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The Cancer Registry in South Africa – Exploring some of the Ethical and Legal Considerations

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A research report submitted to the Faculty of Health Sciences, University of Witwatersrand in partial fulfilment of the requirements for the degree of Master of Science in Medicine in the field of Bioethics and Health Law, Steve Biko Centre for Ethics

Johannesburg, 2011

Declaration

I, Yasmin Goga, declare that this research report, *The Cancer Registry in South Africa, Exploring some of the Ethical and Legal Considerations*, submitted in partial fulfilment of the degree of MSc Med in (Bioethics and Health Law) at the University of the Witwatersrand is my own unaided work except where I have explicitly indicated otherwise. I have followed the required conventions in referencing the thoughts and ideas of others. My research report has not been submitted before for any degree of examination purpose at this or any other university.

Signature:



Date: 01 December 2011

Dedication

To my parents, Yacob and Amina ï for their constant and unwavering support and encouragement, without which this would not have been possible.

To my sister Shaeeda ï for always being there.

Acronyms

AIDS : Acquired Immunodeficiency Syndrome

CDC : Centers for Disease Control

CERG : Cancer Epidemiology Research Group

EU : European Union

GMC : General Medical Council

HIPAA :Health Insurance Portability and Accountability Act Privacy Rule

HIV : Human Immunodeficiency Virus

IARC : International Association for Research in Cancer

IALCH : Inkosi Albert Luthuli Central Hospital

KZN : KwaZulu-Natal

MASAC : Medical and Scientific Advisory Council

MRC : Medical Research Council

MS : Multiple Sclerosis

NCI : National Cancer Institute

NCR : National Cancer Registry

NHA : National Health Act

NHI : National Health Institute

NHLS : National Health Laboratory Services

NHS : National Health Service

NPCR : National Programme of Cancer Registries

PAIA : Promotion of Access to Information Act

PIAG : Patient Information Advisory Group

PIR : Privacy International Report

SA : South Africa

SACCSG :South African Childrenôs Cancer Study Group

SAHF : South African Haemophilia Foundation

SEER : Surveillance Epidemiology and End Result Programme

UICC : Union for International Cancer Control

UK : United Kingdom

UKACR : United Kingdom Association of Cancer Registries

USA : United States of America

Preface

I have made all the recommended corrections and suggestions as pointed out by my examiners. I thank them for their wisdom and insight. The referencing system I use is that which is followed by the Steve Biko Centre for Bioethics. I have also up-dated this submission in light of the new South African Cancer Registry.

Research Report Summary

To understand and learn from the diseases they encountered, physicians have, from the beginning of medicine as a practice, always consciously or unconsciously collected data about their patients. The information tended to remain with individual physicians, and was published or shared, either formally or informally with colleagues. As the population has expanded so has the drive for knowledge and research. The great advances in research and information technology means that more statistics, facts, figures and records are being collected and shared between groups of physicians and researchers than ever before. Underlying the collection of data was the tacit understanding, between doctors and patients, that all information garnered was confidential; given to the doctor in the context of the ethical precepts of the doctor-patient relationship. The collection of data in its current format by registries has challenged many of these age-old practices.

Current issues for discussion include: maintaining confidentiality, and exploring the limits of confidentiality. I will also look at the issue of informed consent asking if it is necessary to obtain informed consent in the context of

cancer registries. From an ethical perspective, collection and use of information can be viewed from different perspectives such as utilitarianism as a social good, and respect for persons (often considered as respect for the autonomous choices persons make) as an individual good. Privacy and the right of an individual to maintain control over the type and the degree of information shared with others is increasingly becoming a more important topic, especially with the advances in the communications field and the computerisation of huge amounts of data.

In South Africa, the National Cancer Registry is being re-established. Cancer registration in South Africa has become mandatory via statutory regulations. In this research report some of the primary ethical and legal issues around data collection in South Africa will be explored. I will specifically look at issues arising in the formation of cancer registries with focus on whether registration of cancers infringes on privacy. Privacy in South Africa is assured in our Constitution and it is also addressed in Common Law. In addition there are other South African laws which are relevant; these include the National Health Act, the Promotion of Access to Information Act, as well as Privacy Laws (which are still

being developed). I will explore several of the issues concerning the functioning and controls of Cancer Registries in some other countries as well as various international legal considerations. International experiences can serve to inform South African healthcare, the public, policies, education and research which are all associated with the new South African National Cancer Registry.

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CHAPTER ONE: The South African Cancer Registry

1.1. Introduction

Africa has struggled for decades with the burden of infectious diseases such as malaria, tuberculosis, diarrhoea and pneumonia. However, the profile of diseases in Africa is set to change; the incidence of cancer is projected to increase rapidly over the next two decades (Valssechi and Steliarova-Foucher, 2008:159). Cancer in Africa carries a stigma similar to that of HIV and it is simply not spoken about by patients or their families. Internationally, over 50% of cancer cases and approximately 60-80% of the deaths from cancer occur in low-income and middle-income countries (Valssechi and Steliarova-Foucher, 2008:159; Cavalli, 2008:810) and this figure is probably significantly under-estimated. Cancer was projected to be the worldôs leading cause of death in 2010 and will kill more people than AIDS, tuberculosis and malaria combined (Cavalli, 2008:810). Cancer rates in Africa are set to increase by 400% over the next 50 years (Morris, 2003:5).

Overall cancer survival rates in Africa are abysmally low. Survival rates did not exceed 22% for any cancer in the Gambia, and in Uganda survival rates did not exceed 13% for any cancer site except breast cancer, which was 46% (Sankaranarayanan, et al. 2010: 165). Other middle-income and low-income countries like China, South Korea, Singapore and Turkey showed significantly higher survival rates ranging from 63-82% for breast, cervical and bladder cancers, and 44-60% survival for large-bowel cancer (ibid:165). Cervical cancer is the commonest cause of death in women in developing countries, and mortality rates approach 80% in most regions in sub-saharan Africa (Denny, 2011: 469). Persistent infection of the cervix with high-risk Human Papilloma Virus (HPV) has been established as being causative in the development of cervical cancer. The mortality is higher in Africa than in high-income countries, and is mainly due to lack of access to diagnostic and anti-cancer therapies (ibid: 470) as well as a lack of secondary prevention measures which include national screening programmes and HPV vaccination.

South Africa, despite its affluence, does not have a fully-functional or wholly effective national cytology

screening programme for the detection of cervical cancer. Despite the cervical cytology screening programme being slated as a Department of Health priority, state oncology departments remain overwhelmed with patients presenting with advanced cervical cancer, who require intensive treatment (Personal Communication Dr Neil Narsai, Consultant Oncologist, Dept of Oncology, IALCH). The state oncology departments, including radiotherapy services, cannot meet the current demands.

The World Cancer Declaration, as noted by Cavialli (2008:811) has set out goals for 2020, particularly pointing out the requirements for well-planned diagnostic and curative services, as well as a preventative arm. This is because the financial considerations of cancer treatment and prevention are extremely costly.

Cancer prevention, diagnosis and treatment are enormous problems in low-income and middle-income countries where healthcare budgets are often constrained in the first instance. At the same time without the knowledge of the types and rates of cancer, no preventative measures can be enacted. It

is therefore necessary that cancer registries be established in each country to support this plan to provide for the effective management of cancer.

1.2. The World Health Organization (WHO), Union for International Cancer Control (UICC) and the International Association for Research in Cancer (IARC)

The World Health Organization (WHO) has promoted the development of cancer control plans in which the role of cancer registries are well defined from as far back as the 1950s (Jensen, et al. 1991: 5). The International Association for Research in Cancer (IARC) was established as the specialised research centre of the WHO in 1965 (ibid: 6) The Union for International Cancer Control (UICC), which was formed in 1933, is the worldôs largest international non-governmental organisation dedicated to global cancer control (UICC, 2010). In 2006, as a call to the global cancer world for action to deal with the crisis of increasing numbers of patients with cancer (as well as the lack of cancer programmes in most countries), the UICC put forward an updated World Cancer Declaration (Cavalli, 2008:810).

