



Medical Technology
Association of Australia



*Draft Concept of Operations:
Relating to the introduction of a personally
controlled electronic health record (PCEHR) system
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MEDICAL TECHNOLOGY FOR A HEALTHIER AUSTRALIA

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1. Executive Summary

This submission is in response to the release in April 2011 by the Australian Department of Health and Ageing of the *Draft Concept of Operations: Relating to the introduction of a personally controlled electronic health record (PCEHR) system*. The draft report was prepared by the National E-Health Transition Authority Ltd (NEHTA). The Medical Technology Association of Australia (MTAA) welcomes the opportunity to comment on the report and make specific recommendations.

MTAA recommends:

- That early consideration be given to the future use of data from electronic records for the development of high quality clinical registries.

2. About the medical technology industry

The Medical Technology Association of Australia (MTAA) represents the manufacturers, exporters, importers and distributors of medical technology products in Australia. The medical technology industry manufactures many products that contribute to the health and wellbeing of Australians. These include a range of assistive aids and appliances, implantable prostheses (e.g. cochlear implants), medical consumables and technologies that can be used to monitor individuals in their homes (e.g. alarms, sensors, vital signs monitors, sub-acute medical products etc). The medical technology industry had sales in Australia of more than \$7.6 billion in 2009-10 and employs over 17,500 people.

3. Comments on the Draft Concept of Operations: Relating to the introduction of a personally controlled electronic health record (PCEHR) system

The PCEHR draft Concept of Operations is a living document that will be updated as the system progresses and e-Health lead sites become operational. The Government will invest \$466.7 million over two years in the first release of the PCEHR system and from July 2012 individuals will be able to register for a PCEHR. There will be three first wave e-Health implantation sites and nine second wave implementation sites.

MTAA recognises the strengths of an electronic health record system as being:

- Continuity of care between systems
- Better access to information regarding medication, which will increase the safety and effectiveness of medical management and decrease the rate of adverse events
- Improved diagnostic and treatment capabilities via enhanced access to health information.

MTAA takes this opportunity to be able to provide comment on other areas of planning that should be considered. Electronic health records have the potential to do more than share electronic data from various sources between computers. The draft concept of operations focuses in great detail on aspects of privacy and personal control. However, there is little detail in regard to the dynamic way in which medical data captured in electronic records can be used, e.g. to feed into clinical registries. Some of the potential enhancements to PCEHRs mentioned in the draft Concept of Operations include support for collection of a broader range of health information such as health information from registries (Section 2.1).

Many strategies put in place now (e.g. achieving interoperability) can benefit the potential uses of EHRs for registries in the future. MTAA recommends that early consideration be given to the best ways of enabling future uses of data from electronic health records.

4. Electronic health records (EHRs)

It is not uncommon in hospitals and ambulatory settings for medical records to contain incomplete information such as medical history and laboratory results. Direct electronic data entry systems that automatically perform data scans and checks are likely to be more reliable than those that rely on pen and paper. The EHR is a record of health information on an individual that conforms to specific standards. Its key function is to integrate disparate pieces of information such as demographics, diagnosis, medical history and test results into one system. Records will interface with data from laboratory, pathology and pharmacy. For example, the Government and Pathology Services have agreed to integrate pathology results within e-health records over a five-year period¹. The medical technology industry would welcome the future integration of information on use of medical devices and surgical procedures which may be fed into clinical registries.

The PCEHR will not be a comprehensive health record, only key health information shared from participating source systems will be available. The record will not contain full details of a record of care (e.g. a full hospital record), rather it will contain a summary of care. Additionally, the record will not take the form of a central national database, as information will come from multiple sources.

Clinical documents including health, discharge and event summaries, pathology reports, imaging reports and letters from specialists will be captured and stored within multiple secure repositories. Information may be accessed from Medicare Australia (e.g. organ donor status, immunisation history), and the Pharmaceutical Benefits Scheme (PBS). Healthcare providers will be able to access health records using a range of options, for example clinical systems for healthcare delivery and a provider portal. Individuals will be able to enter certain information. Patient generated data are a good source of general health information; individuals are able to provide valuable information such as the presence or absence of certain tests. Less reliable is the ability to report test results (e.g. cholesterol levels)(1). Some of the details regarding the information available from electronic records will be subject to further community consultation.

