I have read the Consultation Paper, Australian Safety and Quality Goals for Health and I strongly support efforts to improve safety, and reduce probability of avoidable harm in the health care system.

I believe it would be useful for there to be increased efforts to reduce harm from adverse medicine events that occur with the correct use of medication, for its intended therapeutic purpose. While harm due to medication use is acknowledged in the consultation paper, the emphasis is on medication errors ie adverse events that occur due to misuse of medications.

Information on deaths due to adverse reactions to medication when used correctly is not collected systematically in Australia at the present time. Sentinel event systems collect information regarding adverse events due to incorrect administration of a drug, rather than avoidable deaths due to reactions to medications used correctly for their intended therapeutic purpose. Reporting of adverse drug reactions to the TGA is voluntary, and medical deaths are not subject to external review or audit as would a child death, obstetric death or surgical death. As such, opportunities to reduce risk of recurrent events may be missed.

Some specific examples of these kinds of adverse events are angioedema with ACE inhibitors. These medications are widely used for cardiovascular risk reduction. Angioedema is a class related adverse event with this group of drugs, may cause airway obstruction, and has been recognised and described since the mid 1990’s. Yet in 2010 a patient died from this condition, which was unrecognised by the treating general practitioner (Andrew, NH, Gabb GM, Del Fante Australian Family Physician 2011 ACE inhibitor angioedema: a review and case report). There is currently no reliable information on the extent, severity and impact on the health system of ACE inhibitor angioedema.

Another example is statin myositis (see attached poster, presented at the 2nd Indigenous Cardiovascular Health Conference in Alice Springs 2011).

It would be useful if there could be increased efforts directed at adverse events and outcomes occurring with corrected use of medication for its intended therapeutic purpose. This is especially important at the present, as medications are increasingly being used to modify risk (as opposed to treat disease) in increasingly low risk populations.

Some strategies to consider may be

-redefining the medication related sentinel events, to include deaths due to correct use of medication for its intended therapeutic purpose

-reviewing professional guidelines etc to make sure they include appropriate safety information

-working with professional bodies where there are ‘gaps’ in external audit processes of deaths etc to increase the rate of detection of avoidable deaths

-audits and surveillance and feedback to prescribers of recognised significant adverse reactions eg angioedema and ACE inhibitors, myositis and statins

Thankyou for considering this submission,

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DOCUMENT NOT YET CLASSIFIED
Catastrophic statin-induced myopathy in Aboriginal and Torres Strait Islanders

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Objectives

To describe a clinical case of statin-induced myopathy in an Aboriginal Australian.

To describe a case series of catastrophic statin-induced myopathy in Indigenous Australians.

To contribute to knowledge regarding drug safety for Indigenous Australians.

Methods

Direct clinical experience

Search strategies

Medical literature data bases – systematic search of MEDLINE (1966-present), EMBASE (1980-present), IBIS (1998-present), Cochrane Database of Systematic Reviews, PUBLISH and SCCMD was conducted with the search terms: 'Australia' and 'aboriginal' AND 'statin' OR 'HMG-CoA reductase inhibitors' AND 'myopathy' OR 'myositis' OR 'rhabdomyolysis'.

Office of Product Review, Therapeutic Goods

Adverse reports – a systematic search of adverse drug reactions (2008 to November 2010) was conducted using adverse drug reaction, statin in Aboriginal and Torres Strait Islander. and prior terms of 'myopathy' OR 'myositis' OR 'myoglobinuria' OR 'rhabdomyolysis'.

Internet search (Google) – using the terms 'statin myopathy' in Aboriginal.

Results

Case series

Case Source Demographics Symptoms Investigations Duration (months) Adverse Events Risk Factors Synonyms
1 1989-99 female, 90 years old AMLODIPINE, WAVOS, PAGODA, WINSTON laboratory, CK 11-fold 3 months elevation in serum creatine kinase, decreased myoglobin, muscle pain, creatine kinase, elevated
2 6-07 male, 48 years old 1999-2001 laboratory, CK 21-fold 2 months elevation in serum creatine kinase, decreased myoglobin, muscle pain, creatine kinase, elevated
3 6-07 female, 50 years old 2005 laboratory, CK 20-fold 1 month elevation in serum creatine kinase, decreased myoglobin, muscle pain, creatine kinase, elevated
4 1997-98 female, 66 years old 2000 laboratory, CK 21-fold 2 months elevation in serum creatine kinase, decreased myoglobin, muscle pain, creatine kinase, elevated

Discussion

Case report

Although statins are generally considered safe and well tolerated, this Aboriginal woman has experienced severe statin-induced inflammatory myopathy.

Biopsy showed an inflammatory myopathy - Evidence of persistent myositis (elevation of CK) continued despite cessation of statin.

Immunosuppressive treatment with high dose steroids was required for resolution of myositis.

Long term prognosis is uncertain.

Cost of the patient hospitalisation at tertiary hospital is estimated at $600,000.

Case Series

Four unique cases of catastrophic (three deaths, are prolonged ventilation) statin-induced myopathy in Indigenous Australians have been identified, from a population of approximately 40,000 people.

Factors which may contribute to diagnostic difficulty include:
- late presentation
- reduced awareness of potential for statin-induced myopathy with delayed recognition
- diagnostic confusion due to weight loss and weakness
- absence of pain
- relative young age of onset.

Treatment medical literature searches failed to identify any cases of severe statin-induced myopathy in Aboriginal and Torres Strait Islander, however cases were identifiable with an internet search.

Conclusion

Statin myopathies exist on a spectrum of myalgia, to the very severe and potentially fatal rhabdomyolysis.

Recent initiatives which improve access to medicines for Indigenous Australians could herald improved outcomes in Indigenous cardiovascular health, but potential benefits will be reduced if catastrophic adverse events are not recognised and appropriately managed.

It is important for strategies directed at drug safety to accompany improved availability of medications.

Guidelines and recommendations from authoritative organisations must acknowledge uncertainty regarding drug safety, and encourage robust pharmacovigilance practices.

References