According to Cavalli (ibid: 811) the targets of the updated World Cancer Declaration are to: ómake available cancer control plans in all countries; realise a substantial improvement in the measurement of global cancer burdens; work towards a substantial decrease in tobacco consumption, obesity and alcohol intake; strive for universal vaccination in areas affected by the human papillomavirus (HPV) and hepatitis B virus; dispel misconceptions about cancer; work towards substantial improvements in early cancer detection programmes; improve globally the diagnosis and access to cancer treatment, including palliative care, make effective pain control universally available; greatly improve training opportunities in oncology; work for a substantial decrease in migration of health workers; and to obtain major improvement in cancer survival rates in all countries.ô

In order to fulfil these goals, all countries will need to:

- Assess the extent of their cancer burden;
- Calculate their existing capacity to diagnose and treat cancer; and
- Monitor the effectiveness of their interventions.

To be successful, these activities should be co-ordinated at each countryôs national level. In the

International Association for Research in Cancerôs (IARC) review publication, ó*Cancer Incidence in Five Continents (Volume IX)*ô, there are very few low-income countries which have collected and submitted data. Moreover, concerning the data reported by the few reporting low-income countries, there appears to be a problem with the quality of the data (Parkin, et al. 2003). The quality of cancer registry data is evaluated by its ñcompleteness, validity and timelinessò (Brooks, et al. 2000: 1131-1140). In Africa, there are only five countries that have national population-based registers (Morris, 2003:5, Bray, 2010). South Africa initially had, then lost, and now has a National Cancer Registry again.

One of the major problems in low-income countries is that cancer registries require funding to be able to function effectively. According to Valssechi and Steliarovia-Foucher (2008:159), cancer registration in low-income countries may be perceived as a luxury and therefore has a lower priority in the allocation of resources. It follows that without understanding the extent of the cancer problem nationally, it is impossible to create any type of cancer control, treatment and prevention programmes. To bridge this

gap, cancer registers should be considered a necessity rather than a luxury (ibid). The reasons for this are many. Data obtained from a national population-based registry will assist in e.g. identifying the trends in cancer development which will guide further studies in causal relationships. It will assist in the assessment of the success or failure of preventive interventions and support planning of complete cancer care programmes at national levels.

Low and middle-income countries however, are fraught with challenges compared to their affluent counterparts. Some of these include the fact that accurate population statistics are often not available; the healthcare infrastructures needed to diagnose and treat cancer are poor, health information systems are often non-existent; health care priorities are skewed towards infectious diseases, and the political will to accept and recognise cancer as a significant future challenge is simply lacking.

1.3. Overview of the history of some national and international cancer registries

Initial efforts at cancer registration started in the 18th century. In the 1930ôs it was suggested that all cancer cases be subject to compulsory notification (Valsecchi and Steliarova-Foucher, 2008:160). In the beginning, cancer registries were hospital-based, which provided some insight into pockets of disease from a clinical perspective. However, a national picture, which should translate into meaningful government policy on cancer, requires a population-based, public-health approach to data collection. Some examples of these types of national registries follow.

The first well-functioning population based register was established in Germany (ibid). However, the German registry was paralysed in mid-1990 as data collection drew to a halt because of the increased requirements which followed the enacting of privacy laws. Two groups submitting data to the German Registry in the mid- 1990ôs required informed consent before information was submitted to the Cancer Registry; and as a result, 70% of cases were not registered (Duedeck, 2001:9; Bellach and Schon, 1996:34).

In the United States of America (USA), the *Surveillance Epidemiology and End Result* (SEER) programme registry is part of the National Cancer Institute (NCI). This programme collects and provides information on cancer incidence and survival for 28% of the USAôs population. Data collection began in 1973, and continues to expand. The SEER programme collects data on patient demographics, primary tumour site, tumour morphology and stage at diagnosis, first course of treatment and follow-up for vital status (SEER, 2010).

The USAôs National Program of Cancer Registries (NPCR) under the Centers for Disease Control (CDC, 2010) was established by the USA Congress though the *Cancer Registries Amendment Act* in 1992 (ibid). Prior to the Act, ten US States had no cancer registry, and existing registries lacked resources and the legislative support needed to collect data. As of 2010, the NPCR covers 96% of the USAôs population and, together with the SEER programme, the entire country is covered. The importance of the SEER programme is aptly reflected by R. T. Croyle, Director

of the Division of Cancer Control and Population Sciences (NCI) as follows:

> *'The SEER program is one of NCI's most important data collection and dissemination activities. In addition to providing essential information for tracking the Nation's progress against cancer, SEER data and data analysis tools provide researchers with unique opportunities to explore and explain cancer trends. The impact of SEER on science, policy, and practice reflects both the quality of the data collected and the creative expertise of the many scientists who use it.'* (SEER Brochure, 2008)

According to the USA's NPCR, the functions of cancer registries are to: 1) Monitor cancer trends over time; 2) Determine cancer patterns in various populations; 3) Guide planning and evaluation of cancer control programmes; 4) Help set priority for allocating health resources; 5) Advance clinical, epidemiologic and health services research; and 6) Provide information for a national database of cancer incidence.

In the United Kingdom (UK), the United Kingdom Association of Cancer Registries (UKACR) was formed in 1992 in response to rapid changes in both information management systems as well as demands for accurate data from multiple organisations, for the purpose of audit and research (UKACR, 2011). Prior to this, cancer registration was fragmented and done by several bodies. These individual registries realised the need for a formal organised cancer registration body to oversee the various registries and created the UKACR (ibid).

The Danish Cancer Registry was established in 1942 and its founder, Johannes Clemmerson, initiated the worldwide coordination of cancer registration in 1946 via the WHO and UICC (Valsecchi and Steliarova-Foucher, 2008:160).

Worldwide cancer reporting coordination was initially located under the auspices of the WHO and UICC, and later under the *International Association for Research in Cancer* (IARC). Over 65 years ago, they established four principles regarding cancer reporting:

- ôTo gather data from as many different countries as possible;

- To follow an agreed standard as regards data collection;
- To have a central record in every country; and
- To have an organisation that correlated the data from a worldwide perspectiveô(ibid: 160).

Currently, the IARC regularly publishes an estimate of cancer incidence and mortality worldwide which covers 182 national populations and 20 world regions (Bray, 2010). Startling but unsurprising figures on cancer registration, according to the IARC, show extremes in world cancer registration coverage ranging from highs of e.g. 99% in North America and Canada, 86% in Australia, to mid-lines e.g. 57% in Europe and Russia; to lows of 21% for South America, 11% for Africa and 8% for the Middle and Far East (ibid).

As shown in these examples, formalised national cancer registries have the potential to feed into their own countryôs science and technology research and development programmes. Moreover, if national cancer registries contribute to a global system, then cancer knowledge and control has the potential to benefit all humankind.

1.4. South African National Cancer Registry (NCR) and other South African cancer registries

The South African National Cancer Registry (NCR), based at the National Health Laboratory Service (NHLS), had collected data from pathology laboratories in both the state and public sectors from 1986. This data was based on cases identified via pathology laboratories since 1985. The reporting of cancer data was done on a voluntary basis (LABRAP, 2011:1).

However, in 2001, many private laboratories refused to submit pathology data citing issues of confidentiality, infringement of privacy and the lack of informed consent as obstacles (NHLS, 2007 and 2008). Moreover, the reporting of cancer confined to only a pathologic diagnosis failed to recognise the impact of the HIV/AIDS pandemic on clinical practice. For example, cancers such as Kaposi's sarcoma, common in HIV/AIDS, are clinically recognisable based on patient history and clinical presentation (personal experience). If notification is based on pathology reports only, such cancers will not be included in the registry.

Additionally, those cancers diagnosed on the grounds of biochemical and haematological results also were absent. Clinically-diagnosed hepatocellular, breast and cervical cancers, particularly those identified in rural areas without laboratory support, would also not be included in only a histopathology-definitive reporting system (LABRAP, 2011:1).

Mainly the issues of confidentiality, infringement of privacy, lack of informed consent were concerns which lead to the demise of South Africaôs cancer registry. South Africa has not had an annual cancer report published since 2001. This has had an impact in many public health related areas such as epidemiology and is considered by many healthcare professionals to be an unacceptable situation.

During this time other agencies developed or maintained particular-interest registries. For example, the South African Childrenôs Cancer Study Group (SACCSG) and the Medical Research Councilôs (MRC) Cancer Epidemiology Research Unit (CERG) to which I now turn.

