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PRINCIPLES OF THE MANAGEMENT OF RADIONUCLIDE THERAPIES

by the
Advisory Committee on Radiological Protection
and the
Group of Medical Advisers

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EXECUTIVE SUMMARY

This report is intended to review the management of patients who have been given therapeutic doses of radiopharmaceuticals as well as those patients who have had brachytherapy sources placed within them. Unavoidably, these patients are a source of exposure to others, either directly in the form of gamma rays or potentially indirectly in the case of radiopharmaceuticals, through contamination of the environment and subsequent contamination of others. The dose received by persons in close contact with the patient, such as health care providers, family, friends and co-workers, will be proportional to the time and proximity of contact and the care taken to minimize contamination. If the needs of the patient are to be met, some radiation exposure of others is inevitable, and a balance has to be struck between the risk of radiation exposure on the one hand and the necessity of meeting these needs on the other.

It is the current practice to admit patients to hospital for certain radionuclide therapies, most often simply for the purpose of isolation until levels of radiation have diminished to an arbitrary level. This is usually followed by an additional number of days during which the patient is instructed to minimize contact with others. This practice is rooted in the past and is based on an overly simplistic physical dose model, and in part, on a system that did not take into account that patients might have both rights and responsibilities in the implementation of their treatment.

In Canada, there are clearly defined safeguards for workers and members of the public who are exposed to radiation from radionuclide therapies and sealed brachytherapy sources. On the other hand, effective measures to ensure patient and family safety in the delivery of radionuclide therapy are not applied uniformly in Canadian centres. Instead, reliance is placed upon the application of commonly accepted safety practices and upon the training of the professional staff. The Advisory Committee on Radiological Protection (ACRP) and the Group of Medical Advisers (GMA) expressed concern that the management of exposure to the family, clinical support staff and the public from patients given radionuclide therapy, was shown to vary across the country, and undertook to gather the radiation protection principles suitable for comprehensive uniform guidance for all Canadian medical institutions performing new and established radionuclide therapies. These principles are consistent with current Atomic Energy Control Board (AECB) regulations, current International Commission on Radiological Protection (ICRP) thinking and the practices applied in most western countries.

The number of radionuclide therapies is increasing and is predicted to increase dramatically. From an estimated $48 million dollars revenue in 1996, a 9.2 fold increase to $440 million is predicted in 2001 (Fr98). By 2020, a further 13.6 fold increase to 6 billion dollars is predicted. If this prediction is correct and results in the more widespread use of radionuclide therapies, and if radionuclide therapy is managed as it is at present in Canada, large additional expenditures will be required simply to quarantine the increased number of patients being treated to reduce the small radiation risk to others. This expenditure is unlikely to be acceptable when compared with the costs we are willing to accept to avoid other risks of a similar small magnitude.

This report will also summarize the results of a survey of patients' perceptions on the isolation currently employed in radionuclide therapy.

The ACRP/GMA recommends that the criteria for releasing patients from hospital post treatment with radionuclides be based on a more precise and realistic estimate of the dose to family members, care givers and members of the public, rather than the current retained activity.

The recommendations may be conveniently divided into two categories:

A. OUTPATIENT MANAGEMENT

1. The criteria for the release of a patient from hospital following radionuclide therapy should be dose-based, rather than activity-based. Pending the development of an acceptable quantitative method for estimating the dose to others from a specific treatment, a conservative activity-based criterion may be temporarily warranted.

2. When an outpatient radionuclide therapy regime is adopted, the adult family caregivers of such patients should be subject to a dose constraint of 5 mSv for the course of treatment. The public annual dose limit of 1 mSv should be retained for children and pregnant women in the patient's family, co-workers and other members of the public.

3. The appropriate professional organizations should review the existing protocols produced elsewhere to reduce doses and determine if they are applicable to the Canadian situation.

and

B. CHALLENGES OF NEW PROCEDURES

4. All centres providing radionuclide therapies have the responsibility to ensure that facilities, education, training and care are of a high standard.

5. It is recommended that the Medical Facility ensure the availability of multidisciplinary treatment teams for the implementation of more complex applications of radionuclides therapy procedures.

6. The accuracy of information acquired by the general public and the health-care workers and physicians peripherally involved in radionuclide therapy is generally poor. The treating physician should make every effort to improve the availability and accuracy of the information provided to these groups.

7. The Regulatory Authority should allow these treatments to be accessible to patients without undue burden on the institution, as long as accepted radiation protection principles and good practices are maintained. This attitude is especially important during trial phases of new modalities of treatment.

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1. INTRODUCTION

1.1 Background

Many types of cancer and some other non-malignant diseases can be treated with the radiations emitted by radionuclides. The three types of treatment are: teletherapy, radiopharmaceutical therapy and brachytherapy. Teletherapy is not discussed in this report. Radiopharmaceutical therapy with unsealed sources and brachytherapy with sealed sources are identified in this report as radionuclide therapy.

Radionuclide therapy in hospital has been commonplace for several decades. In recent years, however, new radiopharmaceuticals have been introduced and both sealed and unsealed sources are being used in the treatment of malignant and non-malignant diseases. In Canada, clearly defined safeguards have been developed to protect workers and the general public who are exposed to radiation from traditional therapies. However, similar safeguards to ensure protection against the newer radionuclide therapies are by no means as finely developed. In addition, effective measures to control the doses to family members even from the traditionally used radionuclide therapies, are not uniformly applied in Canadian centres. Instead, reliance is placed upon the application of accepted safety practices and professional judgement. In view of the rapid expansion in radionuclide therapy and the variation in the application of safety principles across the country, the Advisory Committee on Radiological Protection (ACRP) and the Group of Medical Advisers (GMA) undertook to review such therapies, identify the radiation protection principles involved and develop principles for the safe management of patients in the established therapies and in the expanding field of new radionuclide therapies.[1]

Iodine-131 is a useful reference therapeutic radionuclide because of its widespread use and the presence of an external radiation field from its energetic gamma emissions which irradiates other people. Historically, if the administered activity of Iodine-131 exceeded 1.1 GBq, the patient was admitted to hospital and isolated, a so-called activity based action. More recently, high dose radiopharmaceutical therapy is being administered to outpatients in some Canadian centres, based on the assumed dose delivered to others in contact with the patient [Ca99]. However, since other radionuclides have a different metabolic pathway, radioiodine should not be used as an exclusive model.

1.1.1 Populations at Risk from Radionuclide Therapies

An out-patient or a discharged in-patient treated with radioactive material has the potential to expose other individuals with whom he or she comes into proximity and also the potential to contaminate his or her environment. Thus all members of society are potentially at risk of exposure whether at hospital, home, work, or in a public place. However, based on time and distance considerations, it

[1] In September 1999, the GMA was folded, with some modifications, into the ACRP.

is reasonable to conclude that, in the overwhelming majority of cases, the individual most exposed to radiation or radioactive contamination coming from a patient will be an occupationally-exposed Nuclear Energy Worker (NEW), a primary caregiver or a member of the family.

The potential contamination of the home environment of the patients treated as out-patient should be considered. The excretion of radionuclides by patients into the sewage system has been shown not to pose a hazard to the public or sewage workers [AE96]. See Appendix A for more details.

1.2 Other Relevant Guidance and Regulations

1.2.1 United States of America

The National Council on Radiation Protection and Measurements (NCRP) has a long history of providing radiation protection advice going back to 1928. It has emerged as the US national advisory body on all aspects of radiation protection and measurements. It has no regulatory powers, but its Reports are regarded as authoritative. Radiation regulations in the US are only slightly different from those in Canada, and NCRP reports can therefore be considered applicable to the Canadian situation, and their recommendations might be regarded as "good practice", even if they are sometimes more stringent than the requirements of Canadian regulations.

While it is based on a model which is not regarded as very accurate today, NCRP Report No. 37 entitled: "Precautions in the Management of Patients who have Received Therapeutic Amounts of Radionuclides" is still a useful document, containing facts and figures and recommended procedures for handling radionuclide therapies, including I-131 therapies, the release of patients from hospital, emergency surgery or death of radioactive patients, and burial or cremation.

NCRP Commentaries, such as Commentary No. 11 "Dose Limits for Individuals Who Receive Exposure From Radionuclide Therapy Patients", provide preliminary evaluations, critiques, reviews, the results of exploratory studies, or are extensions of previously published NCRP reports.

The US Nuclear Regulatory Commission (NRC) has revised their Regulations (10 CFR 35.75) to include dose-based, as well as the traditional activity-based criteria for the release from hospital of patients after radionuclide therapy [NR97]. In addition, new dose constraints are established for those persons exposed to a released patient. It is expected that these changes will permit many radionuclide therapies to be undertaken on an out-patient basis [Si99].

1.2.2 European Commission

The work of the European Commission in radiation protection is governed by the EURATOM Treaty and its Council Directives. The most significant of these directives is the Basic Safety Standards Directive (BSS) on the radiation protection of exposed workers and the public (80/836/EURATOM), which was revised in 1996 (96/29/EURATOM). Article 31 of the EURATOM Treaty enables

guidance on special subjects to be developed with the assistance of a group of health experts. Under this article, the European Commission published guidance on "Radiation Protection following Iodine-131 therapy (exposures due to out-patients or discharged in-patients)" in 1997 [EU97].

Such guidance is not legally binding on Member States of the European Union. However, the guidance on Iodine-131 treatment is a clear exposition of the current radiation protection principles and practices required to ensure optimal safety.

1.2.3 Britain

A Working Party of the British Institute of Radiology, which included wide representation from other relevant groups, has published guidelines for the release of patients following radionuclide therapy, which is compatible with the Directives of the European Commission, and follows the current trend towards a more flexible approach [BI99].

2. THERAPY WITH RADIOACTIVE SUBSTANCES

As noted in the Introduction, radionuclide therapy embraces radiopharmaceutical therapy (unsealed radioactive materials), and brachytherapy (sealed radioactive sources).

2.1 Radiopharmaceutical Therapy with Unsealed Sources

The radionuclides used in radiopharmaceutical therapy are usually relatively short-lived beta emitters, but alpha emitters are under active investigation. Most of these radionuclides also emit photons, which usually contribute minimally to the treatment dose, but which produce an undesirable radiation field emanating from the patient.

The most common types of radiopharmaceutical therapy are the oral administration of capsules or the intravascular administration of liquids (systemic therapy) and the instillation of colloidal suspensions into closed body cavities (intra-cavitary therapy).

The radiopharmaceutical may be completely retained within the patient's body until the radionuclide has decayed to background levels. In this case, the only risk to a member of the public is the photon field surrounding the patient's body. However, most therapeutic radiopharmaceuticals are taken up with less than 100 percent efficiency and are altered by biological processes, and some fraction of the administered activity may appear in mucous secretions, sweat, vomitus, faeces or urine.

In their simplest forms, radiopharmaceuticals may be inorganic salts (e.g., $Na^{131}I$) that are able to enter a metabolic compartment and, being indistinguishable from the normal substrate, become concentrated in the cells of the target tissue. The concept of therapy with this class of drugs is half a century old.