It is recognised that the system will grow over time. A number of additional optional information sources will be considered in the first release including – specialist letters, pathology results, diagnostic imaging reports, Medicare claims history, PBS data, ACIR and organ donor information, referrals, prescriptions/dispense notifications and the location of advanced care directives (if applicable).

Section 2.1 of the draft Concept of Operations outlines potential enhancements to the PCEHR. The draft report proposes that the capabilities of the system be expanded over a four-year implementation period. The potential enhancements of most relevance to the medical technology industry include:

Support for collection of a broader range of health information such as:

- Pathology and diagnostic imaging requests
- Diagnostic images
- **Health information from registries**

¹ Media Release, The Hon Nicola Roxon MP, Minister for Health and Ageing (11 April 2011).

- Care plans
- Assessment tools
- Reports from practice-based diagnostic tools (e.g. electrocardiograms)

The addition of consumer-oriented features such as:

- Integration with consumer-oriented personal health records
- **Collection of information from consumer devices such as blood pressure monitors, blood glucose monitors etc**

Addition of new views to support the needs of specific groups such as:

- Integration with consumer-oriented personal health records
- Views to support the management of chronic diseases
- Views to support organisations and their representatives
- Views to support specific healthcare providers such as nurses and allied health providers

The use of EHRs will grow significantly in the next few years. Given that health records are a major source of clinical data on a patient they will be able to provide large amounts of valuable clinical information for registries. Interfaces will be needed so that information from an EHR can cross-populate a registry or vice-versa. A well designed EHR should feed data into registries which should in-turn feedback into Health Technology Assessment (HTA) and support the Therapeutic Goods Administration's (TGA) oversight of safety through post-market surveillance.

5. Registries

Registries provide real-world data on clinical practice, patient outcomes, safety and the comparative effectiveness of different treatments (e.g. pharmaceutical versus device for the treatment of a cardiac condition). There are a number of different types of registries, for example device or procedure specific registries (which collect data on medical device or surgical procedure), class registers (which collect data on all devices and procedures used in a specific class or intervention) and comparative registers (which look at a range of options for treating a specific disease, e.g. drug, surgical procedure or medical device)². Registries are able to effectively collect large amounts of real world data to monitor the safety and quality of drugs, procedures or devices at a population level. In some cases registries provide benchmark data and enable clinicians to compare their treatments and outcomes to those of others.

There are a number of potential uses for well-designed registries based on EHRs in Australia. Registries can be used to:

- Support safety (including post-market surveillance)
- Perform comparative effectiveness research (e.g. compare drug and device treatments for a specific condition)
- Gather data on new therapies
- Evaluate healthcare at the population level
- Examine patient outcomes over extended periods of time
- Assess clinical and cost effectiveness
- Assess the reliability and validity of performance measures
- Compare specific disease management protocols.

² Submission 39. Medical Technology Association of Australia. 22 May 2009.

6. Government recommendations for registries

Improvements in e-health and data linkage (via EHRs) will lay the groundwork for the development of quality registries in Australia. The 2009 Federal Government review of health technology assessment (HTA) in Australia recommended the creation of registries for high risk implantable items and/or procedures³. High risk devices include Class III and active implantable medical devices (e.g. implantable pacemakers, defibrillators and nerve stimulators). Recommendation 15 of the review recommends that data from registries be used to provide additional information for post-market surveillance of safety and efficacy. There is the potential for data from registries to be applied to future HTA.

A 2009 report by the National Health and Hospitals Reform Commission also recommended that Australia have systems in place to “provide comparative clinical performance data back to health services and hospitals, clinical units and clinicians”(2). A recent article in the Medical Journal of Australia recommends that prioritization of registries in Australia focus on high cost areas of medicine (in particular areas where resources may be inappropriately used), sequenced care (treatment where positive outcome depends on a well-timed and well-performed sequence of events, e.g. trauma care), devices, procedures and drugs (medium to long-term monitoring where there is a need to establish safety) and areas where registries could be developed with relative ease to monitor disease or compliance(3).