The South African Childrenôs Cancer Study Group (SACCSG), a registry based at Tygerberg Hospital, collects hospital-based data from all units treating paediatric oncology patients in South Africa. The SACCGS collects data on a named patient basis, and does not require informed consent. Unfortunately, access to data from the SACCSG registry has been immensely problematic. To date, there has been no publications reporting on the data collected, nor has the data been made available to participating units (personal experience).

As part of the Medical Research Councilôs (MRC) ôCancer Case Control Studyô certain cancer data began in 1995 (MRC, 2010). Of note, their researchers obtain informed consent for all information used. One major area of research concerns breast and gynaecological cancers in black South African women. Another area of their research is the CERG PROMEC-Oesophageal Study, which collects data on the epidemiology of upper gastrointestinal and oral cancers (ibid).

Cancer registration in South Africa should have been of a quality that warranted its inclusion in the IARCôs

ó5 Continents Cancer Reportô, but unfortunately collection of data largely collapsed. Recognising a problem, the National Department of Health held a workshop in 2008 to address the issue of notifiable conditions and disease surveillance. At the workshop, it was decided that cancer would be placed on the new list of notifiable conditions to be added to the *National Health Act, 61 of 2003.* And so it was, in the form of a Draft regulation, gazetted in December 2009.

On April 26, 2011 the new Cancer Registry legislation was introduced by the South African Minister of Health, Dr. Aaron Motsoaledi. The National Cancer Registry (NCR) is a specialised division of the National Health Laboratory Services (NHLS).[1] It is a population-based registry which

> *… requires all doctors and [healthcare] facilities that confirm cancer cases to report their findings to the NCR* (LABRAP 2011:1).

[1] Published in notice 380 of Government Gazette 34248 dated 26 April 2011, the regulations state that the NCR will be responsible for collecting, validating, recording, managing and analysing all information in South Africa relating to cancer. Any such information will be made available to organs of state and the public for research (NDoH, 2011).

Now signed into law, private laboratories have legal protection around issues such as confidentiality, infringement of privacy, lack of informed consent. Now data can be submitted without fear of potential breaches that may result in litigation as this concern is covered under the new regulations. Moreover, the regulations recognise that cancer may be confirmed by other than histopathologic diagnosis only e.g. by hematologic, biochemical and clinical diagnosis as well.

1.5. Principles of Cancer Registration

In order to understand the ethical and legal issues involved in cancer registries, one must understand the process of cancer registration as well as the type of data collected. In this section, I will explain this process.

Cancer registration, as defined by Jensen, et al. (1991:22) is

> *…the process of continuing, systematic collection of data on the occurrence and characteristics of reportable neoplasm's with the purpose of helping to assess and control the impact of malignancies on the community.*

> Cancer registries may be defined as
>
> *… organised systems for the collection, storage, analysis and interpretation of data on persons with cancer* (Coleman, Muir, and Menegoz, 1992:1143).

Registries are a critical cornerstone to any cancer control programme. This is because the data they contain affords the planning for cancer control, provides for aetiological hypotheses to be identified, allows the success of interventions on an individual case basis to be assessed and is a vehicle through which the impact of public health interventions can be measured. Registries may be either hospital-based, population-based or defined according to a particular speciality, e.g. breast cancer registry, or a paediatric oncology registry. Each of these has their roles to play in the effective surveillance and management of cancer.

Hospital-based registries focus on the clinical features, clinical management and treatment outcomes in a small and defined population. Population-based registries, serve to identify overall incidence and trends over time in a defined

geographical area. Sources of information vary according to the type of registry. For hospital-based registries gathering information would entail extracting a patientôs details from e.g. the medical records department, radiotherapy departments, as well as outpatient areas and inpatient wards. Pathology based registries would need to collect information from both the anatomical pathology and haematology laboratories. Beyond these are other sources of information including speciality registries, national government death registers, private clinics and hospitals.

Data is usually collected by either active or passive reporting. In active reporting there can be an established cancer registration service that goes to the source e.g. a clinic or hospital, and identifies patients at that level. The SACCSG and the PROMEC-Oesophageal Study are both examples of active reporting. The South African National Cancer Registry (SA NCR) was also a form of active reporting, the source being the histology samples from pathology laboratories. Patients may also opt to report their cancers themselves; this is called ópassive reportingôand is not well-documented in the literature.

Active registration is the recommended method of data collection (Chokunonga 2010, IARC Workshop)

According to the IARCôs Guidelines on Confidentiality (2004:12), data required for a cancer registry is termed ópatient-identifiableô data, as the patientôs name, surname, gender, date of birth, place of birth, current residence, marital status and occupation are collected. The reason for collecting data on a identifiable-patient basis is to prevent duplications. Patient-identifiable data is also required for informed epidemiological assessments. The links of cancer to e.g. occupation, geographic area, age and sex are required to correctly identify trends in presentation and survival, as well as the potential risk factors for the development of certain cancers.

Registries can opt to collect basic data as per the IARC requirements or, if resources are available, can expand the amount of optional data that is collected. The IARC Guidelines for Confidentiality for Population Based Registries divides data for data collection into Basic and Optional data as follows:

1. Basic Data:

1.1 Patient demographics: name, sex, age, date of birth, usual residential address, and ethnic group.

1.2 Basic tumour data: the date of diagnosis, basis of diagnosis, tumour topography, morphology, and tumour behaviour as well as the source of information.

2. Optional Data:

2.1 Optional patient demographics: personal identification number, place of birth, marital status, nationality, and occupation.

2.2 Optional tumour related data: the clinical extent of disease,stage of disease,site of metastasis,multiple primaries,initial treatment type, outcome (based on date of last contact, status on last contact, date of death) and HIV status (dos Santos Silva, 1999:389).

1.6. Elements of cancer data collection

It is critical to understand the elements of data collection, in order to understand the ethical and legal challenges that arise.

Cancer registry data is usually captured by registries and de-identified to anonymise the data if it used in research. Each region within a country may have its own registry that collects data according to agreed

datasets. A central co-ordinating body may either hold the data centrally or may co-ordinate an annual analysis of the data. Registry data is held on either central or local servers and encryption of data usually meets the highest security levels.

If data were collected on an unnamed basis the ethical challenges would have been far less, as would have been potential public objection. However un-named / non-identifiable data is definitely less useful, and there is a clear case for collecting data on a named patient basis together with other identifiers. With non-identifiable data, for example the presence of duplicate patientsô reports, multiple biopsies from the same patient, and repeat notifications as a ónew caseôwhen a patient has relapsed will all lessen the strength of the data and decrease the integrity of the database. It is pointless for a registry to exist, unless the data is of high quality. Identifiable data can be further analysed and used for cancer epidemiology research and preventative policy purposes. The use of non-identifiable data, I suggest would result in a

weak registry that ultimately would undermine the functioning and success of any cancer programme.[2]

1.7. Concluding Remarks

Following from the discussion thus far there are three issues that may be seen to be in conflict with each other. The first is the balance with regard to the relationship between the physician and his patient versus the public dimensions of a disease like cancer. Second are the legal and ethical frameworks which govern this relationship ï viz. individual doctor-patient confidentiality and informed consent against public health issues. The third relates to making cancer a notifiable condition and how best to create the balance between legislation governing privacy and that of research for the greater benefit to society.

I will develop further some of these issues in my second chapter, identifying some of the ethical issues which are vital to consider in the formation of a cancer registry.

[2] My suggestion is not unique. See for example SEER 2007; Joishy and Driscol 1989.

CHAPTER TWO: Exploring Some Ethical Aspects of Cancer Registries in South Africa

2.1. Introduction

Cancer registration in South Africa has become mandatory. As noted, some of the ethical questions that concern cancer registries include: whether informed consent is required and how confidentiality and privacy would be maintained.

Informed consent, confidentiality, and privacy are all issues which fall under the principle of respect for the autonomy of persons. The idea that we should respect persons derives from the works of Immanuel Kant (Kant, [1785] 2005). He considered all humans to be of intrinsic value, dignity and worth. Because of this, we are required to respect not only our own dignity, but also the dignity of others. Kant included categorical imperatives in his works. His second formulation of the categorical imperative tells us that all rational persons possess dignity and so they cannot use themselves or any others as mere means to an end. This represents a proscription on using others as only a means to an end (ibid: 425). Through respecting a person's autonomy we give that person dignity in that we value his or her freely made

decisions concerning the course of his or her life. It follows then that the ideas of informed consent, confidentiality and privacy are related to respect for persons. Kantôs theory is called ódeontologicôbecause it encompasses the individual duties we have to ourselves and to others. Another part of Kantôs theory focuses on the intentions of our actions. He believed that what matters most is that we always act from what he calls a ógood willô This means that our inner intentions matter. For example if we tried to do something good but it turned out badly, for Kant it does not matter because our intentions were good.