Advances in biological knowledge at the molecular level have resulted in the development of a class of radiopharmaceuticals that concentrates in the cells of target tissues through a variety of mechanisms, including concentration in neurosecretory storage granules, e.g. ^{131}I-mIBG, affinity for hormonal receptors, e.g. variously labelled somatostatin analogues, or by immunologically mediated means, such as ^{131}I-monoclonal antibodies. In these often chemically complex drugs, the structure of the carrier molecule provides the means of localizing the attached radionuclide to the target cells.

Another class of radiopharmaceutical is that of drugs that concentrate in bone mineral rather than in living cells. These drugs are used to irradiate painful bone metastases, thereby relieving severe pain. The historic prototype of this class is ^{32}P-phosphate, the use of which is associated with significant bone marrow toxicity. ^{89}SrCl and ^{153}Sm-EDTMP have exhibited less toxicity in this regard and are now approved in Canada. Other similar drugs are being developed for this application.

A table of the physical properties of radionuclides currently in clinical use or that show promise for radiopharmaceutical therapy can be found in Appendix B. Verbruggen [Ve90] and Hoefnagel [Ho91] have identified a list of available tumour-seeking radiopharmaceuticals (Appendix C).

2.2 Brachytherapy with Sealed Sources

Brachytherapy is the treatment of small volumes of tissue by sealed radioactive sources placed a short distance from the target tissue, frequently by a surgical procedure. Such sources may be designed to remain in the patient's body permanently, delivering the dose to the treatment site over a prolonged period. Others may be removed after a shorter period of irradiation ranging from a few minutes to several days.

Sealed sources were implanted manually for the first half of the 20th century as interstitial and cavitary inserts. Later developments, however, involved the positioning of the "cold" brachytherapy device first, then later loading it with the radioactive source. This technique, known as afterloading, reduced the radiation exposure of the radiotherapy personnel. Since the 1970s, developments in the field of automated remote afterloaders have led to greater versatility in brachytherapy use. The activity distribution within the catheters could be changed, allowing more flexibility in treatment dosage, and radiation treatment could now be delivered at a low dose rate while the patient was hospitalised for a few days, or at high dose rate according to clinical circumstances. High dose rate treatments can often be completed in a few minutes on an outpatient basis in specially built rooms in the radiation oncology department.

Although remote afterloaders have replaced most of the older techniques, manual brachytherapy is still used for the treatment of some malignant and non-malignant diseases in the form of temporary or permanent implants. For example, ^{125}I seeds are inserted into an eye plaque and left in place for a few days and ^{90}Sr is used to treat superficial lesions of the eye, such as pterygium.

Radionuclides used for permanent implants and for extended-duration outpatient brachytherapy are relatively long-lived photon emitters which are contained in durable needles or seeds. Where the photons are of low energy and the sources are deep within the patient's body, the external radiation field is usually of little concern. However, the sources may be placed near the surface, so that even low energy photons can create a measurable field. In the case of the ^{125}I or ^{102}Pd seeds used to treat prostate cancer, this external field is low and the dose is not considered to be a major problem to the family or public. Implants using sources that emit high energy photons may irradiate other people regardless of the treatment site.

If a seed works its way out of the treatment site and appears in excreta, or falls out of a plaque into clothing, bedding or onto the floor, this rare type of accident may present a radiation exposure risk to others. The death of a patient containing a permanent implant may also result in radiation exposure to other persons.

The field of endovascular brachytherapy has been developed recently and is rapidly expanding. An investigation of permanent vascular implants with low activity ^{32}P placed in the coronary arteries in the form of radioactive stents is currently underway to assess their efficacy in preventing coronary re-stenosis. Trials are also being conducted on the use of hand-held devices and remote afterloaders containing beta or gamma emitters for high dose rate treatment of diseased coronary arteries.

Different radiation protection considerations will accompany the introduction of these new applications of radiation therapy in hospitals. Radioactive sources will be handled in locations not initially designed for this usage and by personnel not familiar with radiation therapy. Each new procedure needs to be reviewed before its implementation in order to assess the appropriateness of the location, any required changes to the safety programme, the expertise of the user and the training programme required for the personnel involved. Some of these procedures will necessitate a multi-disciplinary approach and demand close collaboration between the specialists involved in performing the procedure.

Another type of radionuclide therapy consists of combined radiopharmaceutical therapy and brachytherapy. Unsealed sources can also be introduced into a specific treatment site. This type of treatment will lead to different radiation protection needs than systemic therapy where a radiopharmaceutical is administered orally or into the vascular system. Such types of therapy include the instillation of a colloidal suspension into a closed body cavity like a joint. It could also be in the form of microspheres deposited in a tumor by vascular catheterization, as in the treatment of liver tumors with high activities of ^{90}Y. Unlike radiopharmaceutical systemic therapies such as ^{131}I thyroid cancer therapy, these treatments do not pose an external radiation hazard for the family or public when alpha and beta emitters are used and will not lead to the same level of contamination. Nevertheless, specific radiation protection measures will be required during the performance of the procedure.

The physical characteristics and clinical applications of many of the radionuclides used in brachytherapy can be found in Appendix D.

3. POTENTIAL EXPOSURES FROM RADIONUCLIDE THERAPY PATIENTS

3.1 Sources of Exposure

Radionuclide therapy with both radiopharmaceuticals and brachytherapy produces radiation fields that are usually detectable outside the patient's body. The magnitude of these fields varies dramatically, depending on the activity administered, the abundance of photon emissions and the spatial distribution of the radionuclide within or upon the patient's body.

Radiopharmaceutical therapy is generally ill-suited to external shielding, since the radionuclide tends to be distributed throughout a large volume of the patient's body. The only practical way to control the dose to a member of the family or the public from the external radiation field of most radionuclide therapy patients, is to minimize the contact time and to maximize the distance from the source.

3.2 Doses from Contamination

Historically, doses to caregivers from radiopharmaceutical contamination were monitored and controlled while patients were hospitalised for treatments. In the case of iodine-131 treatment after thyroidectomy for thyroid cancer, as much as 95% of the administered activity could be excreted in the first few days. Although the major source of exposure to other people is the gamma field associated with the patient, patients had to be instructed that their bodily secretions and excreta contain radioactive material. Depending on the type of treatment, patterns of excretion needed to be explained to the patient, and they required counselling on how to minimize any contamination which could affect others.

3.3 Exposed Populations

3.3.1 Medical Facility Patients

Some radionuclide therapy patients must be confined for medical care following administration of the radioactive material. A "medical facility" is a hospital or any other type of special facility, other than the patient's own home, that might be employed for therapy and medical confinement. When the exposure rate is appreciable, the patient must be isolated from other patients, usually by requiring the patient to remain in a private room until other radiation safety precautions are sufficient. There is some variation in the protective measures required to minimize the dose to other patients in order to remain within the dose constraints of 500 μSv for non-radiation therapy patients. Often this criterion can be met merely by re-arranging the beds, but some hospitals, with heavy radionuclide therapy workloads and limited private rooms, have constructed specially shielded rooms. These expensive measures are made necessary by the need to assume that the radionuclide therapy patient will irradiate patients in adjacent rooms 24 hours per day, and a survey of the dose distribution in adjacent rooms may be necessary to ensure that the dose constraints are not exceeded.

3.3.2 Family Members

A "family member" is any person who spends a substantial amount of time in the company of the patient on a regular basis, providing support and comfort, and whom the patient considers a member of their "family", whether by birth, by marriage, or by virtue of a close, caring relationship.

Any malignant or non-malignant disease is quite rightly regarded by the patient and the family as a serious illness, with the possibility of job loss, economic hardship and even death. During such times of stress, families tend to be drawn together and rely on each other for emotional and psychological support. While there is individual variation from family to family, most members feel that they should make the effort to support the patient and other family members. If treatment with radioactive materials is required, this adds a further dimension of concern to both family and patient. In such circumstances, any unnecessary restrictions on access to the patient should be avoided. If the patient is confined in hospital for medical reasons or because the home situation does not permit treatment at home, visiting privileges for family members should be given and visits by adult members of the family encouraged. It is very unlikely that a vistor would ever receive a dose above 5 mSv, the allowable dose (see Section 4.1 and 5.l.l), during daily visits to the patient and this measure could reduce the stress that might accompany staying in hospital and provide psychological support to the patient. Unnecessary isolation, especially for long periods, should be avoided. (Appendix E).

3.3.3 Members of the Public

The category "members of the public" applies to any person who is not a radionuclide therapy patient, a NEW nor a family member. These people are subject to a 1mSv annual dose limit. Within the health care institution, it includes all workers who are not classified as a NEW, but who attend the patient, such as nurses, orderlies, and urology personnel for prostate implant therapy, or some personnel in the cardiology department. In the case of a patient treated on an out-patient basis, it includes members of the general public, his or her colleagues at work and home visiting caregivers. It also includes personnel of nursing homes where older patients may be treated and who are subject to the 1 mSv annual dose limit. With an ageing population it is not unreasonable to foresee that these caregivers might be in contact with more than one therapy patient in a single year.

It is essential that the potential exposure to members of the public be assessed by the licensee for new modalities of treatment implemented in hospitals and for radionuclide therapies administered on an out-patient basis. It is also important that the occupationally exposed professional health care giver who is not classified as a NEW has sufficient specialised training to limit his or her exposure while not compromising the delivery of high quality care.

3.4 Special Situations

Patients should be alerted to unusual or special situations where events which are very rare may occur and what they should and shouldn't do in such cases and where they can access advice when

needed. For instance, brachytherapy sources are durably encapsulated and are unlikely to rupture and result in a contamination risk from dispersal of the material. However, a possible situation, where a considerable dose to the intestinal tract could be expected, is if a child swallowed a dislodged brachytherapy seed. Such an accidental event would be extremely rare and impossible to prevent. Nevertheless, the patient should be aware that a source could be dislodged and should be able to recognise a seed and take the necessary precautionary action if such a situation arises.

Patients should be made aware of the actions that they should take to minimize the contamination that may result from unforeseen incidents such as vomiting or stress incontinence. Other potential exposure of the health care community to contamination might arise when there is an unexpected death soon after therapy or when surgery is undertaken for an unrelated disorder. Again, these events will be extremely rare and can be largely avoided by adequate record keeping. In addition, the routine protective actions taken against infection from pathogens will provide some measure of protection against the contamination and exposure of unknowing hospital personnel. However, therapeutic radiopharmaceuticals and permanent sealed source implants could conceivably constitute a hazard at emergency surgery, at autopsy or as a result of cremation. These potential circumstances of inadvertent exposure have long been recognized, but their importance is limited by their infrequency as well as the existence of protocols in treating institutions to deal with them. In the case of permanent implants, such as for the treatment of prostate cancer, the frequency of such events may increase with the increasing use of these new modalities, and measures should be implemented to prevent loss of sources. There has been some concern expressed about exposure of crematoria personnel to the dust of patients treated with ^{89}Sr, given the long half life of this radionuclide. The recent approval of ^{153}Sm, a short-lived radionuclide for the same application, will displace some use of ^{89}Sr, further minimizing the potential inhalation doses. It should also be emphasized that the more realistic health concern for these workers is the exposure to the fine respirable ash which occurs after every cremation, rather than the radiation exposure from the inhalation of radionuclides.

In essence, the likelihood of a significant dose from contamination being acquired by caregivers or other incidentally involved health personnel from an accidental exposure will be small and as long as there is an awareness and an ability to deal with the issue will require any specific preventative measures.

