

## Pharmacy Intranet Scheme

1997

### 1. Introduction

1.1 The Australian Medical Association (AMA) recognises the benefits which will accrue to the community from quality use of medicines and the Government's need to generate data to underpin policy decisions in this area. As professionals, doctors and pharmacists have a shared responsibility in this area.

1.2 The AMA invites the Pharmacy Guild to work with the AMA in developing an agreed approach to the coordination of patient care for the benefit of the community. Consequent to such an agreement would be the joint creation and promotion of supporting working arrangements and infrastructure, including appropriate information technology, at peak industry and local practitioner levels.

1.3 However, the AMA holds serious concerns regarding the proposed Pharmacy Intranet scheme and believes there are major flaws in the concept, structure and processes of the scheme. Principal concerns are detailed below. A range of issues is discussed under the heading *Privacy Issues - Matters Of Principle*. Other matters are dealt with under *Processes, Professional Issues, Health Outcomes* and *The Demonstration Trial*. The AMA would welcome a frank discussion of the issues.

### 2. Privacy Issues - Matters of Principle

2.1 At this stage significant matters of principle have not been resolved. There are outstanding questions relating to the need for a clear and precise definition of the 'original purpose' for the Pharmacy Intranet's data collection; the potential for linking data; ownership of, and access to, the Pharmacy Intranet and its Central Data Base/Information System (CDIS); the repository for the data base; and the nature of consumer participation. The AMA believes these are threshold issues requiring resolution prior to the commencement of the demonstration project.

#### **2.2 What Is The Real Purpose Of The Pharmacy Intranet?**

2.2.1 The AMA asserts that the full purpose of a National Pharmacy Intranet has not been clearly formulated or articulated. At one level, objectives are to establish an 'on-line' interactive prescription claiming system' to speed up communication between pharmacists and funding/regulatory bodies; and facilitate electronic lodgement, assessment and payment of prescription claims. Such objectives are appropriate. Others are of greater concern.

2.2.2 Privacy principles surrounding collection of personal data across most jurisdictions reflect the following concepts: collection limitation; fair, lawful and non-intrusive collection; openness, security; quality of data; access and correction; and use and disclosure limitation. In relation to the latter, an organisation can only disclose or use information for the purpose for which it was originally collected or for a purpose that is directly related to the original purpose of the collection (unless the subject has consented to further use, use will reduce a serious threat to life or health or use is required or authorised by law). It is crucial, therefore, to define the 'original purpose' for which the data are intended. OECD Guidelines on the Protection of Privacy and Transborder Flows of Personal Data state that the purpose must be specified *before* data is collected and subsequent uses of data should be limited to those uses or compatible purposes.

2.2.3 It is proposed that a purpose of the data facility is to enable the 'real time adjudication' of the provision of prescription medicines in relation to a claim on the Pharmaceutical Benefits Scheme. If this is the purpose, the case has not been clearly stipulated; nor have the enabling processes and protocols. It is unclear as to where the adjudication takes place and who has the authority to authorise/refuse a claim. Is this to become the responsibility of the pharmacist or does the ultimate accountability reside with Government agencies? If so, how is this to be exercised? What appeal rights does the patient have? How is the doctor included?

2.2.4 The extent of data linkage between Government agencies, such as HIC, DHFS and the Department of Social Security, particularly to facilitate entitlement checking, is an important issue which requires addressing both publicly and with Health/Community Services industry representatives.

2.2.5 If the purpose of Pharmacy Intranet is to give effect to the Pharmacy Guild's National Council resolution (April 1997): *'to develop a patient centric data collection network that will deliver total health information to pharmacists, other health providers and the community aimed at achieving cost effective health outcomes for all Australians*, a comprehensive consultation process throughout all health/community services industry sectors and community/consumer groups must be initiated.

2.2.6 The AMA views proposals to facilitate commercial uses of the technology and data, including links to wholesalers and manufacturers, as unacceptable. The Guild has not disclosed the full extent of any proposed use of the data base for commercial purposes. The AMA asserts that the stated premise of the Pharmacy Intranet, which is to make savings through improved/reduced use of medications, is negated by allowing data from the same source to be made available to the manufacturers and wholesalers of drugs for the purposes of improved marketing.