7. Current registries in Australia

There are 28 registries operating across multiple sites in Australia, however there are few national registries. Those registries with national coverage collect data on renal dialysis, joint replacements and organ transplantation. The National Joint Replacement Registry (NJRR) collects data on orthopaedic prostheses and is a doctor-led registry which achieved clinical buy-in via the Australian Orthopaedic Association (AOA) encouraging its members to comply. Since it was established in 1999 the NJRR estimates that it has reduced the number of unnecessary revision operations by 1,200 procedures per year. One of the limitations of the NJRR is that the only endpoint is revision (which may incorrectly assume failure of the prostheses, likewise no revision may incorrectly assume the device is performing well). There have been attempts to set up a registry for cardiac procedures. The Australian Cardiac Procedures Registry (ACPR) was developed through a pilot project sponsored by the Australian Commission on Safety and Quality in Healthcare (ACSQHC), however a sustainable funding source has not been identified for future development.

Evans et al. (3) surveyed Australian registries that collect clinical outcome data. The authors found that the majority of registries require modifications to their procedures in order to provide useful and reliable information for quality improvement purposes. The biggest issues were failures to audit data, collect information for risk adjustment, provide long term follow-up and feedback, collect data on major confounders, recruit more than 80% of the relevant population and capture data so that it can routinely link with other databases. These are some of the types of difficulties that may be ameliorated if data can be fed into registries from EHRs.

³ Commonwealth Government of Australia, Review of Health Technology Assessment in Australia, December, 2009.

8. International registries

8.1 United States

Data from registries provide valuable real-world evidence. Since 2005 the Food and Drug Administration (FDA) Center for Devices and Radiological Health has called for over 100 post approval studies, many of which use registries to assess real-world effectiveness of medical devices⁴. The FDA has also recently launched the Sentinel Initiative⁵. This comprises of a national electronic system that aims to track the safety of drugs, biologics and medical devices. The system integrates multiple sources of data including EHR systems and claims databases.

In the US large registries have been set up based on EHRs, for example the Chronic Kidney Disease Registry includes over 57,000 patients and has been shown to be feasible, valid and reliable in a large health system(4). In the US, the ability of commercial EHR systems to generate registries by diagnosis is a requirement of the Certification Commission for Health Information Technology (CCHIT) criteria for ambulatory EHR certification⁶.

The American Heart Association (AHA) recognises the value of linking registry data to supplementary data for clinical research and monitoring of patient safety. One of the biggest challenges for data linkage in the US is the lack of a unique patient identifier. In some cases data linkage can only occur as a result of the use of complex matching algorithms. If data can be linked to EHRs it can be used for longitudinal follow up or evaluation and to assess outcomes, other procedures, readmissions and mortality.

The AHA makes specific recommendations regarding the integration of clinical registries with EHRs(5). These include ensuring that:

- Government provides positive incentives for the adoption of EHRs
- EHRs collect sufficient information to permit registries to assess quality of treatment and provide feedback based on outcomes and performance
- EHRs facilitate the uploading of digital data in a format that can be used by registries and include contingencies to deal with missing data
- EHRs are designed in such a way that standardized data can be uploaded, according to specific health information exchange standards and shared with registries.

All of the above recommendations are applicable to the development of clinical registries based on EHRs in Australia.

In some cases collection of data for a registry may be a condition of coverage. In the US the National Cardiovascular Data Registry for Implantable Cardiac Devices (NCDR ICD registry) collects national data on implantable cardiac defibrillator implantations and tracks the relationship between in-hospital patient outcomes and physician training in order to improve care for patients with implanted cardiac devices. After the Centres for Medicare & Medicaid (CMS) linked procedure reimbursement to participation in the registry under the CMS Coverage with Evidence Development policy, participation reached nearly 100% within four months. Hospitals are required to submit data to the registry prior to receiving reimbursement from Medicare for the procedure.

⁴ www.fda.gov/Safety/FDAsSentinelInitiative/ucm2007250.htm, accessed 29 April 2011.

⁵ www.fda.gov/Safety/FDAsSentinelInitiative/default.htm.

⁶ Certification Commission for Health Information Technology, authors. CCHIT Certified 2011 Ambulatory EHR Certification Criteria, April 7, 2010, <http://www.cchit.org/>.