4. CURRENT AND EVOLVING MANAGEMENT OF RADIONUCLIDE THERAPY

4.1 Radioiodine Treatment Model

The external radiation exposure to others is directly related to the quantity of administered activity, its effective half-life, and the amount of time spent in proximity to the patient, particularly in the early hours and days after treatment.

For many years in the USA and Canada, it was the practice to admit patients to hospital for certain radionuclide therapies, most often simply for purposes of quarantine until levels of radiation had reached an arbitrary lower level (1.1 GBq in the case of ^{131}I) followed by an additional number

of days during which the patient was instructed to minimize personal contact with others [NC70, MA93]. This practice is derived from an old inadequate model of the patient as an I-131 point source with close associates at 1 metre distance for 8 hours per day and whose radiation dose was limited to 5 mSv to complete decay. The external radiation field emanating from patients undergoing ^{131}I therapy for hyperthyroidism and thyroid cancer at various times after the administration of activity has been studied extensively by a number of authors [Ba96, Ba96a, Be92, Ca95, Cu92, Gu96, Hi91, Mo98, O'D93, Th95, Th96, Wa93]. These studies provide a more realistic estimate of the dose to others by regarding the patient as a distributed source with significant attenuating properties. It has also been found that the dose to others in proximity to the patient can be significantly reduced by behaviour modification. For example, Barrington et al. [Ba96] have monitored patients' homes and families following ^{131}I therapy. Patients were given instructions about self isolation in their homes and provided with diaries to record instances of unavoidable breaches and all family members were fitted with dosimeters for several weeks. In 85 of 87 cases they found that children received doses less than 1 mSv with patient administered activities of up to 700 MBq. These investigators determined that patients could be expected to behave reasonably if given clear instructions and that outpatient treatment can be provided safely. The revised US NRC (10 CFR 35.75) regulations agree in general with these findings and will permit more radionuclide therapies to be performed on an outpatient basis [Si99]. Widespread reassessment of all these factors leads to the conclusion that even high dose radionuclide therapy on an outpatient basis may be feasible under specified conditions and for certain patients after appropriate assessment.

Moreover, it should be pointed out that health care delivery has evolved over the last fifty years. Technological development of diagnostic and therapeutic machines, advances in pharmaceuticals and treatment regimes and other allied advances have led to sophisticated treatment modalities which not only improve medical treatment, but also add to the escalating cost of health care provision. With this evolution have come changes in the attitudes and relationships between patients and the providers of their health care. Where possible, health care is provided on an outpatient basis, and, for instance, day surgery is undertaken on this basis to avoid costly hospitalisation.

ICRP 60 (IC60) and, more recently ICRP 73 (IC73), have recognized that patients are often best supported during their treatment by members of their families who "willingly and knowingly" accept a radiation exposure in order to provide care and comfort. Depriving a patient of close family support by isolation at the very time when they are under threat by disease is contrary to this trend, and tends to promote resentment. The isolation protocol also serves to reinforce the notion that the patient is caught between a threatening disease and a dangerous therapy. The family members, for their part, may feel an equally urgent need to give support and comfort, even at some notion of risk to themselves whether the patient is isolated in hospital or treated at home. A treatment protocol should acknowledge the benefit of such support within the limits of safety (Appendix E).

Since these exposures are unlikely to recur frequently in any family, it is the ICRP recommendation that they be excluded from the 1 mSv annual limit so long as they are likely to remain below 5 mSv and can be averaged to 1 mSv/annum or less over 5 years. It is the responsibility of the treating

physician or the treatment team to ensure that the dose limits and dose constraints are not exceeded when multiple therapies are undertaken.

The European Commission has established common principles and standards for radionuclide therapies among its member countries. The onus is now on each member country to revise its legislation and regulations in conformity with the agreed standards. However, it is evident that in differing national cultures, the standards are capable of being interpreted in quite different ways [Ho99]. At one extreme is Germany where every radionuclide therapy patient was, until recently, admitted until the body burden fell below 74 MBq, and even the safety of this level has been questioned. In Germany there are 800 hospital beds currently committed to radionuclide therapy and there is a movement to increase this number to 2000 by the end of the next century so as to reduce therapy waiting times to an acceptable length. Germany has recently found it necessary (1998) to raise the discharge limit because increasing numbers of patients were seeking treatment outside the country in preference to waiting for beds to become available.

In Canada, the 1.1 GBq limit for outpatient ^{131}I therapy has been part of most practice guidelines [MA93]. However, the Atomic Energy Control Board (AECB) has been amenable to variations from this guideline subject to meeting reasonable assurances of radiation safety, such as acceptable arrangements for travel to home, suitably separated sleeping quarters and toilet facilities, and the capability to avoid close contact with small children or pregnant women. In this way, it is possible to discharge safely some high dose therapy patients to their homes with body burdens greater than 1.1 GBq.

Several software products are available that facilitate dose estimation to family and care givers. Barrington et al [Ba 96] have developed a software package (Canterbury) for dose estimation for family members of treated patients. A flexible product has been produced by Cormack and Shearer (Co98) that takes the radiopharmaceutical, time and exposure distance as well as the population vulnerability (e.g., children vs adults) into account. This product is adaptable for use with any radiopharmaceutical and is helpful for patient education as well as documentation of expected exposures through unavoidable contacts and as a guide in behaviour modification to reduce the dose to others. (See Appendix F). Because many new developments are expected in this field, it is difficult to recommend a single program, although some committee members report satisfaction using this product.

4.2 Psycho-Social Issues

Serious illness results in a reduction of the quality of life, as the patient is subject to the restrictions imposed by investigations, treatment regimes and a lack of well-being. Furthermore, psychological stress from anxiety and a reduced self-esteem can lead to emotional problems [Ho84]. In the past, radionuclide therapy has been largely undertaken in hospital and required the isolation of the patient and restricted visiting. Such isolation, if prolonged, may augment the psychological effects of the illness, not only for the patient, but also the family.

In a study to explore the experience of receiving radioactive iodine (Appendix E), 63% of patients, who received high dose treatments as an inpatient, experienced fatigue, 52% dry mouth, 51% felt down and depressed. Patients who received a lower dose of radioactive iodine, also reported distressing symptoms, 56% reported fatigue, while 52% reported anxiety. Both groups had a low number of respondents who reported receiving adequate help to deal with these symptoms. Family members also reported a range of issues they were dealing with during the interval of the radioactive iodine treatment. Anxiety was identified by more than half of the family members in both the inpatient and outpatient groups. The types of issues were similar between the two groups of family members and included feeling apart from the patient, fear and feeling down or depressed.

Having access to information was very important to patients receiving treatment either as an inpatient or outpatient. The types of information which respondents cite as most difficult to obtain were: the opportunity to speak to another patient in the same situation, availability of counselling services, emotional effects, and diet and nutrition. Family members also indicated that information about the patient's treatment and condition were important for them to know. Only half of the family members who responded to the survey indicated they were satisfied with the information they received. Family members indicated a need to talk to someone else about the issues related to the disease and the treatment, but very few individuals had the opportunity to attend self-help groups or support services.

As new treatments develop and existing treatments change, it will be essential that patients and their families are kept informed, and have access to needed support. It is evident that information and support are required for patients receiving low dose treatment as an outpatient, or high dose treatment as an inpatient. It was also noted in this survey that outpatients with a diagnosis of a non-malignant disease had similar information and support needs as those who received high dose treatment as an inpatient for a malignant disease. Enhancing the education provided to patients and families also implies educating family physicians, nurses and other team members who come in contact with them during their treatment, to ensure that the information they receive is correct, current and consistent.

4.3 Societal Values

The responsible use of scarce health resources in modern society is basically controlled by a cost/benefit approach. If too much is spent on controlling trivial problems, less will be available for matters of major health significance. The importance and necessity of an institutionally controlled and monitored quarantine needs to be evaluated and compared with other possible approaches. Patients recall these hospitalizations as having been experiences to endure, without any apparently justifiable value. Outpatient treatment is a better use of health care resources, provided that the patient's circumstances allow for the essential behavioural modification for the appropriate post therapy interval. In general, patients currently tend to be better informed by government programs and self-help groups, and are much more capable of participating in the provision of their treatment, although as noted above, this is not always the case.

Canada has become a complex multicultural nation and it is necessary that our regulatory processes reflect its diverse cultural practices. Among some groups, there can be safety issues involved in the event of the death of a patient with radionuclides still present in the body. Traditional rituals for preparation of a body for burial can conflict with regulatory requirements, but families need the comfort of their familiar rituals at this stressful time, and the regulations should be applied with sensitivity. It is increasingly important for authorities, whether institutional or governmental, to be flexible and to use judgment, not only to develop and enforce a written policy, but also to seek solutions which recognize the human and psychological needs while honouring the necessary radiation protection principles.

There is also the social issue of the responsibility of professional people to promote a balanced public view of advances in medical technology. When dose avoidance considerations at very low doses are allowed to dominate considerations of basic humanity and practicality, then the practices convey an exaggerated message of the hazard, thereby increasing public anxiety. All professionals engaged in the provision of therapy with radioactive materials have a clear duty to provide accurate assessments of the radiation risk as well as the utility of such treatments, to patients, other health professionals and the public.

4.4 Radiation Burden to Hospital Workers

Throughout the history of Nuclear Medicine there has been a research thrust to develop therapeutic radiopharmaceuticals. In recent years a number of these efforts have matured and there has been rapid progress in the development of useful new agents. The number of radionuclide therapies is increasing and will continue to increase dramatically. Frost & Sullivan were commissioned by Battelle Pacific Northwest National Laboratory to provide an economic forecast of the growth of therapeutic radiopharmaceutical markets in the United States [Fr98]. From an estimated $48 million revenue in 1996, a 9.2 fold increase to $440 million is predicted in 2001. By 2020, a further 13.6 fold increase to $6 billion is predicted. However, this growth rate has not been seen largely because of the lack of government funding for these new drugs.

When this projected growth of brachytherapy starts to materialize, this will result in an increase in radiation exposure of hospital personnel. Many of these procedures will be performed under ultra-sound guidance or in interventional radiography theaters. Most of these procedures use low energy gamma emitters or beta emitters that do not produce a significant radiation field around the patient, so that the exposure to staff will be restricted to the personnel who handle the sources and perform the procedure. This projected increase in utilization and implied increase in staff dose cannot be accommodated by current practices, particularly if the treatments produce a significant associated radiation field around the patient and hospitalizations become more prolonged. It is the responsibility of the licensee to ensure that all workers involved in providing radionuclide therapy are adequately trained and appropriately classified as to minimize the dose. Sufficient staff, including those working in radiopharmacy, will be needed for rotation through high-dose activities.

5. PROPOSED PRINCIPLES OF OUTPATIENT MANAGEMENT OF RADIONUCLIDE THERAPY

Recommendation 1: **The criteria for the release of a patient from hospital following radionuclide therapy should be dose-based, rather than activity-based. Pending the development of an acceptable quantitative method for estimating the dose to others from a specific treatment, a conservative activity-based criterion may be temporarily warranted.**

5.1 Suitability for Outpatient Treatment

Before discharge to home after treatment can be contemplated, the treating physician needs to be assured that the patient and family caregiver are willing and capable of following the protocol required for home treatment. Some brachytherapy treatments with sealed sources and instillation of beta emitters are easy to perform on an out-patient basis without involving modifications of the patient's life-style. For example, ^{125}I seeds in eye plaque implants or prostate implanted seeds, may require only that information be given to the patient and family on emergency measures in case of loss of a source or death of the patient.