This is a different perspective to the theory put forward by utilitarians. Utilitarianism is type of consequentialism. Consequentialist theories look at the type of results of actions to judge its morality or immorality; if the results are good for all concerned, then the action was right. Over two centuries ago, Jeremy Bentham (1789) developed a new moral principle. Differing from Kant, Bentham said that the goodness of an action should not be judged by our intentions. Instead, he argued that what we should use to judge our actions as right or wrong is the utility of its consequences (Bentham, 1976). His theory was

later refined by John Stuart Mill. Utilitarianismõs first principle is õthe right action is the one that provides for the greatest amount of utility (usually conceived as happiness, good or pleasure) for the greatest number of peopleõ(Mill, 1957).

The differences in these theories, particularly finding a balance between respect for an individualõs autonomy and the publicõs good, are issues I will explore further. In the following section, I will contextualise these. First I will relay my personal experience in the Kwa-Zulu Natal Paediatric Haematology Unit, and then I will explore the ethical issues of confidentiality and informed consent which arise from it.

2.2. KZN Paediatric Haematology Oncology Unit experience

Reflecting on the two registries that my unit (Paediatric Haematology Oncology in KwaZulu-Natal) regularly submits data to, together with the new cancer registry law that has now been acted upon, sparked my interests in both the cancer registry and other disease specific registries.

Submissions from our unit at Inkosi Albert Luthuli Central Hospital (IALCH) to the South Africanôs Childrenôs Cancer Study Group (SACCSG) cancer registry, based at Tygerberg Hospital, are done by an administration assistant who works between her home and IALCH. There are inadequate facilities at IALCH to permit her to do all the required work at the hospital. This means that there are hard copies (paper copies) of the oncology cancer registry data in her possession as well as data stored at her home at any given time. The SACCSGôs current data collection method is that data forms are faxed, emailed or posted to the registry in Tygerberg. An administration assistant at Tygerberg then captures the data onto their computer. All data collected is on a named patient basis and the data capture sheet is modelled along the IARC requirements. The registry manager is a consultant based at Tygerberg hospital.

The Paediatric Haematology Oncology Unit in KwaZulu-Natal unit has previously received minimal funding for registry management. More dedicated administration support for registry management was received for the first time in 2010. The unit has no dedicated computer with secure access to store data.

Further, data security is a problem, as there is no dedicated office space or computer from which to work.

Due to the infrastructural challenges, the access code to the computer is shared and the computer itself is used at a general work station. Furthermore, while it is recognised that data should not be leaving the hospital premises, especially as it is being handled by a non-medically trained person, this happens out of necessity. In addition, the Unitôs administration assistant has not signed a confidentiality agreement, as none has been created by the SACCSG. She has verbally agreed that she is bound to maintaining confidentiality, but the lack of a signed agreement is of concern to her.

To the best of my knowledge there are no documents which detail the function of this registry, e.g. its day-to-day logistics and management, issues around confidentiality and informed consent, data security and the use of data collected by the registry. In exploring such issues, my concerns are raised about the following issues:

1) The unavailability of details relating to the security of data at Tygerberg;

2) The type of system being operated e.g. GLOBOCAN or an Access / Excel based system;

3) The absence of a formal confidentiality agreement which should be drawn up by the SACCSG registry for staff involved in the registry;

4) The absence of reciprocal feedback mechanisms and information sharing between persons contributing to the registry and the registry;[3]

5) The lack of patient involvement. Patients are not aware of the existence of the registry, nor do they know what its aims and objectives are or how the information is to be used; and

6) The absence of transparency or accountability concerning the registry in its current format.

These concerns and objections to the current state of the registry were tabled at a SACCSG meeting in 2008 and again in 2009. A request was submitted that a committee, with a representative from each contributing unit, be constituted to manage the

[3] As of this writing, no report has ever been issued from the registry to those who submit data. Requests for figures of Paediatric cancer incidence in South Africa, as well as figures for KwaZulu-Natal have been ignored. Such data was to be used in presentations to the MRC as well as to the Department of Health to motivate for additional staff to expand the current units; as a result, the failure of the registry to supply such information to the contributing units compromises each unit's ability to improve cancer-related health care.

registry. To date there has been no further response or action on the concerns raised and suggestions submitted. As such, the current functioning of the SACCSG Registry is considered to be irregular and sub-optimal, and the registry does not follow the principles detailed in the IARC guidelines.

The second registry, the Paediatric Haematology Oncology, unit submits data to the Haemophilia Registry previously based at the Red Cross Childrenôs Hospital. This, like the SACCSG was initiated by a consultant with an interest in haemophilia. Data is collected on a named patient basis, as is done in the National Cancer Registry.

The significant difference is that additional data relating to HIV (Human Immunodeficiency Virus), Hepatitis A, Hepatitis B, and Hepatitis C is collected as these are of particular relevance to patients with haemophilia. In addition family trees are included. This registry was previously Excel-based. Data is stored on a computer in the registry administratorôs office at Red Cross Childrenôs Hospital. Further details pertaining to the security around the data as well as access to the computer is not available. Data

was submitted to them by a clerk employed by the South African Haemophilia Foundation (SAHF) by fax and email. All data including data of a sensitive nature (viral studies) are stored on the only computer in the clinic at King Edward Hospital, which is also the general work station.

In 2008, the SAHF decided that there should be a change made to a web-based registry and each centre should input their data directly. A Registry Committee was established and issues pertaining to registries in general were explored in great depth. These covered all aspects of the Registry, from the aims of the registry, day-to-day functioning, to data encryption, secure servers, confidentiality agreements, registry reports and access to data. Considerable attention to both the legal and ethical issues and an in-depth analysis of international registries was done to inform our process. The question of the need for informed consent was particularly important as data of a sensitive nature is also being collected.

The recommendations of the Registry Committee were presented and tabled for discussion at the

annual Medical and Scientific Advisory Council (MASAC) meeting. The main challenge to the Haemophilia Registry has been the lack of personnel to input data. The issues of control over the registry have been partially addressed yet this remains a contentious issue.

The web-based South African Haemophilia Registry serves as a model as to how the process should occur in contrast to the current SACCSG cancer registry. There is clear definition of the aims and functions. Confidentiality issues have been addressed both in terms of data security as well as personnel who are required to sign a confidentiality agreement. The Haemophilia Registry has a patient information leaflet which explains the registry and provides details of people to contact should there be any public or patient queries. As virology results are being collected, it was decided that informed consent would have to be taken. The registry will also apply for ethics approval at contributing centres; this has thus-far been granted for the Western Cape and Free State. In addition, funds have been made available for a dedicated computer and to assist with paying registry staff. The SAHF is a patient organisation that is

extremely pro-active and they are the key drivers behind the registry. This is because they are acutely aware that haemophilia is an expensive condition to treat and that in order to lobby government effectively, they require a well-functioning registry.

The differences between these registries set the context to discuss some ethical issues. These include confidentiality, informed consent and the use of data in research. The direct involvement of haemophilia patients in their registry will allow discussion of the concepts of respect for individual autonomy versus the public goodô

2.3. Confidentiality

In an individual doctor-patient relationship, confidentiality is one of its key components. The idea of keeping patient confidences is recorded in almost all of the Oaths, ethical guidelines and declarations concerning medical practice. For example, part of the Hippocratic Oath says,

... What I may see or hear in the course of the treatment, or even outside of the treatment, which of no account one must spread abroad, I will keep to myself ...[4]

Keeping patient information confidential is also a practical consideration in medical practice. This is because patients would not trust a doctor who was known to tell their intimately confided information to other people (Knapp van Bogaert and Ogunbanjo, 2009: 194). In an individual doctor-patient encounter, the personal nature of the information a patient gives to his or her doctor is grounded in trust (Beauchamp and Childress, 1994: 420). Patients rely on their doctor to ensure that the information they give will not be divulged to a third party without their permission. In order for a patient to speak freely and frankly, confidentiality must be guaranteed (Jones, 2003:348). The link to Kantôs idea of respect for persons is demonstrated in the idea of keeping patient confidences.