8.2 United Kingdom

In the UK registries have been developed for the purposes of HTA. For example, the Nuss procedure registry was designed to assess a minimally invasive procedure used to treat a congenital chest malformation by the National Institute for Health and Clinical Excellence (NICE). Similarly, the UK National Joint Registry (NJR) was set up to collect information on all hip, knee and ankle replacement operations and to monitor implant performance. Data are supplied via hospitals. All hospitals are encouraged to submit data, however not all comply.

8.3 Scandinavia

A system of national quality registries has been established in Sweden. There are about 70 registries and four competence centres that receive central funding. The national quality registry contains data on patient medical interventions, technical equipment used in operations and outcomes. The registries are designed so that treatment can be monitored for both individuals and groups of patients. Each person in Sweden has a unique identifier and the health system is working to ensure that certain health-metrics will be available electronically no matter where a patient is being treated across the nation. Many registries cross-match data with that from other databases such as the deaths register. One of the biggest challenges in Sweden has been integrating a large number of patient record systems across the country.

Another example of a registry based on a unique identifier is the Danish Orthopaedic Common Database which includes data on knee and hip arthroplasty, cruciate ligaments and shoulder alloplasty. The registries are population-based, nationwide clinical databases, which aim to facilitate continuous improvement of outcomes for joint replacement surgery. The registered preoperative data include the patient's civil registration number. Data are collected prospectively by the operating surgeon before, during and after the surgery, using a standardized form.

9. Benefits of integrating EHRs and registries

The Australian healthcare system holds within it vast amounts of data that are not uniformly merged. The introduction of electronic records provides an opportunity to use this type of information in the future. A large amount of information that will be collected as standard in an HER can be included in registries, for example patient demographics, history, co-morbidities, medication compliance and treatment protocol (drug, procedure or device/technology). The data that are most likely to be relevant to registries are structured data such as ICD-9 diagnoses and laboratory results.

Research has determined that practices with an EHR are more likely to be able to carry out registry functions based on diagnosis (80%), laboratory results (56%) and medication use (56%)(6). The authors note that EHRs should have an inbuilt ability to query across patient records or to extract patient data which are able to be fed into other applications. Registries report good inter-rater reliability between data from medical records and registries. The fields likely to show poor reliability include recordings of time of symptom onset or time to initial scan(5).

Drolet and Johnson (7) reviewed the literature and provide a framework for medical device registries. All of the elements they report are also pertinent for EHRs, for example:

- Data from multiple sources must be able to be merged

- The same standardized data should be collected for each patient
- A data collection protocol should be established
- Observations should be able to be associated over time
- Information regarding outcome data should be available.

Both registries and EHRs utilize clinical information at the patient level and the introduction of EHRs in Australia provides an opportunity to capitalize on the overlap of functionality. The standardization of health records over time will decrease the challenges associated with interoperability between data from health records and registries. Consideration should be given to the future interfacing of EHRs and registries. Given that EHRs will be the first port of call for healthcare professionals, the health record could be a gateway to a registry or multiple registries. EHRs may assist in some of the functions that are required for registries, for example the collection of standardized data and storage of data. Consistent coding and standardized collection of data are needed for EHRs and registries to be interoperable(8).

The use of unique patient identifiers and data linkage via EHRs will make it easier to track patients who have been treated with a particular drug, procedure or device. Data collection should be broad enough to enable identification of other issues, such as clinician performance, safety and quality of the procedure setting and healthcare environment.

The collection of data from electronic records for registries has many advantages. It means that separate registries do not need to be set up for every type of device or procedure, avoiding the unnecessary duplication of data capture. EHRs capture data and information on routine care within a clinical context and enable efficient data access. Registries based on EHRs would avoid duplication of data across different registries and mean that clinicians do not have to supply the same information repeatedly for the same procedure. The draft principles that underlie the PCEHR such as standards for privacy and data reliability, should apply to the way that data are collected for registries.

An important element to include in the development of registries based on PCEHR data is the way that information is fed back to health professionals. A review of the way in which registries provide feedback found that the most influential factors were data quality, motivation, organizational factors and outcome expectancy of those receiving feedback(9).

