinded) 0.5	No (impossible)	No
5. All participants were accounted for conclusion	No (acceptable & omitted)	Can't tell 0.5	Yes	No (acceptable & omit)	No	No (acceptable & omit)
6. Participants were followed up and data collected in the same way	Can't tell	Can't tell	Can't tell 0.5	Can't tell	Can't tell	Can't tell 0.5
7. Sufficient sample size	Can't tell	Can't tell	Yes	No	Can't tell	Yes
8. Presentation of main result(s)	acceptable 0.5	Poor	Fair 0.5	Poor	Fair	Satisfactory
9. Precision of result(s)	Fair 0.5	Poor	Fair 0.5	Poor	Fair 0.5	Fair
10. Applicability of results	Yes	Yes	Yes	Yes	Can't tell (doubtful)	Yes
Level of evidence (% of criteria fulfilled)	1+ (50%)	1- (35%)	1+ (70%)	1- (38.9%)	1- (25%)	1+ (66.6%)

APPENDIX 8C CLINICAL TRIALS, BEFORE AND AFTER INTERVENTIONAL STUDY (CASP appraisal tool for RCTs)

	Laight, 1996	Ezra et al., 2005	Suresh et al., 2000	Parkin et al., 1997
1. Clearly-focused question	Yes	Yes	Yes	Yes
2. Appropriate to carry out a RCT	NA	NA	NA	NA
3. Appropriate allocation to intervention and control groups	NA	NA	NA	NA
4. Blinding (performance/ observer bias)	No	No	No	No
5. All participants were accounted for conclusion	Yes	Yes	No	Yes
6. Participants were followed up and data collected in the same way	Can't tell	Can't tell	Can't tell	Can't tell
7. Sufficient sample size	NA (omit)	Can't tell	Can't tell	Can't tell
8. Presentation of main result(s)	Poor	Fair	Fair	Poor
9. Precision of result(s)	Poor	Fair	Poor	Poor
10. Applicability of results	Can't tell	Can't tell	Can't tell	Can't tell
Level of evidence (% of criteria fulfilled)	2- (28.6%)	2- (43.8%)	2- (25%)	2- (31.3%)

APPENDIX 8D COHORT STUDY (CASP appraisal tool for cohort study)

	Desalu et al., 2008
1. Clearly-focused question	Yes
2. Appropriate to carry out a cohort study	Yes
3. Cohort was recruited in an acceptable way	Can't tell
4. Exposure was accurately measured to minimize bias	Can't tell
5. Outcome was accurately measured to minimize bias	Can't tell
6. A) Authors identified all important confounding factors	No
B) authors have taken account of confounding factors in design and analysis	Yes
7. A) Follow up of subjects was complete enough	Yes
B) Follow up of subjects was long enough	Can't tell
8. Main result(s) of study, presentation	Fair
9. Precision of result(s)	Fair
10. Believe the results	Can't tell
11. Results can be applied to local population	Can't tell
12. Results fit with other available evidence	Yes
Level of evidence (% of criteria fulfilled)	2- (50%)

APPENDIX 9 GRADING FOR OCULAR SURFACE DISEASE SEVERITY

(Ezra et al., 2005; Mercieca et al., 1999; Sivasankar et al., 2006)

I	Punctate epithelial erosions (PEEs) involving the inferior third of cornea
II	PEEs involving more than the inferior third of the corneal surface
III	Macroepithelial defect
IV	Stromal whitening in the presence of epithelial defect
V	Stromal scar
VI	Microbial keratitis
VII	Other ocular surface disorders