[4] It is interesting to note Gostinôs (1997:370) comments that while some have interpreted the Hippocratic Oath as requiring physicians to maintain patientôs secrets, others have observed that there must be some information that "ought to be spread abroad".

Here it is important to consider that information is transmitted directly to an individual doctor during a consultation as well as by other ways as well, for example through diagnostic laboratory tests and radiographs. In common hospital admission practice additional personal information is required such as oneôs financial situation viz. hospital deposit, medical insurance, next of kin, name of current medical complaint, previous operations, telephone number of friend, and so forth. This type of information falls out of the healthcare professional-patient relationship. Thus, both private and strictly medical information now computerised and linked to other networks may and occasionally does become part of the public domain (Knapp van Bogaert and Ogubanjo 2009:194).

The focal point of confidentiality in this regard concerns an individualôs choice about whether, to whom and how their information is transmitted (ibid). Privacy is similar in that it concerns oneôs person and is value-laden. The distinctions between confidentiality and privacy however are often unclear.

To begin with, confidentiality in cancer registration must take into account the sensitive nature of the diagnosis. The desire by some cancer sufferers to hide this information from others is variable; some patients are happy with disclosure of their condition to family, friends, and the community; whilst other patients are extremely secretive. There are several levels at which confidentiality needs to be considered.

On one level, the patient is an individual who has a relationship with a healthcare professional and confidentiality is a cornerstone in the doctor-patient relationship. On another level, the patient is a member of society; because of this it can be argued that he or she has a responsibility to other members of society and vice versa. In order for society to respond to the needs of communities as a whole, and to the individuals that constitute that society, it is imperative that information be collected from individuals to inform the needs of society. On yet another level, the patient, in the context of the cancer registry, can also be considered a research subject. The type of research however is generally epidemiological in nature as opposed to clinical research, and confidentiality issues in these two contexts differ.

As previously noted, confidentiality includes a set of constraints that apply to health information of a private or sensitive nature which a person has chosen to reveal to a treating physician or healthcare professional but which should not be revealed to others (IARC, 2004:11). Confidentiality in the doctor-patient relationship from a lay perspective means that whatever is disclosed by the patient to the doctor and vice versa must remain between these two individuals, unless the patient agrees to disclosure to another person or healthcare professional. This is of course an ideal situation and is based on the notion of a single doctor being able to address all of his/ her patientôs needs.

In most countries confidentiality is addressed in legislation or professional codes of conduct. For example, in the United Kingdom (UK), medical professionals are required by both the UKôs Medical Act 1983 and the National Health Systemôs (NHS) Codes of Practice 2003 to treat personal information disclosed during care as confidential (Baird, et al. 2009:92). The expectation is that the physician will act responsibly in controlling the flow of patient-identifiable information.

Confidentiality also enhances the idea of the autonomous patient, as the patient is afforded the ócontrolôconcerning what to do (or not to do) with his or her personal information.

The reality of todayôs medical environment is very different to that of Hippocrates in 5th BCE when there was a single patient and a single physician attending to his or her care. As science has advanced, the number of individuals involved in the care of a single patient has grown phenomenally. In most units, whilst the initial consultation is with a single doctor, there are now several teams of doctors that interact with the patient. There are some specialities like Radiology, and Laboratory Services, where the doctor often has no direct interaction with patients.

Patient information which was previously limited to a single file is now available and accessed by multiple users, many of whom are non-medical staff. The ultimate responsibility for maintaining the confidentiality of data lies with the primary treating physician (IARC, 2004:18). Whether a physician submits data to a registry voluntarily or in fulfilment of a legal requirement a patientôs right to confidentiality

should be actively protected. In keeping with this, a physician has the right to expect that the cancer registry will also adhere to strict rules of confidentiality.

For the purposes of a Cancer Registry, any data collected and stored by the registry, which could permit the identification of an individual patient is considered confidential data (ECRN, 2002: 5). This may include single data fields like name or identity numbers, or linked data e.g. date of birth combined with sex and address.

According to the IARC *Guidelines on Confidentiality* (2004:2),

> *…. confidentiality in the context of health and biostatistical research concerns avoiding the disclosure of sensitive and identifiable information about a patient to a third party*.

Although there may be an understanding that all staff working at healthcare institutions will maintain confidentiality, there is usually a distinction made between medical and non-medical staff. The duty to

keep all patient information confidential is part of the ethos of all healthcare professionals. The nature of the relationship that non-medical personnel have with patients is different, as it is often less direct and less intimate. It is often viewed as a client-clerk relationship as opposed to a healthcare professional-patient relationship. It is for this reason that many institutions do not assume that non-medical staff will automatically maintain or respect confidentiality, and require that a confidentiality agreement or code of conduct to be signed.

The IARC in an earlier document on confidentiality (Coleman, et al. 1992:1148) recommended that the registry staff should sign a declaration stating that they will not release confidential information to any unauthorised person, and that this declaration should remain in force even should they terminate their employment. As far back as 1990, the IARC had addressed confidentiality and devised a formal Code of Conduct to be followed by its member registries. The IARC maintains

> *… that adequate safeguards for the patient's right to privacy can be obtained by*

> *adherence to an appropriate code of conduct in the operation of the cancer registry* (Coleman, et al. 1992:1143).

These guidelines were revised in 2002, following the European Unionôs (EU) directive on the protection of individuals with regard to processing personal data. Both the International (IARC) and the *European Cancer Registries Network's (ECRN) Guidelines on Confidentiality* deal in detail with the cancer registry requirements for confidentiality. Such requirements include storage and transmission of data, access to data, responsibilities of the registry manager, an oath of secrecy or confidentiality document for all staff, physical access to the registry, access to computers and servers, and the need for encryption and de-identification of data. Analysis and access to data by researchers, health care planners and individuals are also included.

Relating these issues to the idea of medical confidentiality, it is clear that providing information to a national cancer registry, at least when viewed as part of the individual doctor-patient relationship, might have some difficulties. That is why the idea of

utilitarianism, which looks at the good of society, is probably a better argument to use. Seen as a public good, in that the information gathered has the potential to lead to knowledge concerning, e.g. possible causative agents leading to cancer development, areas of cancer prevalence, environmental factors which may contribute to cancer, and racial predispositions towards certain cancer types provide an argument for submission of information which may be considered as confidential. In addition, the recognition of confidentiality as an important ethos in all doctor-patient relationships is supported in ensuring that patient-identifiers will be anonymised after factual input.

Concerning the idea that individuals working with sensitive information should be involved in keeping patient confidence, registry guidelines make clear that a formalisation of a confidentiality agreement should occur. Moreover, the type of information technology systems, their encryption and access should be of great concern. As noted in previously in my two registry examples, the facts that e.g. 1) there is no dedicated computer in a private area set aside for patient input, 2) individuals of good will, willing to take

on the responsibility of patient input, are often without formal support, 3) computers used for data input are, by necessity, removed from a ósecureô setting to at-home use because of lack of support, 4) the unknown recipientôs data capture system, 5) the lack of feed-back from registry officials; 4) codes or agreements of confidentiality although desired which are not formalised and 5) the non-involvement of patients are just some elements which may contribute to unintentional breaches of patient-data confidentiality.

