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Developing and Implementing Guidelines for the Safe Handling of Cytotoxic Drugs and Related Waste: The Queensland Experience

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Introduction

A greater understanding of the nature of cancer and the role of cytotoxic drugs in treating malignant and non-malignant disease has led to an increase use of chemotherapy in a variety of clinical and non-clinical settings. Traditionally, patients have been managed in large tertiary treatment facilities in the major cities. However, the increasing use of cytotoxic chemotherapy, improvements in side effect management combined with demands for cost containment, advances in technology and a greater emphasis on consumer needs has contributed to increasing numbers of smaller centres providing chemotherapy services in cities as well as in rural and remote areas.

Chemotherapeutic agents have been demonstrated to be mutagenic, teratogenic and carcinogenic. Concern about the potential adverse effects of occupational exposure to cytotoxic drugs and their waste, grows from the recognition that cell damage produced as a therapeutic effect may appear in those exposed to the drugs and their waste within the work environment. Therefore, long term low level exposure to these agents during preparation, administration and disposal may constitute an occupational hazard.

While the literature suggests that there was evidence for the concern of healthcare workers involved in the handling of cytotoxic drugs and related waste in the 1970s, guidelines were not published before 1980. Letters and the results of a number of studies alerting workers to the risks of exposure appeared in a number of journals in the late 70s^{1,2,3}. However, the data from these studies reflect practices before guidelines were published, when safe handling practices were poor and provision of personal protective clothing was inadequate.

Background

The Society of Hospital Pharmacists of Australia published guidelines for the safe handling of cytotoxic drugs in 1980. These guidelines addressed issues relating to preparation and administration of cytotoxic drugs and were the first published guidelines worldwide. Revised guidelines in 1990 included personnel safety monitoring, waste, spills, storage and the transport of the agents⁴. The Royal Australian Nursing Federation followed the pharmacists' lead and released their policy on safe handling of cytotoxic drugs in 1984.

In Australia, each state and territory has its own Workplace Health and Safety authority. Therefore Codes of Practice and Guidelines for managing cytotoxic exposure have been independently developed by some state authorities. The South Australian Health Commission produced a Code of Practice for Safe Handling and Disposal of Cytotoxic Drugs in 1988 which was replaced in 1993 by Guidelines for the Safe Handling of Cytotoxic Drugs and Related Wastes in Health Units and Services⁵. NSW WorkCover Authority distributed safe handling guidelines, for use in New South Wales in 1992⁶.

In 1994, the Nursing Consultative Committee (NCC) which represents nursing concerns to the Queensland State Government's Minister for Health invited the Queensland Oncology Nurses Group (QONG) to identify issues that were of concern to their membership. QONG utilised this opportunity to raise concern about the increasing use of cytotoxic drugs in a variety of healthcare settings throughout Queensland with the NCC as well as the

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In December 1995 QONG met with representatives from the Division of Workplace Health & Safety. This forum was an opportunity to inform the Division of the increasing use of cytotoxic drugs in the workplace and to raise concern regarding the limited legislation that specifically covered cytotoxic drugs and related waste. From this meeting it was determined that the best direction for the QONG would be to consult directly with the Community Services Industry Workplace Health & Safety Committee to develop guidelines to minimise occupational exposure to cytotoxic drugs and related waste. In 1996 the Queensland Oncology Nurses Group and the Queensland Nurses' Union approached the Community Services Industry Workplace Health & Safety Committee and a Working Party was established.

Guideline development

The initial Working Party included representatives from the public and private health sector, domiciliary nursing agencies, Division of Workplace Health & Safety, Department of Health, Queensland Nurses' Union, the Queensland Cancer Fund and the Private Hospitals Association of Queensland. This committee met on a regular basis to develop guidelines and the training competencies for the safe handling of cytotoxic drugs and related waste in Queensland. The guidelines were adapted from the ***Guidelines for handling cytotoxic drugs and related waste in health care establishments*** prepared by the NSW WorkCover Authority. Committee members provided institutional policies and guidelines as part of this review process and consulted widely with industry colleagues in an effort to expand the relevance of the final document.