APPENDIX 10 SIGN 50: A GUIDELINE DEVELOPER'S HANDBOOK: ANNEX B: KEY TO GRADES OF RECOMMENDATIONS

A At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; *or*

A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

B A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 1++ or 1+

C A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 2++

D Evidence level 3 or 4; *or*

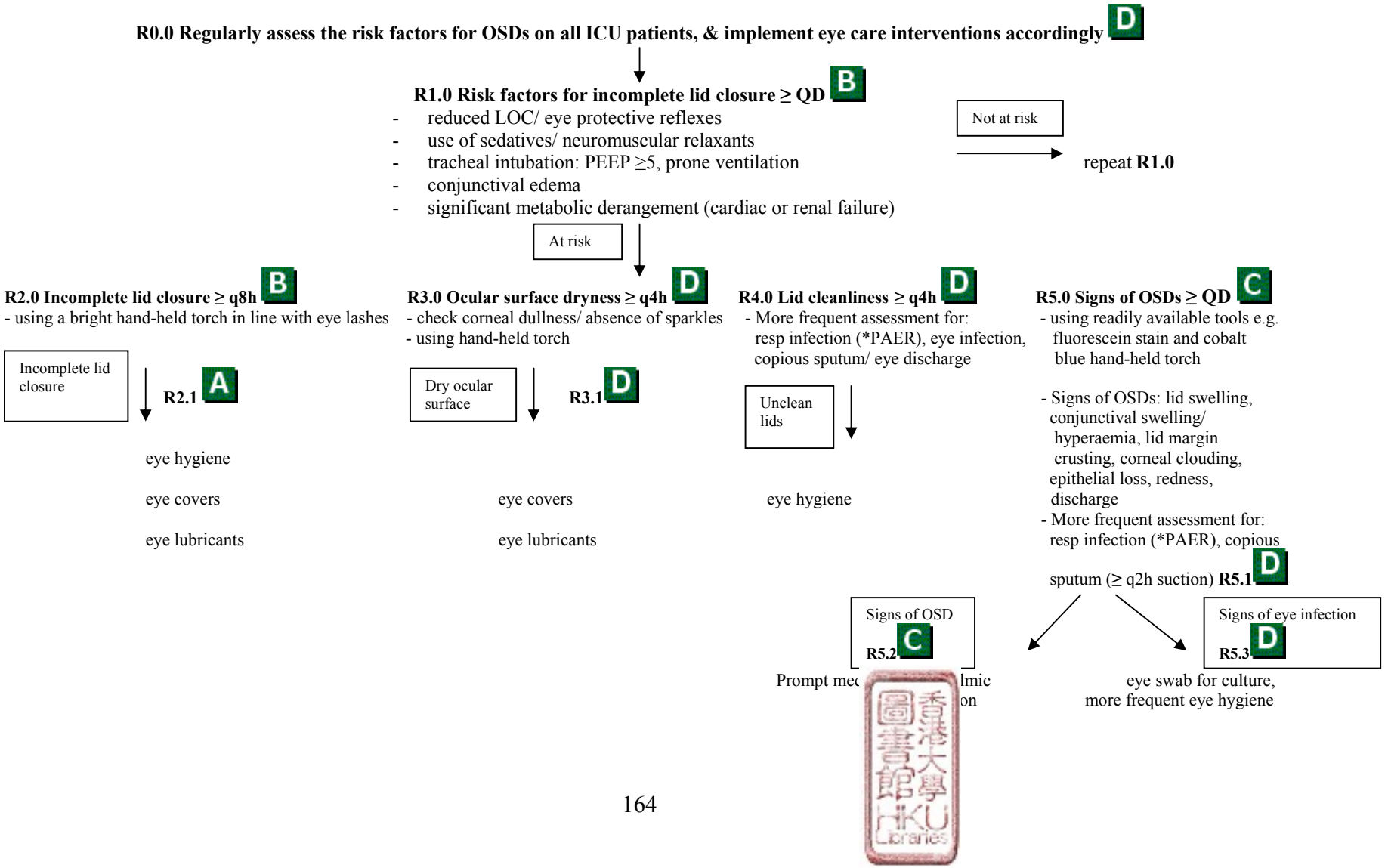
Extrapolated evidence from studies rated as 2+