As a remedy to this, The Institute for Clinical Evaluative Sciences (ICES) has listed a number of safeguards to ensure confidentiality of personal health data. These are, as listed in Gershon and Tu (2008: 873):

- *ëDe-identification of data or, if de-identification cannot occur, the substitution of an encrypted unique numeric identifier for personal identifiers by a designated data custodian;*
- *Designation of a privacy officer to implement and monitor compliance with all security and confidentiality policies and practices;*
- *Stringent physical and electronic security of data;*

- *Limitation of physical and electronic access to the data;*
- *Cultivation of an atmosphere of respect for privacy and confidentiality, inclusion of confidentiality and data protection obligations in employment contracts, requirements for employees to sign confidentiality pledges yearly and to receive adequate and on-going training;*
- *Implementation of strict policies and procedures to handle, access, use, disclose, retain and destroy data;*
- *Established penalties for unauthorized attempts to access or disclose data, or to re-identify de-identified data;*
- *Assessment of potential privacy and confidentiality risks for every observational study;*
- *Limitations on data use to a need-to-use basis;*
- *Controls on disclosure of study results including the stipulation that only aggregate results are allowed to be reported; and*
- *Regular reviews and audits, transparency to the public, firm oversight and approval by independent parties.*

The lessons learnt from personal experience thus far have been that there are possible and unintentional breaches of confidentiality in some of the registries. This is because data has not been collected according to the various guidelines on confidentiality. The majority of the contributors to the two registries work in state hospitals and deal mainly with indigent patients. The data collected for the registries has been collected with the aim of improving care and services for patients. However, the doctors who submit data have a responsibility for ensuring the confidentiality of data.The doctors have submitted the details in good faith, and the assumption is that the registry would be run ethically as regards confidentiality and security of data. Indigent patients, it has been shown, have less awareness of their rights, and the obligation and responsibility of doctors regarding confidentiality (Britz and Ackerman, 2006). Maintaining confidentiality and protecting patient rights underlie ethical medical practice. Data has been presented at international conferences, but there has never been any feedback to the affected population or the greater South African society.[5]

[5] I have had personal experience with this problem. South African Childrenôs Cancer Registry data was presented as the society International Oncology conference in Mumbai, 2007 coordinator.There

The re-establishment of the National Cancer Registry in South Africa (NCR) should set a precedent in determining how cancer registries and other disease specific registries should be run in South Africa. There should be a clear supervisory role built into the NCR, which will ensure that all current breaches of confidentiality do not continue or occur in the future. Individual cancer registries should all apply to local ethics committees for approval; this will also help to prevent breaches of confidentiality. The NCR should draw up a code of conduct to govern functioning of other cancer registries that may exist independently or for those which feed data from a regional area into the National Register. These are some of the ways in which confidentiality may be assured.

Now I turn to another ethical issue in cancer registry, the idea of informed consent

2.4. Informed consent

Cancer registries have a host of functions and one of these is in the area of research. Research ethics falls under the jurisdiction of many national and

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has been no feedback in the form of an annual report or press releases from the registry coordinator.

international directives, rules, and guidelines. These regulations all focus on the overall aim of protecting the subject/participant. In research, great emphasis is placed on informed consent. Cancer registries collect sensitive information on a named-person basis and this is analysed by the local and national registries. In addition, cancer or epidemiologic researchers may apply for access to information from the cancer registry so a single source in which the data is ósecureô may not be completely assured. The question then is whether informed consent should be obtained from the patient to have his or her data entered.

There are many guidelines detailing the requirements for informed consent in research.[6] The current expectation is a patient-rights or autonomy-centred approach. In this perspective, patients have the right to information, the right to knowledge, the right to have their choices treated with respect, the right to exercise free choice, as well as the right to control their participation in research e.g. to withdraw without prejudice.

[6] See for example, The Declaration of Helsinki (2008), The Belmont Report (1979), The CIOMS Guidelines (2002), and The Medical Research Council's Research Ethics Guidelines (2002) .

There are very few exceptions to the need for informed consent and these require that there be negligible danger to the individuals concerned. Cassell and Young (2002:314) note that whilst the Helsinki Declaration is the explicit standard under which ethics committees evaluate research, it does not provide useful guidance on the issue of consent for health systems research. The Helsinki Declaration addresses ethical issues concerned with the effect of individual level interventions on an individual. The Helsinki Declaration also divides research into two groups, therapeutic and non-therapeutic research (ibid).

Individuals participating in non-therapeutic research are afforded extra protection, as there is no direct benefit to the participant, but there may be significant risk. The Helsinki Declaration (2008) states:

> *… Subjects must be volunteers and informed participants in the research project' and 'each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the*

discomfort it may entail. The subject should be informed of the right to abstain from participation in the study.

There has always been debate around what constitutes informed consent. For example, common questions are: How much information should be given? What form should it take? Is it acceptable for there to be differing standards for literate versus illiterate populations? Kottow (2004:565) describes 3 levels of standards of disclosure:

1. Professional practice standard ï technical information
2. Reasonable person standard ï what the subject would normally need to know in order to render an informed consent
3. Actual/subjective personal standard ï the subjects avidness for information which could become limitless

In research, full disclosure is required about the intervention (treatment, limits of participation, etc.) together with details of the risks and possible benefits; however, in clinical practice the patient generally does not receive information that is detailed to this extent.

Chalmers calls this the ódouble standard for consentô (Cassell and Young, 2002: 315). He finds the practice scandalous as there is evidence that patients treated on research protocols do much better than those treated routinely. How can this be debate be applied to the cancer registry? Is it at all applicable?

It is quite clear that the process of informed consent works well for consent in relation to an individual. However this process does not work for health systems research. Health systems research looks at what is required by the population and how best to deliver this. Cancer registries potentially have both components.

Cassell and Young (2002) considered the impact of the need for informed consent in organisational research within the UKôs NHS. They note that organisational change in the NHS, which has been spurred on by rapid technological progress, is driven by the results of medical research. The NHS has experienced problems in conducting organisational research, with requests for informed consent, and resultant delays at the ethics board review level. They argue that as an alternative, methods for seeking

community consent for organisational research should be acted upon (ibid: 313). Cancer registries are in a similar situation; and its results will inform the organisation of cancer programmes.

The UK has seen low levels of participation within registries due to the requirement for explicit consent (Baird, et al. 2009:92). This has led to unacceptable levels of bias, which then impact negatively on the quality of research. This type of situation could be viewed as unethical in itself. Kalra, et al (2006:196), states that it is a ógenerally held view that explicit consent should be obtained to use identifiable personal data for medical research, particularly for multicentre or secondary research when people who are not part of the original clinical team need access to the data. They suggest that, to avoid having to seek consent again for each study, the alternative is to ensure the data is adequately anonymised (ibid). The problem is that there are no consensus guidelines on how to anonymise data; and anonymising data thoroughly enough runs the risk of losing critical information. Using existing guidelines and laws concerning informed consent, a practice model should be developed to guide the medical community

concerning informed consent and systems research. Moreover, such a model should be widely publicised so that the public understands exactly how, if and when it might happen, their data will be processed and confidentiality maintained. Medical and non-medical staff involved in medical data management will also require special training, as well as on-going reminders of the confidential nature of the information they handle.

According to Haynes, Cook and Jones (2007: 302), the pursuit of informed consent for cancer registration may sometimes be detrimental. There are also concerns that the process itself may result in biased sample groups, as some patients would be less contactable. There is also significant additional costs involved in trying to obtain informed consent and it could well be argued that these resources are better spent elsewhere. In a study by Tu, et al. (2004) it was found that obtaining informed consent from patients for the registry of the Canadian Stroke Network led to important selection biases. Due to the need for informed consent, only 50% of the eligible patients participated. The cost of trying to obtain informed

consent over two years was 0.5 million Canadian Dollars (ibid: 1414).

Because of this is it was recommended that de-identified data be collected without obtaining patient consent, but with the necessary confidentiality measures. This approach has been advocated by others, who argue that where health care is funded by the public, patients have an obligation to allow their data to be used, with the aim of benefiting the overall health care system. Moreover, Tu et al. (ibid: 1419) recommend that informed consent be obtained if the registry includes direct patient interviews and the collection of biological samples. It is also recommended that waivers for informed consent for clinical registries should be carefully considered and should be judged by an independent research ethics board.

The cancer patientôs reality is often one of a struggle for life versus death. The diagnosis and treatment is of cancer is not just an arduous and difficult physical battle, but is also an emotional nightmare. From personal experience, information relating to the cancer has to be given with sensitivity and timing is paramount. Many patients are in shock after the

diagnosis is disclosed. Following this, they have to grapple with the realities of treatment e.g. chemotherapy, dealing with the side-effects of treatment, and the disruption of a normal life routine. At the same time they are confronting their own mortality. Patients can deteriorate rapidly within days of their diagnosis. In this situation, is there ever an opportune time to discuss the cancer registry? The answer, in my experience, is probably no. To a patient in crisis, the things that matter most are the issues that immediately impact upon them.

Reflecting on my personal view ï I have to consider the following. I have made several assumptions: firstly, that post cancer diagnosis, the patient is awash with such personal and complex sets of emotion that he/she cannot be considered to be in a state in which such a question *ought* to be asked. In a related way, seeking consent for inclusion in a cancer registry enrolment is hardly a major concern at this point and probably is of little interest. The question I have to ask of myself is: Am I deciding his priorities? Am I not eroding his autonomy by not seeking informed consent? Where does one draw the line between assuming a paternalistic attitude, and providing full

disclosure? How much of cover do I consciously or sub-consciously obtain by evoking the doctrine of therapeutic privilege?