On 31 August 1997, the definition set out in the ***Workplace Health and Safety Hazardous Substances Compliance Standard 1995***⁷ changed. That is, from that date a substance was defined as being hazardous if it was listed in the ***List of Designated Substances***⁸ or if the substance met the Approved Criteria for Classifying Hazardous Substances⁹. Cytotoxic drugs meet NOHSC's ***Approved Criteria for Classifying Hazardous Substances*** because of the carcinogenic, mutagenic and teratogenic risk they pose to health care workers, and were therefore hazardous substances. The ***Workplace Health and Safety Regulation 1997 – Part 13 Hazardous Substances***¹⁰, which came into force in February 1998, has replaced the Compliance Standard and cytotoxic drugs are now covered under the requirements of this legislation.

The launch of the guidelines was to coincide with the changes to the definition of hazardous substances, however it was postponed to allow for broader consultation with other interested stakeholders. The committee believed that extensive consultation would ensure the final document reflected the current environment in Queensland. To this end the Working Party approached scientists, veterinarians, and representatives from Communicable Diseases Unit, along with the Department of Companion Animal Medicine & Surgery, Department of Transport, Rural Doctors Association, Infection Control & Sexual Health, Environmental Protection Agency, Department of Environmental Health Services, and other aligned departments within the State Government. Broader consultation resulted in a document that had relevance for healthcare as well laboratory settings and veterinary practices.

Dissemination and implementation of the guidelines

In recognition of the significant contribution of the QONG, the final document, ***Guide for Handling Cytotoxic (Antineoplastic) Drugs and Related Waste***¹¹, was launched at the Annual Oncology Nurses Group Conference in November 1997¹¹ by the Executive Director of the Workplace Health & Safety Program. The guide provides practical information for both employers and employees pertaining to the safe handling requirements of cytotoxic drugs and related waste in the workplace. The document is pertinent not only for nurses but also for other healthcare workers in hospital, community, laboratory, veterinary and/or home settings.

While the document does not contain specific procedures for the preparation, administration, management and disposal of related waste, training modules were developed to assist institutions to develop appropriate in-house policies and procedures. It was not the scope of the document to provide practical safe handling information for patients receiving cytotoxic drugs or their families. This remains an area of uncertainty for

patients as well as for healthcare workers and requires further attention.

The guidelines were published in 1997 and disseminated through the Department of Health to all public and private hospitals and domiciliary services throughout Queensland.

The document is also accessible from the Department

of Training and Industrial Relations Website: www.detir.qld.gov.au/hs/guide/gde17.pdf.

Review of the guidelines was to occur in 1999 however this has been postponed.

Evidence suggests that if appropriate measures are employed the potential risks associated with occupational exposure to cytotoxic drugs and related waste will be minimised (Oncology Nursing Society, 1989). However, research has shown that in spite of guidelines and recommendations from professional groups and institutions, healthcare workers do not always practice what they know is safe practice^{12,13,14}. Gullo¹² reports that less than 40% of nurses practice safe handling measures when handling cytotoxic drugs and their waste products.

A number of facilities providing chemotherapy services report that institutional policies and procedures have been reviewed following the dissemination of the guide in 1997. However anecdotal evidence suggests that annual evaluation of competencies related to the safe handling of cytotoxic drugs is not occurring and that certain nonsensical practices remain unchanged.

Conclusion

The issue of cytotoxic exposure remains controversial however sufficient evidence confirms the need for health care workers to exercise vigilance when handling these drugs and their related waste. While the **Guide for Handling Cytotoxic (Antineoplastic) Drugs and Related Waste** is based on scientific evidence it has also taken into account what is unknown and what is suspected.

These guidelines are a minimum standard and are only as good as the implementation process that accompanies them. While monitoring compliance is difficult there is a requirement for greater compliance with the recommendations concerning safe handling practices and personal protective measures to minimise the risk of exposure to cytotoxic drugs and related waste. The increasing use of cytotoxic therapy and demand for chemotherapy services requires legislation in every state and territory to ensure that the recommended facilities for preparing these drugs are available, that adequate personal protective equipment is provided and that workers are provided with adequate educational preparation.

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