2.2.7 The AMA does not believe that a clear purpose, other than for electronic claiming/assessment/payment and checking for eligibility/entitlement has been articulated. As far as eligibility/entitlement checking is concerned, public interest questions surrounding data linking must be aired and resolved. Ill-defined references to 'improving health outcomes' are unacceptable and require greater discussion and resolution. Commercial interests should be disclosed.

### **2.3 Ownership And Access To The Pharmacy Intranet And Its Central Data Base**

2.3.1 The National Pharmacy Intranet proposal involves a private network, owned by the Pharmacy Guild, linking all community pharmacists, Government Agencies (HIC DHFS/PBB) and other users. The stated goal is to link more than 5000 sites. Of major concern to the AMA is the proposal to establish a Central Drug Information System Data Base as the "central core of the Pharmacy Intranet". It is logical to assume that Guild ownership includes the Central Data Base, although this does not appear to be explicitly stated. The AMA believes this question must be debated and resolved prior to the commencement of the trial.

2.3.2 The network and data base will contain personal and private information relating to patient identification, medication history and entitlement level as well as pharmacist and doctor identification. The data will form the biggest collection of sensitive personal information in the nation. The question of whether such a data base, if established, should be owned and/or held in private hands or controlled publicly by a Government authority is a matter of major public importance and yet there has been no public debate on the issue. It must be noted that the private sector is not subject to privacy law but is expected to adhere to self-regulatory codes. In this

context, disclosure of the identity of commercial partners in the project is essential. The Consultative Group has been advised the Guild Commercial is working with a range of prospective commercial partners to establish facilities for the Intranet demonstration, including banks, financial institutions, telecommunications companies, hardware, software and service providers and pharmaceutical companies.

2.3.3 The data base will store and maintain a 14 month medication (including OTC drugs if requested) and 'disease state' history of 'customers'. Clinical information stored is likely to be comprehensive; for example, allergies and other adverse drug reactions and 'problem listing', to enable prescribed drugs to be checked for interactions with diseases and physiological states (renal failure, pregnancy, asthma etc) listed on the patient's "file". It is envisaged that the pharmacist would cross reference the prescription history of clients against other chemists to assess abuse or misuse. The 14 month period for data retention is questionable. Data are likely to be kept longer than 14 months on the basis that a 'disease state', for example diabetes, is experienced over a life-time.

2.3.4 Provision will be made for all community pharmacists, Government agencies and unspecified 'other organisations' to access the Pharmacy Intranet Database at four levels of increasing restriction. HIC and Government have access at the highest level of data intensity and value (level 1). Pharmacists, the HIC, other Government agencies will view confidential patient drug and disease state information, together with the identity of the prescribing doctor and dispensing chemist, for "reporting and investigative purposes" (level 2). Unidentified data relating to types and dosage of medications will be available to Government agencies and other organisations for research activities (level 3). Drug manufacturers and distributors, together with Government agencies and other organisations, will have access, by region/state, to data on the type of medication and total number of dosages dispensed. The potential for the infringement of patient and prescriber confidentiality by non-clinical personnel is significant and has not been addressed.

2.3.5 The creation of a closed (to other health professionals) propriety system flies in the face of current thinking regarding networks designed for sharing and disseminating information. Information technologies have the potential to transform the way in which health care is provided. Poor communication of health information is the primary reason for duplication, and consequent waste, of health resources. A well designed information management/technology system must enable effective integration with other parts of the health/community services industry. AMA/RACGP policy, stated in their *Strategic Framework for Improved Information Management through the use of Information Technology in General Practice*, sets as a goal for good information exchange in health the adoption of nationally consistent standards and codes so systems are open and fully integrated and support acceptable data security. Formation of the Intranet has the potential to undermine the processes of delivering comprehensive and coordinated care. Such a proposal could actually fragment care by allowing such data to be in the hands of a proprietary system.