Therapies with radiopharmaceuticals on the other hand may involve temporary modification of the patient's and caregiver's life-styles. Additionally, the home circumstances must be such as to ensure that the protocol involving semi-isolation and family behavioural modifications can be met. Not all patients are suitable for discharge home soon after radionuclide therapy. Their home environment may be inadequate, there may be no family at home to provide the care, they may be unable or unwilling to do so, or the family group may not be able to understand what is required of them.

It should be recognised that the circumstances and attitude of each family group differs, and that a decision on suitability for treatment needs to be assessed on a case by case basis. It is not sufficient to impose this treatment modality on the sole basis of cost saving, as an individual assessment of the family circumstances is required in each case. In most cases, this assessment will be easily made based on interviews, but in marginal cases, an in-depth assessment of the home circumstances may have to be made by specialized health personnel. To reach a decision on the suitability of a patient for treatment, the patient and members of the family need to be interviewed not only to provide the appropriate written and oral information and instruction, but also to verify that the patient and family understand what is required of them, and that they are willing to comply with these requirements. If there is doubt concerning suitability of a patient, the task of assessment may need to be shared among different members of the health-care providers, such as the treating physician, the nurse and the social worker. The potential exposure of the family members and members of the public may need to be evaluated by the Radiation Safety Officer (RSO) or the medical physicist, and a visit to the patient's home may even be indicated in borderline cases. In the case of non-compliance with

the restrictions given, an estimate of the maximal dose to an individual in the patient's environment should be estimated and taken into account in the decision.

5.1.1 Dose Constraints for Family Members

While it is generally accepted that the annual dose limit of 1 mSv for the general public does not apply, it is felt that there should be a system of dose constraints for most family members. This is reflected in the Recommendations of ICRP, which describes the 1 mSv annual dose as an averaged dose which might be exceeded provided that the total dose does not exceed 5 mSv in a five year dose period. This philosophy has been accepted by NCRP in their 1995 Commentary No. 11: "Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients." One of the important features of the Canadian Nuclear Safety Commission (CNSC) Radiation Protection Regulations Section 2.(2)(b) is the exemption from the normal system of dose limitation for family or friend caregivers knowingly and willingly exposed to a radiation dose while supporting and attending to a radionuclide therapy patient. This exemption from the 1 mSv annual dose limit for members of the public recognizes the very special role these "family" caregivers have in providing support to the patient.

The Committee recommends that the dose to an adult family member not exceed 5 mSv for the course of treatment, and that the dose to children and pregnant women not exceed the annual dose limit of 1 mSv for the same period. As long as such therapy is rare, it is felt that these groups would only be exposed once. Provided that appropriate education of the patient and his or her family members is undertaken, this dose constraint can be achieved without adversely affecting a patient's radionuclide therapy or necessitating the imposition of unacceptable restrictions on the family or patient. It is also consistent with current radiation protection philosophy and recommendations.

Recommendation 2: **When an outpatient radionuclide therapy regime is adopted, the adult family caregivers of such patients should be subject to a dose constraint of 5 mSv for the course of treatment. The public annual dose limit of 1 mSv should be retained for children and pregnant women in the patient's family, co-workers and other members of the public.**

5.1.2 As Low As Reasonably Achievable (ALARA)

It is not sufficient merely to ensure that the dose constraints mentioned above are applied. An effort should be made to reduce doses to family members to levels that are as low as reasonably achievable below these dose constraints, economic and social factors being taken into account. For example, radionuclides such as ^{131}I could be administered early in the morning and the patient kept under supervision for the hospital working day before discharge home. Dose reduction may require a more detailed examination of family activities to determine where behavioural modification can best be

introduced to reduce doses without unnecessary restrictions. Some of the software mentioned in Appendix F may be of value in deciding which behavioural modifications are most effective in dose reduction.

5.1.3 Cost/Benefit Analysis

Contingent upon the maintenance of adequate patient care and radiation safety, any change in the protocol for outpatient radionuclide therapy should not cost more to implement than the current expenditure on the hospital based treatment regime. Ideally, cost/benefit analysis is an appealing tool to reach the decision to adopt a particular choice of treatment, but in practice, there are major difficulties in applying cost/benefit analysis in this situation. These include the perhaps insurmountable problem of placing a dollar value on the benefit (or detriment) associated with the psychosocial aspects of the treatment choices. Another difficulty is placing an acceptable dollar value on the person.sievert. In its document G-129 [AE97], the AECB suggests that expenditures in excess of CAD$100,000 to reduce a collective dose by 1 person.sievert are not justified. A much wider range, between US$18,000 and $630,000 has been used in the US [Gu97]. The ACRP and the ACNS in their document AC-2 [AC91] have made an extensive review of the Marginal Cost of Dose Reduction, which could serve as a guide. In addition, the cost of the hospital bed is dependent on local conditions, the dose to caregivers varies and it is extremely difficult to quantify in monetary terms the cost of the psychological stress experienced by quarantined patients. Thus, it is not possible to arrive at a credible generic national cost/benefit analysis which could be applied in all cases and circumstances.

If cost/benefit appraisals are undertaken, it should be remembered that, theoretically at least, the collective dose should be calculated as the difference between the dose to family members and the dose to hospital personnel saved by early discharge. Intuitively, the dose saved will only be a small part of the dose to the family caregiver, and can probably be ignored as it falls within the errors of dose calculation. In fact, the change in protocol might result in a higher collective dose to the family care-givers than would have been delivered to the hospital personnel. In such a case, the increase in collective dose needs to be taken into account in the cost/benefit assessment. In special circumstances, for example where the treated patient requires specialized nursing care for some other condition, an estimate of the additional doses involved may be called for, and the dose to visiting professional caregivers may also need to be taken into account.

Thus, cost/benefit analysis is a complex procedure which will be highly dependent on the local circumstances and the parameters considered, so that it should only be performed by specially trained personnel. Even then, the result may lack the objectivity that is usually associated with this type of analysis, so that its utility may be questionable.

Once a generic cost/benefit analysis has been performed for a specific type of therapy, it does not need to be repeated every time that therapy is contemplated.

As may be gathered from these comments, the ACRP/GMA considers that cost/benefit analyses only have a subsidiary role to play in the decision to adopt a particular therapy protocol.

Recommendation 3: **The appropriate professional organizations should review the existing protocols produced elsewhere to reduce doses, and determine if they are applicable to the Canadian situation.**

5.2 The Implications of Implementing the New System

In most cases, adequately informed patients and their families will have no difficulty in following the necessary precautions to minimize family caregiver radiation doses during the period of home confinement, usually for a number of days after the radionuclide has been administered. Even though it is a very rare occurrence, it would be very difficult, for example, to separate a pre-school child undergoing treatment from siblings in the home. If confinement within the patient's home or other care facility is impractical, or if compliance with confinement-at-home instructions cannot be assured, confinement in a hospital or other skilled-care medical facility should be used to minimize the radiation dose to members of the public and the patient's family.

6. THE RADIATION PROTECTION CHALLENGES OF NEW PROCEDURES

New radionuclide therapies include the administration of new radiopharmaceuticals and brachytherapy methods with newer radionuclides as described in Appendices C and D, and may involve new procedures of radiation treatment of non-malignant disease or the treatment of malignancy not traditionally treated with radionuclide therapy.

6.1 Obligations of the Medical Facility and Other Health Care Personnel

The medical facility licensed to possess and use radionuclides should be aware of its responsibilities when the use of new radionuclides or new treatments are planned. For established procedures, application guides are often available, but the licensee must ensure that the radionuclides are managed safely. For new therapies, the licensee must investigate and approve the competence and training of all staff, as well as ensure that the infrastructure is appropriate to carry out the new treatment procedure in a safe manner.

It has been shown that the majority of misadministrations of ^{131}I can be traced to lack of attention to detail, non-compliance with established protocols and the absence of written instructions [NR99]. Licensees must ensure that a written directive is prepared prior to administration; that the patient's identity as the individual named in the written directive is verified by more than one method; that each radionuclide therapy is in accordance with the written directive, and that intended deviations from the written directive are identified and evaluated. Licensee employees who administer radionuclides, under the supervision of an authorized user physician, must receive instruction in the licensee's written quality management procedures, and must follow those instructions. Licensees are reminded that they are responsible for ensuring that the instructions are given to the appropriate employees, and for ensuring that the employees can and will follow those instructions. Only by paying attention to detail, and adhering to established departmental and institutional policies and procedures, can many accidents involving the exposure of other people be avoided.

6.1.1 Radiation Safety Committee or Safety Committee

It is recommended that each organization establish a Radiation Safety Committee (RSC) or Safety Committee (SC), the function of which is to monitor, advise on and oversee radiation safety matters. Their role is to advise and support the RSO in the introduction of appropriate radiation safety policies and programs.

The RSC should also establish close links with other safety committees within the organization. Members should be selected because of their recognized expertise and should include representatives from each discipline involved in radiation use. New radionuclide therapy protocols should be submitted to the RSC or SC, which will then make recommendations on the implementation of adequate safety procedures. Such an approval is subject to the individual presenting the project having the appropriate training and expertise. Recent ACRP [AC97] and AECB [AE92] documents provide more detailed information.

The RSO is responsible for advising upper management on radiation safety regulations and practices. The RSO has the responsibility to scrutinize proposed protocols and assess what radiation protection measures are required.

6.1.2 Training of Personnel

Only persons appropriately trained in the handling and use of radionuclides and informed of the hazards should be allowed to participate in the provision of radionuclide therapy. Workers should be individually authorized for radioactive work following special training. Site-specific and task-specific training, as described in C-200 (AE98), should be provided by each organization and tailored to the educational background and the practical needs of each worker. In the development of newer radionuclide therapy protocols, it will be very important to identify any new exposed worker populations and provide them with adequate training. Workers without any experience in the use of radionuclides may become major players in new procedures and they must be given the opportunity to acquire the practical experience necessary to perform their new tasks safely. It is of concern that those with limited formal training or everyday experience in the handling of radioactive materials may be involved in procedures which have the greatest potential for serious accidents. This is particularly relevant in the case of endovascular brachytherapy, where the catheter laboratory team used to working with x-rays may become the main players in protocols involving the use of high activity sealed beta and gamma emitters, and unsealed radionuclides. In view of the high activities used, with the potential for significant harm to workers as well as patients, it is a legal requirement of the hospital management as the licensee to ensure that the training, expertise and experience of physicians and other health care providers are appropriate to discharge their responsibilities safely in the type of treatment undertaken. This would not only include patient safety, but also the appropriate handling of expensive sophisticated equipment to avoid contamination and the establishment of an emergency plan to deal with a variety of accidents.

6.1.3 Suitability of the Physical Environment to the Task to be Performed

The Medical Facility should ensure that the radiation protection program includes requirements regarding adequate space and equipment for the safe handling and use of radionuclides. These considerations will become especially important when new radionuclide therapy practices are being introduced or a different radionuclide is used in an existing practice.