Good practice points

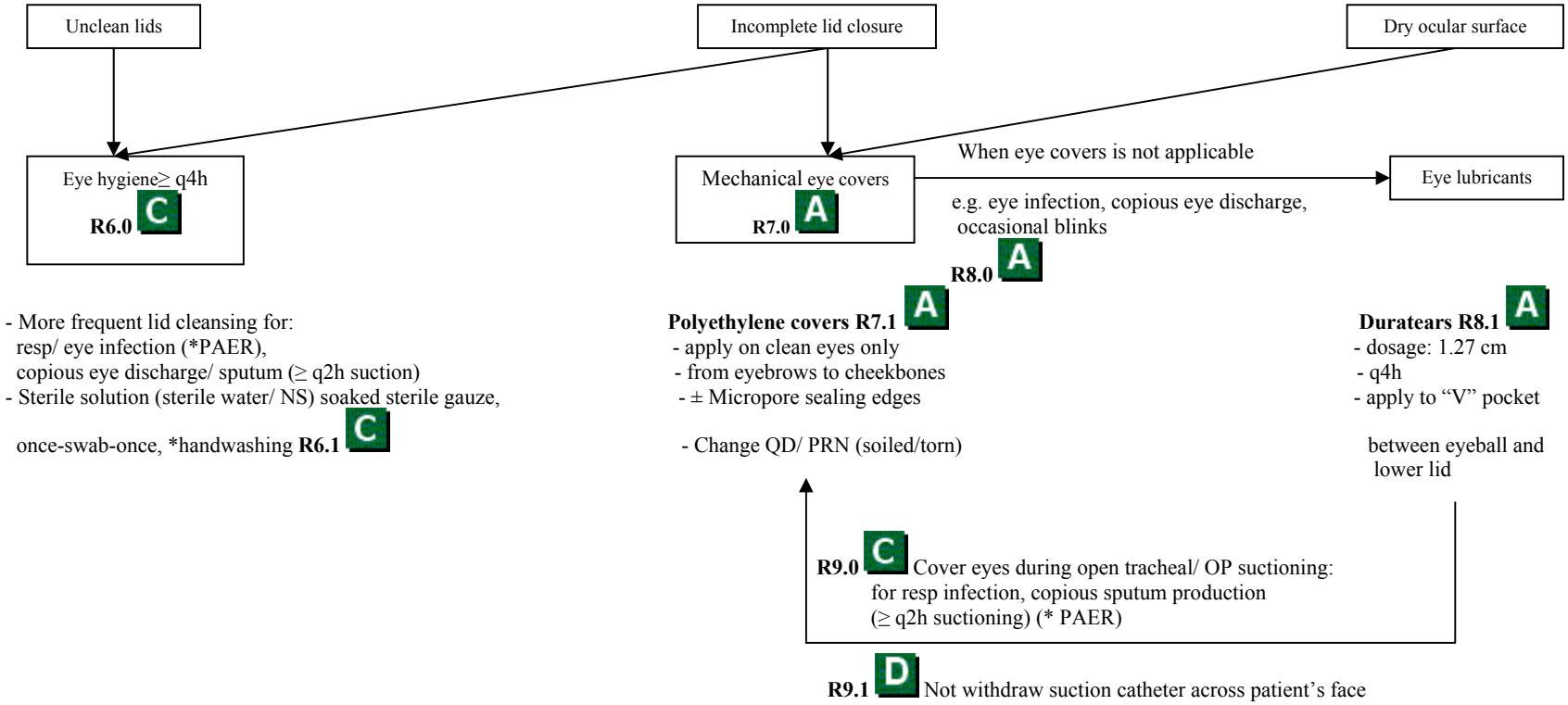
✔ Recommended best practice based on the clinical experience of the guideline development group