The research conducted from a cancer registry is not of a homogenous nature. Registry analysis is primarily epidemiological research, but researchers can request access to further data which may have a clinical or applied component. It is often argued that cancer registration cannot be subject to the informed consent process, as this is too costly, time-consuming and more importantly is unnecessary, as it bears no direct risk to the patient.

However, as we do have a moral duty to ensure accountability, perhaps representation from patient groups is one way around seeking informed consent from every patient. This, together with ethically-minded data managers could cover the epidemiological research arm of the registry. If there are additional research projects that use data from the registry, but are focussed at a more individual level, then ethics committees, together with the patient advisory groups should review each application on a case-by-case basis and decide if informed consent for

further studies should be obtained from the patient or if deceased, from the patientôs family.

The problem with this model is that Ethics Committees themselves do not act similarly when faced with a research protocol. Some committees are more conservative and apply regulations more stringently. A study by Willison, et al (2008:308) into how research committees view the request to access medical records for research purposes showed varying perceptions across different research ethics committees. In the study, thirty research ethics chairs and administrators affiliated to faculties of medicine in Canada were interviewed. The case presented to them for ethical approval without informed consent was that of a retrospective chart review. Included in the discussion was the question of who may have access to the medical record for data abstraction.

The results showed a large variation across sites in the requirements for consent for research involving access to medical records. Forty seven per cent of the sites required individual consent for the study to proceed as proposed, 38% did not require consent, 10% stated that their response would depend on how

potentially identifying variables were going to be managed and 7% suggested notification with an opt-out process (Ibid).

If there are such discrepancies as to how research committees view these requests, then perhaps patientsô faith in these committees will be lessened. This response may be due to misinterpretation of the laws, or could be influenced by personal bias. It is likely that similar results could be found in a survey of research committees in South Africa as well. Either way, there needs to be clear guidelines on data usage and a standard interpretation of the laws governing privacy. If required, the legal and medical fraternity need to work together, to come to a common understanding of ethics and the law regarding informed consent involving medical records. To make inroads into this complex problem, on-going education of research committee members is required.

My initial thoughts on the cancer registry were that it had to be unethical to collect information, to be shared outside the ambit of the treating physician, without obtaining informed consent. On reflection of my experiences with patients, I cannot think of an

opportune moment at which to ask for consent for inclusion of data on the cancer registry. It would be easy to avoid considering the issue of whether informed consent is necessary, by saying that this is legislated. This is the stance many of my colleagues are adopting when the issue of consent is raised. Social contracts can be legislated, and in that case the Department of Health would have to ensure custody of patient data as well as its analysis and reporting. The reality is that just because something is mandated by law, doesn't necessarily mean that it is morally correct. Having considered the following as regards data capture for cancer registries:

- that it is primarily epidemiological research;
- that there would be no ideal opportunity to seek informed consent;
- that there would be unnecessary financial costs incurred; and
- that cancer registries should have active patient advisory groups and community participation

I consider that a reasonable argument can be made against seeking informed consent in the case of cancer registries. The proviso is that any research that goes beyond the epidemiological research would

require researchers to return to the patients, via their physicians to obtain informed consent.

2.5. Patient's views on Registries

Numerous studies have looked at the opinion of patients concerning various registries (Baird, et al., 2009; Helgesson and Swartling, 2008; Barret, et al., 2006; Singleton and Wadsworth, 2006; Robling. et al., 2004; Caulfield, Upshur and Daar, 2003; Willison, et al. 2003). We should look at how these could inform our practice.

Whilst the general consensus is that patients view participation in disease registries positively, there are some studies that have reported figures of 10%, 17% and 25% of patients who refuse to participate (Barret, et al. 2006). They conducted a national survey on the British publicôs view on the use of identifiable medical data by their National Cancer Registry and found that the majority of the British public did not consider the use of personal and identifiable information for the purpose of health service research and surveillance to be an invasion of privacy. Eighty per cent would support a law making cancer registration statutory (ibid). Moreover, a similar study in West Germany in

1983, found comparable figures and findings (ibid). They further note that despite the NHS code of practice on confidentiality assuming that patients will not be happy if their information is used for anything beyond direct clinical care, their study found that patients had no objection to the release of such data if the information was used for public health research and surveillance (ibid).

Studies that assessed patientsô needs for informed consent for the use of personal data show mixed results. In the study by Willison, et al. (2003:373) patients at a general practice were interviewed to find out their preferences for consent to use information in electronic medical records for research. The patients were willing to allow information from their records to be used for research, but most preferred to be asked for consent verbally or in writing.

Barrett, et al. (2006:4) identified that 93% of the public favour the use of non-consent methods in registry-type research. Only 2% of patients who received a study recruitment letter, which included personal contact details, felt that their privacy had been breached. 81% of the participants in this study

supported statutory cancer registration. Previous studies have suggested that patients are content with providing registry data without informed consent and delegating decision making for further use to research ethics committees (Baird, et al. 2009:95).

Caulfield, Upshur and Daar (2003:4) suggest the use of an authorisation model for genetic databanks, where individual informed consent is obtained for initial collection of data and patients then select the level of involvement they wish to have in decision making in any future use of their data. Whilst such a model does grant patients autonomy, it may be challenging to obtain the individual informed consent at the outset and may depend on the type of data collected. Moreover, depending on the type of research conducted, informed consent may not even be warranted.

For patients battling a life-threatening disease the importance of their data might be seen as unimportant as they face greater challenges. Baird, et al. (2009:92) interviewed both patients with multiple sclerosis (MS), and their physicians on their views concerning consent, access to data, and the holding

of personal information in a disease specific register. Whilst all were positive regarding the benefits of the Multiple Sclerosis Register, and patients expressed open and altruistic views on the use of their personal information to facilitate service provision and research, there was an expectation that there should be responsible guardianship and the legitimate use of their information. Patients also emphasised the trust that they had in their physicians to safeguard their interests and to act in an ethical manner.

The MS patients also proposed that there should be a guardianship committee, made up of involved stakeholders to govern the MS Register. These MS patients were also concerned that employers may have access to the information on the registry and they could be further prejudiced.

In the study by Robling, et al (2004:104) which investigated the use of primary care data without consent, there was general support for research, but concerns were expressed about data collection without consent. This included a lack of respect for patients, a lack in the patientsô control over the processes, as well as fears of unauthorised access to

the data by others. Interestingly, the same fears were verbalised, even with collecting data for population-based disease registers. Of note, the anxiety increased with more sensitive conditions, e.g. mental health problems, and the same could be extrapolated to cancer. Patients felt that they should be informed about data collection as a common courtesy, as well as having the option to opt-out. Again, the same themes as in the Baird study with regard to security of data were echoed.

Another study by Helgesson and Swartling (2008:208), considered parental views on data use, confidentiality and consent in predictive screening involving children. Respondents cited altruism and the desire to assist others in a similar situation as well as to contribute to research as motivating factors to allow their data to be used. However, of note, the participants did not want data to be used beyond the reasons for which consent was originally taken.

There are several models proposed for obtaining consent to use personal medical data in research. These include the Opt-in, Opt-out, Social Contract and Anonymous processes (Singleton and

Wadsworth, 2006:256). In an *Opt-in* process each potential participant is individually informed about the study and their consent is sought and possibly formalised in writing. An *Opt-out* process involves individually informing each potential participant about the study and they are included unless they object. A *Social Contract* process involves people being informed generally about the research. In this process information is freely available on specific projects and people are included unless they specifically object. Finally there is the *Anonymous process*. In this method a system is developed which relies on a viable way to anonymise data so that consent is not legally required.

Each option has a different cost implication. The cost per case in the *Opt-in* process is constant, but actual costs are higher, as patients have to be actively recruited. Both the *Opt-out* and *Social Contract* approach require general information campaigns and will incur lower costs, but there will be costs in dealing with objections. In cancer registration, the *Opt-in* and *Opt-out* process both have the possibility of creating result bias. In addition they bring unnecessary costs into the equation.

Patient research into the needs for informed consent as discussed in the various studies above has shown that generally most patients would not object to data collection provided that information about the registry was provided, and that necessary steps to maintain confidentiality were taken. It would be reasonable to use this to justify consent for data usage in cancer registries using a combination of the ósocial contractô model together with anonymisation.