Therapies involving radionuclides may be introduced in new areas of the medical institution, for example in cardiology departments to prevent restenosis of coronary arteries and in urology departments in prostate cancer treatment with permanent implants. The radiation protection measures required by new techniques or new locations should be evaluated and sufficient resources made available for the new procedures to be implemented safely in the new area. Thus a cardiology catheterization laboratory may well require modifications to allow the use of gigabecquerel quantities of unsealed radionuclides for example. Some aspects that need to be considered include:

- Adequate space for the actual treatment
- Adequate space for waste storage
- Adequate protective (shielding, etc.) and monitoring equipment
- Adequate equipment and personnel for radiation protection
- Adequate design to prevent and avoid contamination.

Recommendation 4: All centres providing radionuclide therapies have the responsibility to ensure that facilities, education, training and care are of a high standard.

6.1.4 Treatment Research Protocols

Any radiation exposure to patients recruited in research protocols should be assessed. Follow-up examinations involving radiation should not be forgotten in the assessment of the dose received by the patient in the study, and any additional radiation exposure and its accompanying risk should also be included in the informed consent form signed by the patient. Thus in endovascular radiation therapy, where a verification angiography involving extensive fluoroscopy will be needed as a follow-up in the study, the additional dose should be included.

6.1.5 Treatment Teams

Recommendation 5: It is recommended that the Medical Facility ensure the availability of multidisciplinary treatment teams for the implementation of more complex applications of radionuclides therapy procedures.

Previously, the nuclear medicine physician and the radiation oncologist were the only physicians involved in radionuclide therapies. They supervised the use of radioactive prescribed substances in or on humans and were responsible for providing adequate information to the caregivers, to the patient and the family. There is no reason why the established modalities of treatment cannot continue to be provided in this way. However, with the development of more complex applications in other specialties, as well as their more widespread use, it is no longer feasible to expect a single physician to acquire all the skills and training necessary for their safe use. In addition, the advent of the concept of early home release after radionuclide therapies has placed further responsibility on the single treating physician which may be impossible to discharge safely.

It is for these reasons that the ACRP recommends that under the RSC or SC that consideration be given to the establishment of multidisciplinary teams to supervise those treatments which are highly specialized and complex and which require the services and skills of other professionals, not only in administering the treatment, but also in assessing the advisability of early home discharge. With the administration of radionuclide therapies on an out-patient basis, it would be the responsibility of the treatment team to assess the adequacy of the external support system, the ability of the patient to follow recommendations and to ensure that the patient and the family care providers receive adequate information on hygiene and metabolism as well as what to do in an emergency. Each participant would bring expertise to the team, and the special relation each of them would have with the patient would lead to a more complete assessment of the situation and more appropriate recommendations for treatment. The information to the patient will need to be as complete as possible and presented both orally and in writing, and an opportunity provided for discussion with the patient and the family. This has not always been the case (Br99), and the survey in Appendix E confirms the importance to patients and families of the need for accurate information. Discussion with more than one member of the team may be critical to a patient's understanding, as the presentation of information and the emphasis will be different for each team member. It is also advisable for a member of the team to ensure that the patient and family have fully understood the instructions given.

The treatment team would not only be responsible for the provision of the necessary information to the patient and family, but also for assessing the dosimetry needs and for maintaining appropriate records. It should be emphasized that such a team would not need to review all routine outpatient radionuclide therapies, but only those which were highly complex or where the special circumstances of treatment and/or of the home environment might increase the dose to family members. The treating team should determine the necessity for confinement after treatment and the restrictions to be imposed on the patient upon discharge from the medical facility, including the appropriate waiting

time before returning to work. It is likely that the need for, and the role of, any given team will evolve as the experience with the complex treatments increases and the members become more familiar with the risks and the public health issues.

The radionuclide burden of the patient should be clearly identified in outpatient records during confinement-at-home and a written description of the radionuclide therapy procedure including the special safety measures should be included in the patient's outpatient record. The outpatient record should contain all the appropriate signatures and approvals, and the patient should be given a summary of the outpatient record to retain for the period of time specified by the treatment team.

With the introduction of new radionuclide therapies, medical practitioners in disciplines other than the traditional ones, such as angiographers and urologists, will often be the primary users due to their expertise in performing specialized interventional procedures. The institution must require that the medical practitioners providing these therapies have received specialized training tested by in depth objective-based theoretical and practical examinations, and are judged competent to deliver them prior to being authorized to use radionuclides. It is the joint responsibility of these specialists and the licensee to ensure that the necessary skills in radionuclide use are acquired, including the ability to deal with radiation accidents, and that appropriate radiation protection measures are implemented, and if necessary to involve other specialists. In the implementation of complex new types of radionuclide therapy, the team work philosophy will be of prime importance.

While the composition of the teams should be flexible, the treating physician, the radiation safety officer, the social worker and the nursing staff may need to be included. For outpatient treatment, an outpatient nursing representative, other health-care practitioners and the referring physician would be useful additions to the team. It will be necessary to ensure that the team has a detailed knowledge of radionuclide therapy and that the team members are educated in correct clinical and radiation protection practice. Depending on the training and experience of the treating physician, it may be necessary to include in the team other specialists experienced in radionuclide therapies and radiation therapy procedures.

The treatment team, the RSO and the RSC will all have some responsibility in assisting the licensee to develop the protocols, quality assurance requirements and any other mechanisms to ensure that misadministations and the exposure of other persons are minimized (cf Section 6.1).

Workers involved in the administration of radionuclide therapies are responsible for following the established safety procedures and for performing their duties to ensure the best possible treatment for the patient while minimizing their own exposure. In the traditional patient management, the majority of workers involved in treatment were Atomic Radiation Workers, now called Nuclear Energy Workers, trained in the use of radionuclides as part of their professional curriculum. However, with the expected increase in new radionuclide therapies, workers from different departments without this training will become involved in the delivery of this treatment. Such workers will require training in all aspects of therapy with radionuclides, and the Medical Facility must be prepared to provide this training along with the dosimetry services and instrumentation required to implement safe radiation practices.

Recommendation 6: **The accuracy of information acquired by the general public and the health-care workers and physicians peripherally involved in radionuclide therapy is generally poor. The treating physician should make every effort to improve the availability and accuracy of the information provided to these groups.**

6.2 Obligations of the Patient and the Family

6.2.1 Patient

The patient participates in his or her own treatment and has a primary responsibility to follow the recommendations of the practitioners and other health care personnel of the treatment team. The patient's understanding of basic radiation protection concepts is important to reduce exposure to members of the family and to minimize contamination, especially where large doses of radioiodine are administered on an outpatient basis.

6.2.2 Family

Family members are responsible to provide support to the patient and to cooperate in his or her medical treatment. They should receive oral and written information (see Appendix G for examples) on the measures to be taken to reduce their exposure to radiation and contamination. For patients treated on an outpatient basis, the participation of the family members is very important. Along with the patient, they must also follow the recommendations and restrictions provided by the treatment team.

6.3 Role of the Regulator

These therapies bring new challenges to radiation protection in medical centres. They are often performed in completely different and new working areas by working populations that were never previously involved in radionuclide use. The activities carried out during some of these therapies are often not even categorized in any of the actual licensed activities. As an example, endovascular brachytherapy could be performed in a way that is not typically manual brachytherapy, nor is it remote afterloading and the sealed sources used are not classified as being incorporated into a device. Flexibility is also needed in the application of existing regulations. The locations within the hospital, such as an ultrasound room or catheterisation laboratory, where these new procedures may take place, do not, and surely need not, comply with all the requirements for radioisotope laboratories, and research protocols involving these areas should be allowed by regulators.

Having said this, the requirements for radioisotope laboratories are based on sound practices and experience. If all the requirements are not met, the licencee must be prepared to provide realistic alternatives that meet sound radiation protection principles. The licencee must also be prepared to deal with, and to document how, complications from accidents that would normally be mitigated by adherence to requirements for radioisotope laboratories.

Recommendation 7: The Regulatory Authority should allow these treatments to be accessible to patients without undue burden on the institution, as long as accepted radiation protection principles and good practices are maintained. This attitude is especially important during trial phases of new modalities of treatment.

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Members of Joint Working Group-10

Dr. J.B. Sutherland (Chair)
Mrs. L. Normandeau
Dr. L. Renaud
Dr. A. Driedger
Dr. A. Lees
Ms. K.L. Gordon
Ms. P. McGrath
Dr. P.J. Waight
All the members of the Advisory Committee on Radiological Protection and the Group of Medical Advisers.

Advisory Committee Secretariat

Mr. M.W. Lupien (Scientific Advisor)
Ms. P.A. Kemph

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REVIEW PANEL MEMBERS AND ORGANIZATIONS

J.E. Aldrich, Vancouver General Hospital, British Columbia
J. Blanchette, Hôpital Laval, Québec
R.H. Cawthorn, Atomic Energy Control Board (AECB)
D.A. Cool, U.S. NRC Division of Industrial and Medical Nuclear Safety
S. Fraser, Atomic Energy Control Board (AECB)
N. Gentner, Atomic Energy of Canada Limited (AECL)
R.V. Osborne, Atomic Energy of Canada Limited (AECL) - Retired
M.R. Rhéaume, Hydro-Québec (HQ)
K. D. Steidley, Saint Barnabas Medical Center, New Jersey

Association des Physiciens et Ingénieurs Biomédicaux du Québec (APIBQ)
Association des Spécialistes en Médecine Nucléaire du Québec (ASMNQ)
Association Québécoise des Physicien(ne)s Médicaux Cliniques (AQPMC)
Canadian Association of Medical Radiation Technologists (CAMRT)
Canadian Association of Nuclear Medicine (CANM)
Canadian Association of Radiation Oncologists (CARO)
Canadian College of Physicists in Medicine (CCPM)
Canadian Nurses Association (CNA)
Canadian Organization of Medical Physicists (COMP)
Canadian Radiation Protection Association (CRPA)
Ontario Association of Medical Radiation Technologists (OAMRT)

Ordre des Technologues en Radiologie du Québec (OTRQ)

APPENDIX A

ENVIRONMENTAL RELEASES

(K.L. Gordon)

1. Introduction

In the most common forms of radionuclide therapy, (i.e., Iodine-131 for thyroid disease and Strontium-89 for metastatic bone cancer), the therapeutic radiopharmaceutical is usually administered to the patient either orally or intravenously. A certain fraction of the administered radioactivity will be taken up by target tissues within the patient's body and the rest will excreted within a few days, usually by the kidneys into the urine. Because of the potentially significant radiological hazards to care givers in collecting, handling and storing radioactive urine, the usual practice is to have the patient void urine directly into a toilet which is then flushed in the normal fashion. Thus the excreted fraction of administered therapeutic radiopharmaceuticals enters the local municipal sanitary sewer system as soon as it is excreted by patients.

When a medical use radioisotope licence is renewed (usually every two years), the AECB requests information as to the total activity of each radionuclide purchased over the most recent 12 month period. The amount of radioactivity purchased does not necessarily reflect the amount administered to patients, as some of the purchased material may not be used and will decay in storage. The AECB has not kept a central database of the radionuclide acquisition information submitted by medical licensees, although the information could be assembled with some effort by extracting it manually from all of the relevant AECB licence files.