10. Guidelines

Section 4 of the draft Concept of Operations – 4.6.2 Ensuring Data Quality covers the challenges and the need to achieve high quality data standards. A number of methods of validation will be included to ensure that data validity is maintained, including:

- Stakeholder-driven identification of key metrics, collection protocols, quality dimensions such as accuracy, completeness, consistency, timeliness, fitness for use, provenance and compliance.
- The identification of minimal levels to be achieved within a specified timeframe.
- Preventative and corrective actions to be taken to improve data quality
- The creation of a series of data quality reports to help profile and track different metrics in relation to targets
- The introduction of an issue tracking system to track known issues and progress on corrective actions.

11. National Health and Medical Research Council (NHMRC) Guidelines

The HTA review recommended that the development of registries be undertaken in accordance with the draft principles and technical standards developed by the ACSQHC, NEHTA and the Centre for Research Excellence in Patient Safety (CRE-PS)⁷.

Guidelines and accompanying principles and technical standards for data collection and management of registries have been developed by the NHMRC and outline the key indicators for registries (10). The accompanying Technical Standards and Architecture document outlines technical aspects of data collection and management. The guidelines suggest best practice models to which registries should adhere and include process indicators (activities undertaken as part of the provision of care such as procedures undertaken), outcome indicators (measures used to assess effectiveness of treatment) and structural indicators (setting attributes, e.g. administrative processes that support care). The guidelines were written prior to the introduction of individual healthcare identifiers. In the absence of a unique identifier data matching and cross referencing must rely on 'probability matching' linking variables such as date of birth and other demographics.

According to the guidelines clinical registries should collect a core minimum dataset from multiple locations, incorporate systematic processes for data collection, avoid selection bias, collect data that are objective, reproducible and can be collected from all locations, collect outcome data from all (or as many as possible) patients and collect data for risk-adjustment. The guidelines incorporate data collection, data elements, risk adjustment, data security, data quality, organization and governance, custodianship, ethics and privacy, information output and resources and funds.

12. Relevant Australian Standards

Section 6 of the draft Concept of Operations – 6.1.2 Common Standards and Other Technical Specifications states that the PCEHR system will use a standards-based approach and will leverage existing Australian and International Standards and technical specifications. The final set of standards has yet to be agreed upon. The draft notes that an ICT industry program will be developed to assist eHealth suppliers to take up relevant standards and specifications and subsequent conformance assessment.

Examples of relevant standards and specifications for Australia include:

- The Metadata Online Registry (METeOR) which provides data standards for health purposes
- The Australian standard exchange format for data which is based on the Health Level 7 (HL7) family of standards⁸
- The clinical registry standards map developed by NEHTA⁹
- The International standard for classifying diseases and health issues (ICD-10AM)¹⁰.
- Clinical reference terminology, which is outlined under the Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT)¹¹

⁷ Commonwealth Government of Australia, Review of Health Technology Assessment in Australia December, 2009.

⁸ www.hl7.org/, accessed 29 April 2011.

⁹ National E-Health Transition Authority (NeHTA). Clinical Registry Standards Map. Canberra: NeHTA, 2008; Version 1.0.

¹⁰ World Health Organization. International Classification of Diseases- Australian Modification (ICD-10-AM) 10th revision. Geneva: WHO, 2006.

¹¹ International Health Terminology Standards Development Organisation. Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT), www.ihtsdo.org/our-standards/snomed-ct/.

- Australian Medicines Terminology, which is an extension of SNOMED CT to define medicines and related concepts
- NEHTA Security and Access Framework
- Products listed on the Schedule of Pharmaceutical Benefits (for the purpose of clinical registries implantable items listed on the Prostheses List should be included).

One of the projects within the HL7 is the development and maintenance of Detailed Clinical Models (DCM) which contain all of the elements and technical specifications needed to convey clinical reality¹². DCMs are relevant if we consider future and alternative uses of EHR data, for example clinical decision support, epidemiology, telehealth, algorithms and registries. DCMs support functions such as specification of clinical content for PCEHRs, clinical decision support systems, user interfaces, HL7 messages, clinical content for use in medical devices, national registries, healthcare guidelines, health care and epidemiological research.

13. Global Medical Device Nomenclature (GMDN)

The framework for a PCEHR needs to consider the future application of data for integration into medical device registries. Standardization of medical device terminology is an important part of this process. The Global Medical Device Nomenclature (GMDN)¹³ was based on the standard ISO 15225 and developed by medical device experts from around the world (including manufacturers, healthcare authorities and regulators). The TGA in Australia was one of the early adopters of the GMDN.