APPENDIX 11 EYE CARE PROTOCOL FLOW CHART

ASSESSMENTS



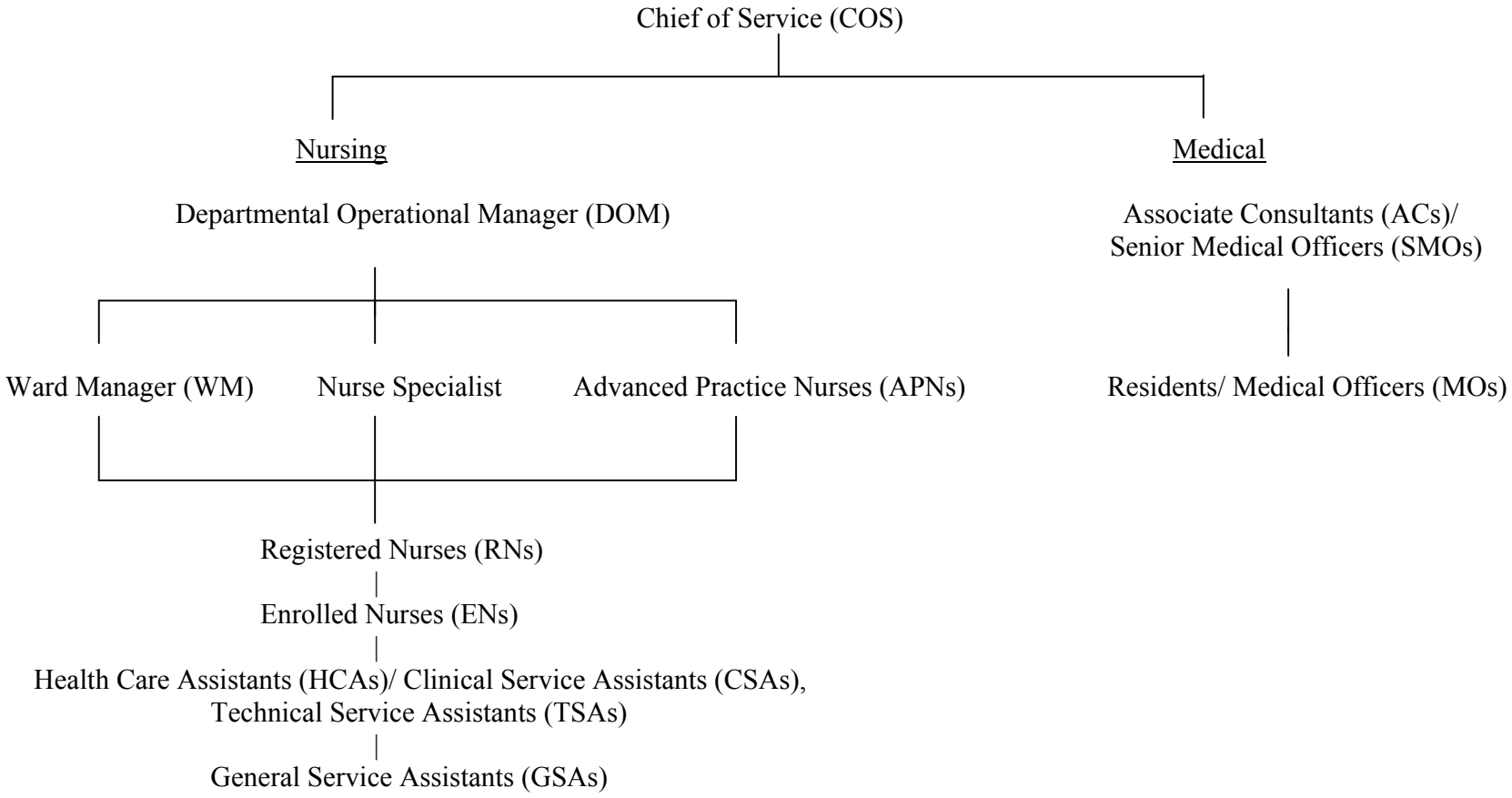
EYE CARE INTERVENTIONS



R10.0 Prevention or management of conjunctival edema D
Elevate the head of the bed, maintain appropriate tightness of airway securing taping

R11.0 Ventilator-associated pneumonia (VAP) prevention D
Prevention of VAP, e.g. aseptic technique during open tracheal suctioning, follow VAP bundle care protocol ted in the ICU