However, precise data on radioiodine therapy administration and estimation of subsequent release to municipal sewer is available for the Province of Manitoba.

2. Manitoba 1994 Release of I-131 to the Environment Subsequent to Radionuclide Therapy

During 1994 in Manitoba, a total of 261 patients with hyperthyroidism were referred to nuclear medicine departments in three hospitals and one clinic for radioiodine therapy. The amount of administered activity per treatment ranged from 185 to 1100 MBq (average 362.8 MBq). The total amount of I-131 activity administered was 100,600 MBq. Assuming that an average of 50% of the activity was excreted in the urine, 50,300 MBq of I-131 was released to Manitoba's sanitary sewer system.

In the same year, 27 treatment doses of I-131 ranging from 942 to 6530 MBq (average 2197 MBq) were administered to patients with thyroid cancer. The total I-131 activity administered to this group of patients was 63,596 MBq. However, because of a very low uptake by post-surgical thyroid

remnant tissue and functional thyroid cancer metastases, the radioiodine excretion rate in this group is very high, in the order of 95%. It is estimated that these 27 patients excreted 60,416 MBq to the sewer system within 48 - 72 hours after administration.

As detailed in Table 1, the total amount of radioiodine administered to 288 patients to treat thyroid disorders during 1994 in Manitoba was 164,196 MBq, with a subsequent total estimated release to the sanitary sewer system of 110,717 MBq [Go97]. The estimated amount of radioactivity released may be high by approximately 10% as it has not been corrected for radioactive decay.

Manitoba has a population of roughly 1 million people and its use of radioiodine in the treatment of thyroid disorders is quite typical in developed countries with modern health care systems. Also, the use of I-131 in radionuclide therapy has been relatively stable in recent years, but may be increased in the future with more therapeutic use of I-131 labelled compounds like MIBG (metaiodobenzylguanidine).

3. Current and Proposed Regulations Governing Release to the Environment of Radioactive Material in Patient Excreta

The release of radioiodine and other radioactive substances to the public domain from radionuclide therapy is real, although the related risk to the public is likely very low and should be offset against very significant benefit to the recipients of this type of therapy. The use of radioactive material in medicine should not be taken out of context with the other substances administered to patients including chemotherapy drugs, hormones and antibiotics, all of which pass through the patient and are released via the sanitary sewer system to the environment. All of these medically administered substances benefit the individual patient and by extension his or her family, and human society in general. However, these excreted materials pass into the environment, usually through the sanitary sewer system and depending on the stability and toxicity of the substance in question may have an effect on non-human species and biota [Ha98a, Ha98b].

In the past, the AECB has funded some research studies [AE96] which sought to detect and quantify medical radionuclides in some major Canadian municipal sewer systems, harbours and lakes. The overall conclusion was that while some radionuclides could occasionally be detected, the concentration was so low that it did not pose a radiological risk to sewer workers or to the public. The current AECB radioisotope licence conditions governing radioactive waste disposal to the municipal sewer system allow for 1 scheduled quantity of radioactivity per 100 litres of effluent, averaged annually.

The approach of the AECB to date has been that once radioactive material is administered to patients for diagnosis or therapy, it is considered “disposed” and the subsequent release of radioactive excreta from the patient is not considered. Neither AECB Consultative Documents C-123 [AE95] nor C-223 [AE98] discuss the regulatory exemption of medically administered and excreted

radioactive materials from the proposed maximum release concentrations proposed for AECB licensees. In the absence of such discussion it is assumed that the present approach will continue into the future.

References

AE95 Atomic Energy Control Board. Proposed Policy Statement "C-123 Radioisotope Release Concentrations". May 1995.

AE96 Atomic Energy Control Board. Research Project 34-6-113-1, Atlantic Nuclear Services Ltd.,1) "Identification and Measurement of Radioisotopes in Municipal Waste Disposal Systems in Montréal - February 1996",2) "Dose Determination Due to Disposal of Radioactive Waste in Municipal Systems: Phase-1" - June 1995.

AE98 Atomic Energy Control Board. "Proposed Regulatory Policy; C-223(E) Policy on Protection of the Environment". November 1998.

Go97 Gordon, K. "Manitoba Release of I-131 to the Environment Subsequent to Radionuclide Therapy". Poster Presentation at annual meeting of Canadian Radiation Protection Association, Victoria B.C. , June 1997.

Ha98a Halling-Sorensen, B. et al. "Occurrence, Fate and Effects of Pharmaceutical Substances in the Environment - A Review", Chemosphere, Vol. 36, No. 2, pp. 357-393, 1998.

Ha98b Hartmann, A. "Identification of Fluoroquinolone Antibiotics as the Main Source of Genotoxicity in Native Hospital Waste Water". Environmental Toxicology and Chemistry, Vol. 17, No. 3, pp. 377-382, 1998.

Table 1. Manitoba 1994 Summary: Thyroid Therapy with Iodine-131

	Medical Facility				
	Health Sciences Centre	St. Boniface Gen. Hospital	Winnipeg Clinic	Brandon Gen. Hospital	Total
Hyperthyroidism:					
MBq I-131 Administered	36141	37414	14286	12759	100600
Est. MBq I-131Excreted (50%)	18070.5	18707	7143	6380	50300.5
# of Patients	99	92	37	33	261
Thyroid Cancer:					
MBq I-131 Administered	46635	16961	0	0	63596
Est. MBq I-131 Excreted (95%)	44303.2	16113	0	0	60416
# of Treatments	15	12	0	0	27
Both:					
MBq I-131 Administered	82776	54375	14286	12759	164196

Est. MBq I-131 Excreted	62373.8	34820	7143	6380	110716.7
# of Treatments	114	104	37	33	288

APPENDIX B

PHYSICAL CHARACTERISTICS OF MOST RADIONUCLIDES FOR THERAPY
(Arranged by ascending maximum range of particulate radiation)

Nuclide	Half-life	Emission	E_{max} (MeV)	$E_{max/avg}$ (MeV)	Maximum Range in Water	$E_{or\ x\text{-}ray}$ peak (keV)
^{80m}Br	4.42 h	Auger	-	-	<10.0 nm	-
^{125}I	60.0 d	Auger	0.004 0.023 0.031	-	10.0 nm	27, 31, 36
^{211}At	7.2 h		6.8	-	65.0 m	-
^{212}Bi	1.0 h		7.8	-	70.0 m	-
^{117m}Sn	13.6 d	Auger,	0.152*		300 m	159
^{111}In	2.81d	Auger,	0.145* 0.219*		?	171, 245
^{169}Er	9.5 d		-	0.34	1.0 mm	-
^{177}Lu	6.75 d		-	0.497	?	113, 208
^{67}Cu	2.58 d		-	0.58	2.2 mm	185
^{131}I	8.04 d		-	0.61 / 0.20	2.4 mm	364
^{153}Sm	1.95 d		-	0.81 / 0.225	2.4 mm	103
^{198}Au	2.7 d		-	0.96 / 0.31	4.4 mm	411
^{186}Re	3.77 d		-	1.08 / 0.35	5.0 mm	137
^{165}Dy	2.33 h		-	1.29 / 0.44	6.4 mm	95
^{89}Sr	50.5 d		-	1.49 / 0.58	8.0 mm	-
^{32}P	14.3 d		-	1.71 / 0.695	9.7 mm	-
^{188}Re	16.98 h		-	2.12 / 1.96	11.0 mm	155
^{90}Y	2.67 d		-	2.28 / 0.935	12.0 mm	-

* Conversion electrons

APPENDIX C

RADIOPHARMACEUTICALS FOR MOST RADIOTHERAPY

Site /Localization Mechanism	Radiopharmaceutical	Application
Intracellular		
DNA incorporation	^{125}I-IUDR	Chorioncarcinoma
Metabolic	^{131}I-iodide	Differentiated thyroid carcinoma
	^{131}I/^{125}I-MIBG	Neural crest tumours
	^{32}P-phosphate	Polycythemia vera
	^{131}I-Rose Bengal	Hepatoblastoma
	^{131}I-iodide	Oncocytoma
Steroid receptor	^{80m}Br-estrogens	Breast carcinoma
	^{125}I-tamoxifen	Breast carcinoma
Non-specific	^{186}Re(V)-DMSA	Medullary thyroid carcinoma
Cell Surface		
Hormone receptor	^{131}I-SMS analog	Neuroendocrine tumours
Immunologic	^{131}I-anti CEA	Colon/medullary thyroid carcinoma
	^{131}I-B72.3	Colon/ovarian carcinoma
	^{131}I-HMFG 1+2	Ovarian carcinoma
	^{131}I/^{90}Y-OC 125	Ovarian carcinoma
	^{131}I-Lym-1	Leukemia/lymphoma
	^{131}I-anti pan B	Lymphoma
	^{131}I/^{90}Y-antiferrin	HCC/Hodgkin's disease
	^{131}I-anti p97	Melanoma
	^{131}I-3F8/UJ31A	Neuroblastoma
Extracellular		
Adsorption	^{32}P-phosphate	Bone metastases
	^{89}Sr/^{85}Sr-chloride	Bone metastases/osteosarcoma
	^{186}Re/^{188}Re-Sn-HEDP	Bone metastases
	^{153}Sm-EDTMP	Bone metastases/osteosarcoma
	^{131}I-BDP3	Bone metastases
	^{90}Y-citrate/EDTMP	Bone metastases
Cells	^{114m}In-A31 cells	Lymphoma
Intracapillary	^{131}I-lipiodol	Liver tumours
	^{32}P -resin microspheres	Liver tumours
	^{90}Y-glass microspheres	Liver tumours/sarcoma
	^{90}Y-resin particles	Liver tumours/sarcoma
Intracavitary	^{32}P/^{90}Y/^{186}Re/^{188}Re-colloids	Astrocytoma/cystic craniopharyngioma
	^{32}P-colloids	Malignant effusions
	^{198} Au/^{32}P-colloid	ALL intrathecal therapy
	^{131}I/^{90}Y-antibodies	Malignant effusions
	^{198}Au-colloid	Synoviorthesis
	^{90}Y-citrate/silicate	Synoviorthesis
	^{165}Dy-FHMA	Synoviorthesis
	^{186}Re/^{188}Re-colloid	Synoviorthesis
	^{169}Er-citrate	Synoviorthesis

Sources: Ho91; Ve90.