2.3.6 Although the Guild's information states that the Pharmacy Intranet *can* provide for 'connectivity/interaction with doctors, pathology laboratories, health insurers and others', such connectivity is not automatic and is subject to authorisation and, very likely, payment. The extent of commercial operation within the Pharmacy Intranet has not been overtly articulated. The question must be asked - should a Government funded project underpin a system which facilitates commercial gain by the Guild,

drug manufacturers and distributors arising from access to a data base of highly sensitive personal information?

#### **2.4 Repository For The Data Base**

2.4.1 Options for housing the repository are currently under discussion, although the details of such negotiations are not available to members of the Consultative Group. The options include the Health Insurance Commission or a private entity, for example, one of Australia's 'major banks'. Information available to the Consultative Group refers to the CDIS being established only *quite probably* through the HIC. It is essential that this question is publicly debated.

#### **2.5 Nature Of Consumer Participation**

2.5.1 The question of voluntary versus non-voluntary participation by consumers has not been resolved. The AMA views this as a threshold issue which should be resolved prior to embarking on the demonstration trial. Although the demonstration allows for voluntary consumer participation, it is highly likely that participation in the final scheme will be non-voluntary on the basis that the Government expects to use the information for auditing purposes. For example, a 'doctor shopper' is unlikely to 'opt-in'. It has been strongly suggested that penalties will apply to those who 'opt-out'.

### **3. Processes**

3.1 The AMA asserts that major conflicts of interest arise with the Pharmacy Guild managing the venture without an open, transparent and inclusive process. There appears to be a certain amount of secrecy and haste, so far, in the development of the project. Consultation is limited. There do not appear to be any plans to include the public in debate via consultative forums of any kind. Even with the establishment of the Consultative Group, membership was by invitation only, papers are not widely distributed, and members do not receive reports from the other committees. This has led to suspicion and division among some industry groups and to inadequate consideration of integrating with other Government and industry activities, such as the National Prescribing Service. There is potential for duplication of activities; at the very least the links between the roles of the two projects have not been addressed.

3.2 No details have been provided about the 'quantum' of funding approved for the project except that the demonstration budget is 'expected to be around \$2m over the period to June 1998'. DHFS has committed \$500,000 at this stage and further negotiations are pending. It has been stated that other amounts are provided by the Guild and 'commercial partners'. In an open process, such information would be public.

### **4. The Demonstration Trial**

4.1 Documentation provided to the Consultative Group states that the demonstration will provide evidence to determine the expected level of savings arising from the full scale project in the form of better administrative practices, faster processing of claims and [unidentified] benefits to consumers through better medication use and avoidance of unplanned hospitalisations resulting from drug misuse.

4.2 A stated purpose of the trial is to determine the feasibility, through the Intranet, of eligibility and entitlement for the PBS. These issues have been dealt with above. In discussion at the second meeting of the Consultative Group, members were told that the Pharmacy Intranet Demonstration would test compliance, identify people at risk and ensure quality use of medicines. The trial would pilot real time adjudication,

privacy issues and technological matters, for example, linking of data, response time, ability to transmit data and encryption. Data stored against individuals will enable appropriate intervention by pharmacists.

4.3 If the data collection is to 'provide the basis for an electronic medication record as an aid to consumers and health professionals in assessing and managing drug utilisation' as is also stated, numerous questions arise. How will consumers and health professionals access the information? Who will determine authorisation? How will appeals be made? How will the record be up-dated? If clinical decisions are made on the basis of the record, where does the medico-legal responsibility lie? The AMA seeks debate and resolution of these questions.

4.4 Without a 'built-in' evaluation plan prior to the commencement of the trial, it is not clear how the demonstration will 'provide sufficient evidence and operation experience to determine, with some certainty, the expected level of savings that could result from a full scale Pharmacy Intranet'. How will 'benefits to consumers and the community...through better medication use and the avoidance of unplanned hospitalisations resulting from drug misuse' be assessed and against what base-line data? It is not acceptable to state that 'towards the end of the demonstration an independent review of the results will be undertaken'. The incorporation of appropriate evaluation procedures is a threshold issue for the trial.