APPENDIX 12 ORGANIZATION STRUCTURE OF THE TARGET ICU



APPENDIX 13 NURSING AUDIT TOOL

APPENDIX 13A NURSING PROCEDURE AUDIT FORM

Adult Intensive Care Unit in Hong Kong

Date: _____

Topic: Evidence-based practice eye care protocol

Assessments						
	Standard criteria	Source of information	Yes	No	NA	remarks
R0.0	Assess the risk factors for OSDs (R1.0-R5.3) for all newly admitted ICU patients	AN/AF/O/CR				
R1.0	Assess the risks factors for the incomplete lid closure at least QD	AN/AF/O/CR				
	Apply eye assessments (R2.0-5.3) to patients who are at risk	AN/AF/O/CR				
R2.0	Assess for incomplete lid closure at least q8h, using a bright hand-held torch in line with eye lashes	AN/AF/O/CR				
R2.1	Apply eye hygiene, eye covers, or eye lubricant (R6.0-9.1) to patients who are unable to maintain complete lid closure	AN/AF/O/CR				
R3.0	Assess ocular surface dryness (dullness and absence of sparkles) at least q4h, using hand-held torch	AN/AF/O/CR				
R3.1	Apply eye covers or eye lubricant (R7.0-9.1) to dry ocular surface	AN/AF/O/CR				
R4.0	Assess lid cleanliness at least q4h	AN/AF/O/CR				
	Apply eye hygiene (R6.0-6.1) to unclean lids	AN/AF/O/CR				
	More frequent assessment for patients with eye infection/ copious eye discharge, and resp infection (especially PAER) with copious sputum (at least q2h suction)	AN/AF/O/CR				
R5.0	Assess signs of OSD at least QD	AN/AF/O/CR				
	(1) fluorescein stain test with cobalt blue hand-held torch	AN/AF/O/CR				
	(2) signs of OSDs: lid swelling, conjunctival swelling/ hyperaemia, lid margin crusting, corneal clouding, epithelial loss, redness, or discharge	AN/AF/O/CR				

R5.1	Assess signs of OSD more frequently for patients with respiratory infection, especially for patients with PAER infection or copious sputum production (at least q2h suctioning).	AN/AF/O/CR				
R5.2	Prompt medical and ophthalmic consultation for any signs of OSDs	AN/AF/O/CR				
R5.3	Save an eye swab for culture for any signs of eye infection	AN/AF/O/CR				
Interventions						
	Standard criteria	Source of information	Yes	No	NA	remarks
R6.0	Perform lid cleansing at least q4h to patients with incomplete lid closure and unclean lids (R2.0 & 4.0)	AN/AF/O/CR				
	More frequent lid cleansing is indicated for patients with eye/ resp infection, and copious eye discharge/ copious sputum (frequent suctioning at least q2h) especially PAER infection	AN/AF/O/CR				
R6.1	Lid cleansing with sterile water/ NS soaked sterile gauze, in once-swab-once manner	AN/AF/O/CR				
	Nurses' hand hygiene is emphasized	AN/AF/O/CR				
R7.0	Keep eyes closed by mechanical eye covers (R 2.0 & 3.0) for patients with incomplete lid closure and dry ocular surface	AN/AF/O/CR				
R7.1	Apply transparent polyethylene covers (Gladwrap) on clean eyes from eyebrows to cheekbones, with Micropore sealing edge if necessary. Change QD/ prn (e.g. soiled or torn).	AN/AF/O/CR				
R8.0	Apply eye lubricant when eye covers is not applicable, e.g. patients with eye infection, copious eye secretion, or occasional blinks.	AN/AF/O/CR				
R8.1	Apply 1.27-cm Duratears to the "V" pocket between eyeball and lower lid q4h	AN/AF/O/CR				
R9.0	Apply eye covers (R7.0-7.1) during open tracheal or OP suctioning for patients with respiratory infection (especially PAER infection) and copious sputum production (suctioning ≥ q2h)	AN/AF/O/CR				
R9.1	Should not withdraw the suction	AN/AF/O/CR				

	catheter across patient's face after suctioning					
R10.0	Reduce or prevent conjunctival edema: elevate the head of bed, maintain appropriate tightness of airway securing taping	AN/AF/O/CR				
R11.0	Prevention of VAP reduces the risk of eye infection, e.g. aseptic technique during open tracheal suctioning, follow VAP bundle care protocol as implemented in the ICU	AN/AF/O/CR				

Please circle the appropriate source of information and tick the appropriate column.