APPENDIX D

PHYSICAL PROPERTIES AND USES OF BRACHYTHERAPY RADIONUCLIDES

Element	Isotope	Energy (MeV)	Half-life	HVL-lead (mm)	Exposure rate constant*	Source form	Clinical application
Obsolete sealed sources of historic significance							
Radium	^{226}Ra	0.83 (avg)	1626 y	16	8.25†	Tubes and needles	LDR intracavitary and interstitial
Radon	^{222}Rn	0.83 (avg)	3.83 days	16	8.25†	Gas encapsulated in gold tubing	Permanent interstitial Temporary molds
Tantalum	^{182}Ta	1.2	115 days			wire	LDR interstitial
Currently used sealed sources							
Cesium	^{137}Cs	0.662	30 y	6.5	3.28	Tubes and needles	LDR intracavitary and interstitial
Iridium	^{192}Ir	0.397 (avg)	73.8 days	6	4.69	Seeds in nylon ribbon; metal wires	LDR temporary interstitial
						Encapsulated source on cable	HDR interstitial and intracavitary
Cobalt	^{60}Co	1.25	5.26 y	11	13.07	Encapsulated spheres	HDR intracavitary
Iodine	^{125}I	0.028	59.6 days	0.025	1.45	Seeds	Permanent interstitial
Palladium	^{103}Pd	0.020	17 days	0.013	1.48	Seeds	Permanent interstitial
Gold	^{198}Au	0.412	2.7 days	6	2.35	Seeds	Permanent interstitial
Strontium	^{90}Sr-^{90}Y	2.24 max	28.9 y	_	_	Plaque	Treatment of superficial ocular lesions
Developmental sealed sources							
Americium	^{241}Am	0.060	432 y	0.12	0.12	Tubes	LDR intracavitary
Ytterbium	^{169}Yb	0.093	32 days	0.48	1.80	Seeds	LDR temporary interstitial
Californium	^{252}Cf	neutron	2.65 y	_	_	Tubes	High-LET LDR intracavitary
Cesium	^{131}Cs	0.030	9.69 days	0.030	0.64	Seeds	LDR permanent implants
Samarium	$^{145}Sm.$	0.043	340 days	0.060	0.885	Seeds	LDR temporary interstitial

LDR - low dose rate; HDR - high dose rate

* No filtration in units of $R \times cm^2 \times mCi^{-1} \times hr^{-1}$

† 0.5 mm patient filtration; units of $R/cm^2/mg/hr$

Source: Pe97.

APPENDIX E

PATIENTS' AND FAMILY MEMBERS' EXPERIENCE OF RADIONUCLIDE THERAPY

(P. McGrath)

A national survey was undertaken by the AECB to gain a better understanding of the patients' and families' experience of radioactive Iodine treatment. The final report is entitled "Patient and Family Members Perspectives on Radioactive Iodine Treatment" [Mc99].

Background

The development and distribution of a national patient/family survey, was stimulated by the lack of information regarding the patient's and the family's experience of radionuclide therapy and isolation. The current literature is based on the Heath Care Provider's perception. The ACRP and GMA felt it was important to have a clear sense of what this experience is like for patients and their family members under the current practice and their perceived needs and concerns with regard to potential changes that may occur in future practice.

The working group chose to use a questionnaire to examine the experience patients in Canada are encountering while receiving radionuclide therapy. Patients receiving radioactive iodine (^{131}I) and their family members were chosen as the sample populations for this study. This group was chosen because of the large number of patients treated with ^{131}I, and because the precautions taken during ^{131}I therapy have been used as a model to guide the approach using other radiopharmaceuticals. The patient selected one family member to participate in this study. To ensure that the survey tool would reflect the patients' and families' experience of ^{131}I treatment, the researchers conducted 21 semi-structured interviews with patients who had received treatment, as either an inpatient or outpatient. Analysis of the interview data focused on the identification of the main content and themes across the interviews. The initial interviews provided descriptions of the experience of receiving ^{131}I treatment and laid the basis for the survey questions. Following analysis of the interview data, the survey questions were formulated and two survey instruments were designed, one for patients and one for family members [Mc99].

A total of 700 patient and family surveys were distributed to physicians at 8 sites across Canada. Locations included: Newfoundland, Nova Scotia, Ontario (2 sites) Quebec (2 sites), Manitoba and British Columbia. A total of 190 patients and 140 family members returned completed surveys, for a return rate of 26% and 20% respectively. Data was analyzed separately for individuals treated as inpatients and those treated as outpatients.

Demographics and Living Arrangements:

The patients who responded to the survey reflected a well-educated, Caucasian sample, despite the distribution of the survey to a multi-ethnic population. Thirty-six percent experienced malignant disease. The majority of the respondents had been diagnosed within the past three years. The majority of both inpatients and outpatients were living with an adult partner at the time they received their radioactive iodine therapy. Many (43% and 39%) were also living with children, of whom half were under the age of 12 years. Following their treatment with radioactive iodine therapy, 84% of inpatients and 78% of outpatients travelled home by private transport. Slightly more than a third (40% and 42%) spent more than an hour going home after their therapy. Of these groups, 3 patients travelled with children under 12 years of age. Almost half (55% and 40%) travelled with their spouse. Over half of the patients in both groups (61% and 52%) had two or more bathrooms at home. Seventy percent in each group had a spare bedroom.

The Experience of Receiving Radioactive Iodine

Of the patients admitted to hospital, approximately three-quarters (73%) were isolated for 2 to 3 days while 16% were isolated for longer than 3 days. The patients, who received their therapy on an inpatient basis, reported experiencing more symptoms/emotions than those patients who received their treatment as an outpatient. For the inpatient group the most frequently identified symptoms were fatigue (63%), dry mouth (52%) and feeling down or depressed (51%). The outpatients reported fatigue (56%) and anxiety (52%) most frequently. When asked whether or not they had received adequate assistance for the problems they had experienced, few inpatients and outpatients reported receiving adequate help. For example, 18% of the inpatient respondents who experienced fatigue reported receiving adequate assistance regarding this issue and 12% of the outpatients did so. For the inpatients that experienced a dry mouth, 15% of the inpatients and 17% of the outpatients reported receiving adequate assistance with this problem. This same pattern was observed with most of the problems patients experienced (see Tables 1 & 2).

Table 1. Proportion of Inpatients Who Experienced Symptoms/Difficulties

Symptom	Percentage of Inpatients	
	Experienced Symptoms/Difficulties (n=100)	Reported Receiving Adequate Help for Symptoms/Difficulties*
Fatigue	63	17.5
Dry mouth	52	15.4
Feeling down or depressed	51	13.7
Feeling isolated	48	37.5
Anxiety	47	21.3
Difficulty concentrating	43	25.6
Appetite changes	40	27.5
Difficulty with child care	40	20
Muscle cramps	40	15
Nausea	37	100
Difficulty with household	37	51.4
responsibilities	37	40.5
Fear	36	8.3
Change in how you feel about your body		

* Denominator used in each case was the number of patients who experienced the symptom/difficulty.

Table 2. Proportion of Outpatients Who Experienced Symptoms/Difficulties

Symptom	Percentage of Respondents	
	Experienced Symptoms/Difficulties (n=90)	Reported Receiving Adequate Help for Symptoms/Difficulties*
Fatigue	55.6	12
Anxiety	52.2	17
Feeling down or depressed	44.4	12.5
Dry mouth	40.0	8.3
Difficulty concentrating	40.0	16.7
Difficulty sleeping	38.9	45.7
Appetite changes	38.9	14.3

* Denominator used in each case was the number of patients who experienced the symptom/difficulty.

The family members experienced a range of symptoms themselves during the period of the radioactive iodine treatment. Anxiety was identified by more than half of the family members in the inpatient (62%) and the outpatient (52%) groups. Both groups identified the same types of issues including feeling apart from the patient, fear, and feeling down or depressed. When asked whether or not they had received adequate assistance for the problems they had experienced, there was considerable variation in the numbers of individuals who felt they had received adequate help.

The Impact of Precautions

When asked which precautions were difficult for the inpatients, the largest number of patients identified being unable to do the things that they usually did (42%), being off the thyroid medication prior to treatment (41%), being unable to get too close to children or family (39%), being isolated (27%) and being unable to have visitors (27%). The outpatient respondents indicated the difficult precautions for them included being unable to get too close to family members or children (29%) and being unable to do the things the patient normally does (24%).

For the family members of inpatients, the largest proportion had difficulty with the patient being off thyroid medication before treatment (49%) and the patient being in hospital (47%). The family members of outpatients identified the inability of the patient to get close to the rest of the family and children (21%) as being difficult.

When patients were asked about the amount of interaction with nursing staff during that period, 29% indicated there was no contact with a nurse, 18% indicated once a day and 32% indicated 2 to 3 times a day. Of the 18% who had one contact per day, that was reported to be less than one minute in 56% of the cases. In terms of telephone contact, 57% of the inpatients reported no contact with the nurse, 15% reported 1 and 21% reported 2 to 3 per day with the nurse. When asked about the adequacy of the interaction with the nursing staff for meeting the needs the patient experienced, 77% indicated that the contact was enough.

Patients identified the following people/items as helpful to them during their treatment: television and telephone in the room (80%), window in the room (70%), nurse (39%), physician (27%), technician (22%), reading/school work (22%) and visitors (19%). Comments written by patients also reflected the desire for more information about the time in the hospital; for example, "A printed copy of instructions when receiving the radioactive iodine in the hospital, rather than just an oral explanation of all the DOs and DON'Ts."

From the perspective of the family member, the items that made it easier for the family member during the isolation period included: knowing the isolation was only for a few days (69%), being able to phone the patient (68%), being able to have a short visit with the patient (25%) and the nurse (21%).

Going Home After Treatment

Patients who received treatment as an inpatient were asked what precautions were in place in the home environment following the administration of the radioactive iodine therapy (see Table 3). For the inpatients who had been discharged home, the precautions identified by the largest number of patients included washing hands thoroughly (91%), drinking lots of fluids (86%) and flushing the toilet twice (84%). For the outpatients, the most frequently identified precautions included washing hands thoroughly (82%), flushing the toilet twice (79%) and avoiding contact with children and women who are pregnant (71%). Overall, more respondents in the inpatient group indicated precautions were in place at home than did the outpatient group. This should be noted for the development of future precautions as they are more critical for the outpatient group.

Patients indicated they did have concerns about the radioactive iodine therapy when they were at home. Interestingly, both inpatients and outpatients identified their concerns as: worry that others would receive a dose of radiation from them, concern about what the radiation would do to the rest of their bodies, and concern about whether the radiation was actually gone. In both groups most patients thought their family members worried about whether the treatment was successful and whether or not the radiation was gone.

Information and Support

Consistent with the findings of studies with other patient populations, having access to information was very important to this group. The majority of respondents in both groups rated information about their medical condition, tests and procedures, treatment choices and side effects of treatment as very important. Topics such as preparing one's home for after treatment, how to relieve physical discomfort, preparing for hospitalization, and diet and nutrition, and emotional side effects were also considered very important by more than two-thirds of the respondents. Across all topics, 72% or less of the respondents indicated feeling satisfied with the information they had received. The topics for which the lowest proportions of respondents indicated satisfaction were how to speak to another patient in the same situation, availability of counselling services, emotional effects, and diet and nutrition.

Table 3. Precautions Taken at Home Following Radioactive Iodine Treatment

Precaution	Percentage of Patients	
	Received Treatment as an Inpatient	Received Treatment as an Outpatient
Washing hands thoroughly	91	82.2
Drinking lots of fluid	86	54.4
Flushing toilet twice	84	78.9
Avoiding contact with children/	77	71.1
Pregnant women	72	54.4
Sleeping alone	70	57.8
Avoid kissing/hugging	59	45.6
Keeping distance from family	57	36.7
Showering frequently	50	51.1
Keeping distance from others	50	51.1
Using own utensils or plastic utensils	44	23.3
Staying by self in separate room	43	26.7
Washing clothes/linen separately	4	1.1
Stop breast feeding	6	7.7
Other	0	3.3
Didn't know I needed precaution		

The majority of family members in both the inpatient (>77%) and outpatient groups (>83%) also indicated information about the patients medical condition, tests and procedures, treatment choices and side effects was important for them to know as a family member. In addition topics such as emotional effects, diet and nutrition, preparing for hospitalization and preparing the home for after treatment were also cited by two-thirds of the respondents as important for the family member to know. Within both family member groups, no more than about half of the respondents indicated they were satisfied with the information they received across all topic areas with the exception of the outpatient group concerning three items: treatment options (61%), the patients' medical condition (57%) and tests and procedures (57%). The following comments reflect the difficulties some family members felt:

"People should be made more aware of what radioactive iodine treatment is. My spouse was sent home from outpatient treatment with very little information on what he should and shouldn't do. I have to admit I was very nervous being around him..."