4.5 The statement that 'privacy principles that apply to a demonstration may not necessarily be the same as, or similar to, the principles that might apply to an operational National Pharmacy Intranet' does not accord with normally expected parameters for trials which should aim to test the design, environment and principles for the expanded program. It is difficult to understand the point of the trial being run under dissimilar circumstances. A trial is designed to be a model for the ultimate project, which cannot be foreshadowed if the principles are not faithfully replicated. Whether the ultimate program employs an 'opt-in' or an 'opt-out' choice for consumers is of utmost importance and should be regarded as a threshold issue for the trial.

## 5. Professional Issues

5.1 It is at the doctor/patient interface where the primary and most effective interventions occur. The Pharmacy Intranet proposal fails to recognise the centrality of the medical record held by the doctor. This record forms the primary repository for information regarding disease management and the adjunctive use of pharmaceuticals. A 'quality use of medicines' program must be based on these concepts. The project has the potential to duplicate the role of doctors.

5.2 Appropriately linked information technology systems on the doctor's desk would facilitate 'real time' medication review correctly interrelated with disease management. This is the only way the system can deliver the concomitant cost savings achieved through 'real time' identification and resolution of potential problems arising from adverse drug interactions, medication management and review, identification of 'doctor shoppers and collection of data on a national basis for use by a health providers, policy makers and researchers. In addition, the consumer is already protected by ethical and privacy codes covering the doctor/patient relationship.

5.3 The adoption of a standard Electronic Health Record (EHR) for use by Australian health providers was the subject of a GP Computing Group seminar on 17 November 1997. A standard EHR would facilitate a standardised, comprehensive

record of each patient's primary care treatment regime, enable effective and timely coordination and integration process with other sectors of the health industry and form the basis for the collection of data to sustain a population model of health care.

5.4 Instead, the Pharmacy Intranet project is technology driven and fails to deliver the systems necessary for a collaborative approach to patient care. Instead, it seeks to give pharmacists authority to over-see the prescribing habits of doctors. The project does not recognise the fact that a diagnostic hypothesis is tested against an iterative process related to a range of treatments of which medication is but one. Prescriptive evidence is used to narrow down the range of possible disease. The pharmacist, as dispenser of the ordered medication, would not have access to the patient's therapeutic plan or have the knowledge base required to understand disease processes and make appropriate treatment decisions.

## 6. Health Outcomes

6.1 Implementation of a system of health care based on outcomes will require acceptance of a complex range of initiatives and a multi-disciplinary approach to implementation. Such initiatives include development and application of valid, reliable and sensitive measures; use of a broad approach to research, development and monitoring which is intrinsically linked to health care delivery, and adoption of policy and practice that is firmly based on evidence of outcomes [Hall Journal of Quality in Clinical Practice 1996 V16].

6.2 With this in mind, and in the context of the Intranet, what is meant by the 'potential for implementing and achieving other outcomes such as improved health outcomes' and 'potential customer satisfaction'? What are these 'outcomes' and how are they to be identified and measured? How will the efficacy of the outcomes be judged and will assessment be based on outcomes of medium or longer term therapy? This is a major threshold issue for the project, including the trial, and relates to the development and incorporation, in the planning stages, of an evaluation plan with measurable and agreed criteria. At this stage there is only a vague mention of an independent review towards the end of the trial and the need to measure benefits and costs versus the loss of privacy.

6.3 There has been no discussion about the assessment process to be undertaken by the pharmacist. If it is to be 'one-off/per prescription' it would be useless in the dynamic process of diagnosis and treatment. If continuous, how is this to be managed? Clearly, there is duplication with the role of the doctor with concomitant additional costs. How will these additional costs be measured?

6.4 No reference has been made to payment for pharmacists in undertaking the proposed medication review and assessment role. Will pharmacists expect a prescription charge for auditing each prescription or for a series of prescriptions related to a treatment regime?

## 7. Conclusion

7.1 The potential pitfalls for the Pharmacy Intranet Project are numerous. There has been no public scrutiny commensurate with the privacy implications. The proposed benefits of the trial, apart from establishing 'on-line' access to facilitate already existing processes, present in some areas as being unsubstantiated and in others illusory or fabricated to fit the purpose.

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