NA: not applicable; AN: ask nurse; AF: ask family; O: observation; CR: check record

Compliance percentage: _____

Auditor: _____

Signature: _____

APPENDIX 13B STANDARD OF JUDGMENT FOR THE AUDIT TOOL

Assessments		
	Standard criteria for assessments	Success criteria
R0.0	Assess the risk factors for OSDs (R1.0-5.3) for all newly admitted ICU patients	Perform eye assessments (R1.0-5.3) to all newly admitted ICU patients before implementing eye care interventions
R1.0	Assess the risks factors for the incomplete lid closure at least QD	Able to identify the risk factors for incomplete lid closure (reduced conscious level/ protective reflexes, use of sedatives/ neuromuscular relaxants, tracheal intubation, PEEP ≥5, prone ventilation, conjunctival edema, and significant metabolic derangement e.g. cardiac/ renal failure)
	Apply eye assessments (R2.0-5.3) to patients who are at risk for the incomplete lid closure	Perform R2.0-5.3 to patients who are at risk
R2.0	Assess for incomplete lid closure at least q8h, using a bright hand-held torch in line with eye lashes	Appropriately assess lid closure using torch, and prevent unrecognized incomplete lid closure by naked eye observation, especially in the medial portion
R2.1	Apply eye hygiene, eye covers, or eye lubricant (R6.0-9.1) to patients who are unable to maintain complete lid closure	Perform eye care interventions (R6.0-9.1) to identified incomplete lid closure
R3.0	Assess ocular surface dryness (dullness, absence of sparkles) at least q4h, using hand-held torch	Able to identify ocular surface dullness and absence of sparkles using torch
R3.1	Apply eye covers or eye lubricant (R7.0-9.1) to dry ocular surface	Apply eye covers or eye lubricant (R7.0-9.1) to desiccated ocular surface
R4.0	Assess lid cleanliness at least q4h	Assess lid cleanliness using naked eye observation
	Apply eye hygiene (R6.0-6.1) to unclean lids	Perform eye hygiene (R6.0-6.1) to unclean lids
	More frequent assessment for patients with eye infection/ copious eye discharge, and respiratory infection (especially PAER) with copious sputum (requires at least q2h suction)	Frequent observation with pupil assessment so as to maintain lids cleanliness
R5.0	Assess signs of OSD at least QD	Able to perform early identification of OSD

	(1) fluorescein stain test with cobalt blue hand-held torch	Perform fluorescein stain test with standardized tools and appropriate skills, and able to identify OSD
	(2) signs of OSDs: lid swelling, conjunctival swelling/ hyperaemia, lid margin crusting, corneal clouding, epithelial loss, redness, or discharge	Able to identify signs of OSDs, and observe ocular surface condition by naked eyes
R5.1	Assess signs of OSD more frequently for patients with respiratory infection, especially for patients with PAER infection or copious sputum production (at least q2h suctioning)	Frequent ocular surface observation for OSD with pupil assessment
R5.2	Prompt medical and ophthalmic consultation for any signs of OSDs	Inform doctor and/or consult ophthlamologist for suspected OSDs as soon as possible
R5.3	Save an eye swab for culture for any signs of eye infection	Sent an eye swab for culture for suspected OSDs with clean procedures
Interventions		
R6.0	Perform lid cleansing at least q4h to patients with incomplete lid closure and unclean lids (R2.0 & 4.0)	Perform lid cleansing by washed hands with appropriate solution, techniques, and frequency. Make sure not to induce cross infection between eyes.
	More frequent lid cleansing is indicated for patients with eye/ respiratory infection, and copious eye discharge/ copious sputum (frequent suctioning at least q2h) especially PAER infection	
R6.1	Lid cleansing with sterile water/ NS soaked sterile gauze, in once-swab-once manner	
	Nurses' hand hygiene is emphasized	
R7.0	Keep eyes closed by mechanical eye covers (R 2.0 & 3.0) for patients with incomplete lid closure and dry ocular surface	Cover clean eyes with polyethylene covers appropriately from eyebrows to cheekbones. Make sure a closed chamber with adequate moisture is created and maintained, and the polyethylene cover is changed when necessary.
R7.1	Apply transparent polyethylene covers (Gladwrap) on clean eyes from eyebrows to cheekbones, with Micropore sealing edge if necessary. Change QD/ prn (e.g. soiled or torn)	
R8.0	Apply eye lubricant when eye covers is not applicable, e.g. patients with eye infection, copious eye secretion, or occasional blinks	Apply eye lubricants only when eye cover is not applicable. Apply Duratears to the "V" pocket between eyeball and lower lid in right dosage. Should not miss doses.
R8.1	Apply 1.27-cm Duratears to the "V" pocket between eyeball and lower lid	