"[we need] informational pamphlets for spouses/children; description of treatments with radioactive iodine; side effects; more open health care professionals."

More than half of the patients and family members indicated a need to talk to someone else about issues related to the disease. Many had someone with whom they could talk and a few were able

to see a professional counsellor. Very few individuals had the opportunity to attend a self-help group or to access the services of, for example, the Thyroid Foundation of Canada or the Canadian Cancer Society. Both of these organizations provide services to patients and families, especially in providing patient information. A challenge for those providing care to this population of patients is to ensure that they are aware of community services which are available to them and how those services can be accessed.

Overall the majority of patients and family members expressed satisfaction with the communication style of the health care professionals with whom they came in contact.

Future Possibilities

The individuals who received their treatment as an inpatient were specifically asked if they would consider receiving radioactive iodine therapy on an outpatient basis should they require another treatment. More than half (58%) indicated they would not consider having future radioactive iodine treatments on an outpatient basis while 22% were uncertain if they would. The concerns they identified included wondering whether other people would receive a dose of radiation from them (81%), wondering how the patient could know that the radiation was gone (73%), wondering if the radiation would contaminate the house (71%) and feeling that they would need more information to receive the treatment as an outpatient (59%).

Twenty-nine percent of family members of inpatients indicated they would not consider outpatient delivery and 25% were uncertain. The concerns they identified included: wanting more information (62%), wondering if other people in the home would receive a dose of radiation from the patient (56%), wondering how to determine if the radioactivity was gone (54%), wondering if they would be able to follow all the precautions (54%), and wondering if the house would be contaminated (50%). Because this study was done retrospectively, it is difficult to determine if this was due to the fact that they were told prior to having the treatment that the treatment must be done as an inpatient for safety reasons. Perhaps sampling a group of patients who have not yet discussed treatment would give a more accurate picture of patient and family concerns.

Conclusion

The Canada-wide study provided perspectives from patients and family members about their experiences regarding radioactive iodine therapy. The data indicate variation in patients' and family members' perceptions about how precautions are to be implemented. Both patients and family members expressed the desire for more information regarding many aspects of the treatment experience. The results of this survey have implications for the development of patient information, continuing education, in particular in the areas of precautions, the provision of access to support and counseling services, and the importance of looking at individual situations of patients and families.

Reference

Mc99 McGrath, P. and Fitch, M. "Patient and Family Members Perspectives on Radioactive Iodine Treatment". Atomic Energy Control Board, August 1999, INFO-0707.

APPENDIX F

SOFTWARE

(K.L. Gordon)

When determining what radiation safety precautions should be applied to radionuclide therapy patients, there are a number of important factors, both assumptions and variables, that must be taken into account. Chief among these are the radiation dose constraint levels for family caregivers and the dose limit for other members of the public, both of which are usually prescribed by the national regulatory authority. The ICRP recommended an annual dose limit for members of the public of 1 mSv [IC91], with the caveat that in special circumstances, a higher effective dose could be allowed in a single year, provided that the average over 5 years does not exceed 1 mSv per year.

The European Basic Safety Standards Directive 96/29/Euratom [CE96] which will come into effect May 1, 2000, adopted the above ICRP recommendation on the public dose limit. However this directive does not apply dose limits to the exposure of individuals, "Comforters and Carers", who knowingly and willingly help, other than as part of their occupation, in the support and comfort of patients undergoing medical diagnosis or treatment. The European Medical Exposures Directive 97/43/Euratom [CE97] required the establishment of dose constraints for planning purposes. The National Radiological Protection Board in the UK [NR93] proposed a dose constraint of 5 mSv per course of treatment for Comforters and Carers.

In 1997, the US Nuclear Regulatory Commission (NRC) published a regulatory analysis document [NR97a] outlining the criteria for patient release. Also in 1997, the NRC published a new Regulatory Guide 8.39: "Release of Patients Administered Radioactive Materials" [NR97b] which changed the rules surrounding the release of patients who had been administered radioactive materials. In summary, the NRC has indicated that, if the radiation dose from a patient to any other individual (family or public) is less than 1 mSv, the patient can be released without restriction. The NRC has further established that the dose to others may not exceed 5 mSv. However, if the dose to any other person is likely to exceed 1 mSv in a year from a single administration, upon release of the patient, the licensee shall: a) provide the patient with written instructions on how to maintain doses to others as low as reasonably achievable; and b) maintain, for three years, a record of the released patient and the calculated effective dose equivalent to the individual likely to receive the highest dose.

Since the publication of NRC 8.39 In the US, it is no longer necessary to automatically hospitalize radionuclide therapy patients receiving more than a given amount of radioactivity. The decisions on whether to admit a patient to hospital for radiation isolation purposes or release the patient with detailed instructions for an in-home isolation regimen is now based on the projection of likely radiation dose to others who might be exposed by the patient. This assumes a case-by-case assessment of each patient's home situation, potential exposure scenarios as well as a number of projected dose calculations.

Calculating patient-specific predicted radiation exposure to others has thus become a very important part of radionuclide therapy, and is a task considerably simplified with appropriate software.

When designing software tools which use patient-specific dose-based systems of determining the applicable minimum safety precautions, the important parameters that must be factored in include:

- dose and dose rate limits or constraints,
- physical characteristics of the radionuclide (i.e. beta /gamma emissions and energies, half-life),
- the biological behaviour of the radiopharmaceutical (i.e: uptake, biodistribution, retention and clearance). The whole body clearance data should be reviewed in terms of the proportion and biological half-life of each clearance component,
- measured or estimated radiation exposure rate per MBq of administered activity at various distances from the patient,
- correction factors to convert measured or estimated surface entrance dose to determine whole body dose [Si99, Sp98] to the "target" person, and
- patterns of contact and potential exposure for various groups of target persons (family sharing the same household, fellow workers, public transport passengers, children and pregnant women, etc). For family members, by far the highest contributor to contact exposure is the act of sleeping in the same bed as the patient [Mo98].

Software tools, primarily spreadsheets, have been developed by a number of authors [Co98, Sa98, Ke96, We96] in the last few years to assist radionuclide therapy licensees in the calculation of potential radiation exposures from patients and, from these, to prescribe appropriate radiation safety precautions to patients and family caregivers.

NRC Regulatory Guide 8.39 Appendix B "Procedures for Calculating Doses Based on Patient Specific Factors" uses a simple set of default equations based on extremely conservative assumptions, and thus is deliberately designed to overestimate the effective dose to the "target" person [Si99]. The patient-specific dose calculation spreadsheet program developed by Samei et al [Sa98] was designed to incorporate the assumptions in NRC Regulatory Guide 8.39 [NR97b] and thus likely overestimates the radiation dose, leading to more restrictive management of the patient than is probably necessary.

Cormack and Shearer [Co98] have developed a spreadsheet program which is considerably more flexible, allowing more user input of parameters like measured dose rate and clearance rates ,

patterns of contact between the patient and household members, etc. At least one Canadian nuclear medicine practitioner is already using this software package to prescribe the appropriate radiation safety precautions to patients undergoing radioiodine therapy [Dr99].

New programs are also becoming available for other areas of radionuclide therapy, for example, treatment planning and occupational radiation safety precautions related to the various forms of endovascular brachytherapy [St99]. This is a rapidly evolving field, and it is highly likely that many more similar software programmes will be available in the future. For this reason, no one program is recommended at this time.

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APPENDIX G

EXAMPLES OF A CHECKLIST AND OF INSTRUCTIONS GIVEN TO AN OUTPATIENT TREATED WITH RADIONUCLIDES

(L. Normandeau)

A) Example of a checklist and instructions to patients

Information on the treatment

Isotope: Activity: Form: unsealed
sealed permanent
temporary; date of removal:

Suitability for treatment on an out-patient basis

1. The following subjects should be considered before each treatment with sealed sources and/or high activity unsealed sources on an out-patient basis be administered:

   External radiation field : may or may not be significant depending on isotope characteristic,

   Contamination : may or may not be present depending on type of treatment,

   Duration of risk : depends on physical and biological half-lives for radiopharmaceutical;
   depends on physical half-live for permanent implants;
   depends on duration of treatment for temporary implants,

   Persons at risk of exposure: family members , home care workers, children, etc,

   Travel conditions,

   Living environment,

   Return to work assessment,

   Implants: measures to be taken in case of emergency such as being dislodged, and

   Measures to be taken in case of patient death.

   Patient understanding and willingness to comply with restrictions should be properly assessed.

The instruction sheet should include the list of persons who were involved in the administration of the treatment, the assessment of the suitability for treatment on an out-patient basis and the training of the patient and/or family members.

Signatures: patient:

physician responsible for the treatment:
others involved:

B) Example of instruction sheets that can be given to an outpatient treated with radiopharmaceutical therapies

1. Patient name:_____
Family member name (s):_____

2. Radionuclide (s):_____

3. Dose given: ... MBq (... mCi) **Date of administration:**_____
Date of discharge:_____

4. General advice

* avoid close and prolonged contact with any individual, especially with children and pregnant women; this should apply to family members and during work place activities.
* avoid contamination (getting dirty) of people and objects with urine, saliva and perspiration.

5. Specific recommendations

For oneself: duration (after hospital discharge): **... day(s)**

* avoid contamination with saliva (e.g. use personal dish and glass, avoid kissing anyone)
* avoid contamination with urine (e.g. wash hands, flush the toilet twice after using it)
* bathe and shower ...a day; wash sweaty clothes immediately
* in case of vomiting, contact a physician

Remark: Washing dishes, cutlery and clothes can be performed as usual.

With regard to a partner: duration: **... day(s)**

* adopt separate sleeping arrangements
* refrain from sexual activity

Remark: If the wife is pregnant, much more strict restrictions should be adopted.

With regards to children: duration: **... day(s)**

* for children under two years of age, avoid close contact unless absolutely necessary
* children must absolutely sleep in a separate room than the treated parent

With persons external to the household: (e.g. friends, relatives, colleagues)

* avoid close and unnecessary contact for **... day(s)**
* avoid contacts with pregnant women for **... day(s)**

With regard to public places: duration: **... day(s)**

* avoid places where the maintenance of distance restrictions are difficult or unpredictable and where the risk of meeting pregnant women might exist (e.g. cinemas, theatres, restaurants, hairdresser)
* avoid prolonged journeys in public transport
* maintain a distance of one (1) metre from all other individuals

If appropriate, you may be eligible for a sick leave for a duration of **... day(s)**.

6. Other Specific information:

_____

_____

_____

John Smith, MD, FRCPC.

Patient Educator (Signature):_____ Date:_____

_____

Patient/Family - Retain copy No. 3, and send copies No. 1 and 2 to file.