The GMDN is a system of internationally recognized coded descriptors that are used to generically identify medical devices (it does not go down to the individual device level, the TGA has proposed reform in this area, however this is not likely to occur until there is a global unique device identifier). Use of the GMDN means that health professionals, medical device manufacturers and suppliers, authorities and conformity assessment bodies are able to use a single naming system at a global level. A code is provided to indicate the generic descriptor within which the device can be identified, by reference to the globally accepted nomenclature. This means that other devices which have similar features but come from a different source are able to be identified. This benefits patient safety, data exchange between authorities, inventory purposes and exchange of post-market vigilance information. The FDA will use the GMDN when they introduce unique product identifiers (UPI). A version of the GMDN is used by the TGA in Australia and this type of nomenclature system should be applied to Australian registries which collect information from electronic medical records. Consideration should be given to including the GMDN within the list of relevant standards for the EHR in Australia. This would enable future expansion of the system to include registry data based on medical devices.

14. Key challenges

The main barrier to integrating EHR data into registries is the difficulty of achieving information exchange between the two systems (interoperability). Interoperability is dependent on accurate, standardized data collection and information exchange. The key elements of interoperability are data exchange (syntactic interoperability) and the ability to understand the data (semantic interoperability)(8). The ease at which EHR data can be integrated into registries depends on whether data can be easily searched and integrated, and the use of standardized terminology and definitions. Interoperability and common

¹² http://wiki.hl7.org/index.php?title=Detailed_Clinical_Models.

¹³ <http://www.gmdnagency.com/>.

standards between databases are crucial for the future exchange of data between EHRs and registries.

Some of the limitations of registries include cases where data may not be collected uniformly, variable consistency of data across sites, difficulties handling information from various sources, lack of inclusion of historical data and wide variation between EHR systems. One of the key issues for registries is the lack of standardised definitions used across databases.

Medical devices provide unique challenges for registries. Device performance depends not only on the device, but also the skill (and familiarity with the device) of the surgeon performing the procedure. This is not a straightforward process to evaluate.

Clinical buy-in is vital for both EHRs and the collection of data for registries. The willingness of health professionals to contribute data depends on how easy it is to participate, costs, use and impact of the data and participation rate (e.g. whether colleagues are also contributing). Registry data are not likely to be reliable unless data are captured from a high proportion of eligible patients. For this reason, opt-off patient consent for registries is often used to maximize recruitment. One of the key underlying principles of the draft Concept of Operations is that the electronic health record will not be mandatory (i.e. patients will opt-on), which will mean that registry data is more likely to be incomplete.

15. Telehealth

Section 2.1 of the draft Concept of Operations outlines potential enhancements to the PCEHR. The draft report supports the future addition of consumer-oriented features such as collection of information from consumer devices such as blood pressure monitors, blood glucose monitors etc. Additionally, feedback to NEHTA from key stakeholders states that the PCEHR system should permit the input of data from in-home monitoring devices¹⁴. MTAA advocates the need for patients to be supported in their own homes, via the provision of funding for technology for home and remote monitoring of people with disabilities and associated medical conditions (telehealth)¹⁵. Federal Government does not fund telehealth in Australia. The introduction of telehealth item numbers to the MBS in July 2011 is likely to cover video consultations only (and not other forms of telehealth such as vital signs or home monitoring). There are a range of peripherals that can be used to assist patients in the home such as home units for measuring temperature, heart rate, blood pressure, glucose levels, oxygen levels and objective symptoms. It could be that the inclusion of data from these types of devices provides an avenue for healthcare professionals to assist patients with routine monitoring of chronic conditions or other ailments.

16. Conclusion

Additional benefits of EHRs can be realised by standardizing data collection and feeding the data into registries. The MTAA recommends that the *Draft Concept of Operations: Relating to the introduction of a personally controlled electronic health record (PCEHR) system* considers interoperability and the future use of data from electronic records for other purposes, in particular, large-scale clinical registries.

¹⁴ National e-Health Transition Authority, ICT Industry and Policy Consultation Report, January to April, 2011.

¹⁵ For MTAA submissions to the Productivity Commission and Pre-Budget submission to Treasury 2011-2012, please see: <http://www.mtaa.org.au/pages/page308.asp>.

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