	q4h	
R9.0	Apply eye covers (R7.0-7.1) during open tracheal or OP suctioning for patients with respiratory infection (especially PAER infection) and copious sputum production (suctioning at least q2h)	Cover eyes with polyethylene covers (R7.0-7.1) during open tracheal or OP suctioning
R9.1	Should not withdraw the suction catheter across patient's face after suctioning	Never withdraw the suction catheter over patient's face and eyes
R10.0	Reduce or prevent conjunctival edema: elevate the head of bed, maintain appropriate tightness of airway securing taping	Perform measures to prevent or reduce the degree of conjunctival edema
R11.0	Prevention of VAP reduces the risk of eye infection, e.g. aseptic technique during open tracheal suctioning, follow VAP bundle care protocol as implemented in the ICU	Aseptic suctioning technique; Perform VAP prevention bundle care protocol as implemented in the ICU

APPENDIX 14 EYE CARE DOCUMENTATION CHART

Demographics

Hospital number:
Age (year):
Gender:
Diagnosis:
Admission date (dd/mm/yyyy):
Discharge date (dd/mm/yyyy): ICU length of stay (day):

Family aspect (*please circle the appropriate one)

Consent obtained: *yes/ no
Explanatory letter give: *yes/ no
Family acceptance (please ask exactly according to the standard question):
"As part of the eye care for your_____ (husband/ wife/ father/ mother, brother, sister, son, daughter etc.), his/her eyes have to be covered by a polyethylene cover. Do you find this acceptable?"
*yes/ no (if no, please specify reasons _____)

Reason of protocol completion

1) Regain blinking reflex or level of consciousness □ Date _____
2) Develop OSD □ Date _____
3) Transfer out from ICU with altered level of consciousness □ Date _____
4) Die □ Date _____

OSD development

Develop OSD: *yes/ no
Date of diagnosis: _____
Diagnosed by: *ICU doctor/ ophthalmologist
Type of OSD: *corneal/ conjunctival: *ulceration/ abrasion/ infection
Severity of OSD: Grade *0/1/2/3/4/5/6/7

Possible confounders (please fill up daily)
Date: _____
Glasgow Coma Scale (GCS): E_V_M_ Ramsay sedation score: _____
APACHE II score: _____

Ventilator settings:
Mode_____FiO2___PC___PS___PEEP___CMV rate___trigger___
Patient peak airway pressure___TV___
Sedation (type of drug/dose):_____ start date_____end date: _____
Muscle relaxant (type of drug/dose):_____ start date_____end date: _____

Septic shock: *yes/ no
Conjunctival edema: *yes/ no
Organ failure: *yes/ no (if yes, please specify_____)
Pupil assessment frequency: q_h

Assessments (please tick the appropriate boxes)
R1.0 Assess the risks factors for incomplete lid closure at least QD

Time (hour)		07	15	23	
↓conscious level					
↓protective eye reflexes					
sedatives					
neuromuscular relaxants					
tracheal intubation					
PEEP ≥ 5					
prone ventilation					
conjunctival edema					
significant metabolic derangement	cardiac failure				
	renal failure				
	others (please specify)				
Risk factor(s) exist(s): proceed to R2.0-5.3					
No risk factor: repeat R1.0					

R2.0-2.1 Assess incomplete lid closure at least q8h

Time (hour)		07		15		23	
Using hand-held torch in line with eye lashes	Yes						
	No (reason)						
incomplete lid closure	Yes (apply R6.0-9.1)						
	No						

R3.0-3.1 Assess ocular surface dryness at least q4h

Time (hour)		03		07		11		15		19		23	
Using hand-held torch	Yes												
	No (reason)												
dullness	Yes (apply R7.0-9.1)												
	No												
absence of sparkles	Yes (apply R7.0-9.1)												
	No												

R4.0 Assess lid cleanliness at least q4h

Time (hour)		03		07		11		15		19		23	
Respiratory infection	Yes												
	PAER infection												
	No												
copious sputum (at least q2h suctioning)	Yes												
	No												
eye infection	Yes												
	No												
copious eye discharge	Yes												
	No												
lid clean	Yes												
	No (apply R6.0-6.1)												

R5.0-5.3 Assess signs of OSD at least QD

Time (hour)			07		15		23			
respiratory infection	Yes	PAER infection								
	No									
copious sputum requiring at least q2h suctioning	Yes									
	No									
fluorescein stain test	Bright greenish stain (apply R5.2)									
	No staining									
signs of OSD (any checked box: apply R 5.2)	lid swelling									
	conjunctival swelling									
	conjunctival hyperaemia									
	lid margin crusting									
	corneal clouding									
	epithelial loss									
	redness									
	discharge									
R5.2 consult ICU doctors	Yes									
	No									
R5.2 consult ophthalmologist	Yes									
	No									
Signs of eye infection	Yes	Eye swab for culture								
	No									

Eye care interventions

R6.0-6.1 Eye hygiene at least q4h

Time (hour)		03		07		11		15		19		23	
wash hands before procedure	Yes												
	No												
sterile gauze	Yes												
	No (please specify type and reasons)												
sterile solution	sterile water (reason)												
	normal saline (reason)												

R7.0-7.1 Mechanical eye covers (Polyethylene cover)

Time (hour)		07	15	23	
Polyethylene cover	Yes				
	No (please specify type and reasons)				
apply on clean eyes	Yes				
	No				
apply from eyebrows to cheekbones	Yes				
	No				
Micropore sealing edge	Yes				
	No				
achieve a moisture closed chamber	Yes				
	No				
Change polyethylene cover	Yes (reason)				
	No (reason)				

R8.0-8.1 Eye lubricants (q4h Duratears)

Time (hour)		03		07		11		15		19		23	
Mechanical eye covers is not applicable	Yes (reason)												
	No												
Duratears	Yes												
	No (please specify type and reasons)												
Dosage: 1.27 cm	Yes												
	No (please specify dosage and reason)												
Apply to "V" pocket between eyeball and lower lid	Yes												
	No (reason)												

R9.0-9.1 Suctioning technique

Time (hour)		03		07		11		15		19		23	
close suction	Yes (skip R9.0-9.1)												
	No												
open tracheal or OP suction (any cheked box, apply eye covers R7.0-7.1)	respiratory infection (especially PAER infection)												
	copious sputum (at least q2h suction)												
withdraw suction catheter across patient's face	Yes (reason)												
	No												

R10.0 Prevention or management of conjunctival edema

Time (hour)		07	15	23	
conjunctival edema	Yes				
	No				
elevate the head of bed 30 degree	Yes				
	No				
appropriate tightness of airway securing taping	Yes				
	No				
Other measures to manage conjunctival edema	Yes (please specify)				
	No				

R11.0 Ventilator-associated pneumonia (VAP) prevention

Time (hour)		07	15	23	
Clinically diagnosed pneumonia e.g. by symptoms/ CXR	Yes (please skip R11.0)				
	No				
sputum culture	Positive (please specify result and skip R11.0)				
	Negative				
aseptic technique during open tracheal suctioning	Yes				
	No (reason)				
follow VAP bundle care protocol as implemented in the ICU	Yes				
	No (reason)				

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