2.6. The individual and society: Impact on research

The *Helsinki Declaration* is used by all Ethics Committees as a fundamental document to guide the research process. Itôs 5th Amendment (Oct 2000) added the following ï ôMedical research involving human subjects includes research on identifiable human material or identifiable dataô The Declaration also states that ethical, legal, or regulatory requirements should not be allowed to reduce or eliminate any of the protections for human participants set forth, and that reports of experimentation not in accordance with the principles laid down should not be accepted for publication. The requirement for informed consent ï preferably in writing ï is explicit.

The reality is that this process is difficult to follow for epidemiological research, and may not be necessary, provided stringent measures to safeguard information are instituted and patient representation, via advisory groups, is present on ethics committees. If the current requirement for informed consent has to be fulfilled, it would cripple any data collection by registries. The World Medical Association therefore needs to review this Declaration and revise it to address the challenges of informed consent in epidemiological and organisational research.

According to Helgesson and Eriksson (2008: 54), The *Council of Europe's Convention on Human Rights and Biomedicine* (1997) states that research that does not have the potential to ―produce results of direct benefit to the health of the person concerned‖ may be authorised if:

> *'(a) the dignity, integrity and other rights and fundamental freedoms of the research participants are respected and protected;*
> *(b) they do not object; and*
> *(c) other standard conditions on research on human beings are applied, such as that*

> *there is no alternative to such research and that it entails minimal risk and burden for those participating.*

While this may serve to show an understanding of the need for systems research, Article 3 of the United Nationsô(UN) *Universal Declaration on Bioethics and Human Rights* (2005) states,

> *ñthe interests and welfare of the individual human being shall prevail over the sole interest of society or science*.ò

... which brings us back to the individual versus societal benefit debate. Perhaps to mediate this the UNôs *Universal Declaration on Bioethics and Human Rights*, Article 14 (UDBHR) (2005) states that the promotion of health and social development for their people is a central purpose of *governments*é ò It further adds that ... ñthe enjoyment of the highest attainable standard of health is one of the fundamental rights of every human beingò and that ñprogress in science and technology should advance access to quality healthcare and essential medicines.ò

The onus would therefore be placed on government to conduct research that would improve healthcare. While we see steps towards recognition of the needs or good of society, it must be noted that overall it remains that the ‘interests of the individual shall always prevail over the interest of science and society’ (Helgesson and Eriksson, 2008: 54). A balance must be found between individual rights and those of society, and this should be formally recognised in ethical declarations and guidelines. Until this is done the tension between the two will remain unresolved. Community involvement, which is essential to represent societal norms, should be via involvement on research committees, rather than through stand-alone communities with final vetting powers.

There is a view, presented by John Harris (2005), which maintains that scientific research is a moral duty. Following the ghastly experimentation on human subjects by the Nazi’s in World War II, research is sometimes seen as the ‘Frankenstein science’ (ibid: 242). The reality is that all of society benefits in some way, either directly or indirectly, from the gains made by medical research. Harris argues

that we have a duty of beneficence to others ï a moral duty to help others in need. This would fit into the concept of fairness, in that we all benefit from medical research and we are obliged to contribute to that body of research (ibid: 244).

The *Declaration of Helsinki,* 2008 states ó In medical research on human subjects, considerations related to the wellbeing of the human subject should take precedence over the interests of science and societyô One can immediately appreciate the potential conflict if this is to be applied to organisational and epidemiological research.

Harrisôs (2005) argument is that we have a moral obligation to help others, to be just and to share, fits very well into the views of our South African society, which espouses to share and care and sees itself as ó oneô When applied to epidemiological and organisational research, our moral obligation to participate in an activity that does not harm self or others and that benefits the greater society should be a compelling enough reason to set aside narrowly constructed arguments adopted from a different type of research.

2.7. Concluding Remarks

The concept of respect for persons includes ethical issues such as confidentiality and informed consent. Views on autonomy and research include ôthe right of people whose body is to be interfered with, be it for therapeutic and/or research purposes ... to be fully informed about the intended procedure, prior to expressing their uncoerced, explicit and revocable acceptance to participate (Kottow, 2004:565).[7]

The conflict between individual confidentiality and the societal good can be addressed by taking a purely utilitarian view on the collection of data.[8] According to Robling, et al (2004:108) ôa perspective in which actions should be guided by what produces the greatest good for the greatest number presupposes a basic confidence in the benevolence of oneôs governmentô At the same time, to neglect the idea of respect for persons would be an ethical wrong. Robling, et al (2004:108) and Doyal (1997:108) both

[7] Kottow (2004) is of the view that subjects have had decreased protection over the last few years and that both informed consent and informed decision-making have been replaced by some degree of paternalism. In the effort to achieve more, on both an individual patient basis as well as for the population, we are risking the rise of paternalism in that decisions or assumptions are made regarding what patients want and how they feel.

[8] There is also a rights-based view which conflicts with a utilitarian view; this will be addressed in detail in the legal perspective, discussed in Chapter 3.

argue for a moral balance between the needs of the individual and community which will offset the moral wrong that is committed in not gaining consent for use of data, against the benefit accrued to the patient and the public. In keeping, we might consider the sharing of personal confidential information in the spirit of ósharing and caringô It is very likely that after consultation with the community we may find the issues around cancer registration i.e. autonomy, and confidentiality may be non-issues. However this cannot be presumed and further exploratory studies would be needed.

The majority of patients in South Africa who seek health care are seen in the State sector, and they are treated by a small number of the available doctors in the country. The majority of the patients have little understanding of their rights and an even lesser understanding of the ethics that govern the individual doctor-patient relationship, much less the idea of data systems collection. These patients are cared for by teams of doctors and the relationship between the patient and his/her doctor is often far from the original ideal. Due to the vast workload, there is very little time available during consultation to address issues

beyond immediate management. In many healthcare settings, social worker and psychology support are either sparse or absent. The patientôs immediate concerns are focussed on their day-to-day survival. In addition, the financial burden carried by many patients is considerable.

The smaller number of patients seen in the private sector will generally have a different relationship with their physician, as there is usually more time available in the consultation and the level of knowledge around their condition is generally higher. Any potential breaches of confidentiality can result in litigation in both the private and public sector. However, the private sector is generally more litigious than the public sector. It is therefore likely that it is on the basis of fear of litigation from breaches of confidentiality, as opposed to ethical concerns surrounding confidentiality that dictates how some doctors conduct themselves. It was this fear of litigation following breaches of confidentiality that led the private pathology laboratories to withdraw from submitting data to the then-SA National Cancer Registry.

The assumption that by making cancer registration a statutory requirement that the ethical ideal of patient confidentiality is taken care may in fact be a false sense of comfort or alternately, can leave one with some moral discomfort. I have suggested that if the IARC guidelines are followed, every aspect regarding confidentiality is covered. All those involved in healthcare - physicians, patients, healthcare workers, politicians and the broader public - need on-going education on the issue of confidentiality in the context of a national cancer registry. There is no doubt that the cancer registry and other disease registries are powerful tools in clinical medicine and public health. However, confidentiality remains a duty. [9] Researchers are reminded that there is a legal and a moral impetus to ensure that research is conducted with maximum respect for participants-confidentiality and informed consent remain fundamental to the ethos of research-even if the research is not linked to clinical care. Underlying all our actions as doctors is the duty that we have to act in the best interests of our patients.

[9] Kalra, et al (2006:196) calls on researchers to strike a careful balance between their pursuit of health improvements for all and their obligation to maintain privacy of individual research participants.

Related to informed consent and confidentiality is the idea of privacy. Privacy usually concerns two things 1) Control over some information about us and 2) some control over who can experience us or observe us (Britz and Ackerman 2006). Privacy is not in itself considered an intrinsic good in ethics. It is related to ethics in that it concerns the causal relationship between an individualôs idea of ôbeing in control of their own livesô or their autonomy. ôIn other words, unless a person is in the position to appreciate that they have the ability to determine their own course of action or to make their own choices, they cannot be considered as autonomous agentsô (Knapp van Bogaert and Ogunbanjo 2009: 195). When aspects of an individualôs life or death are open to public scrutiny, then they are open to public experience and evaluation, this may imply a disvaluing of oneôs autonomy (Rachels, 1975: 333). The idea of privacy first became an issue under the domain of the law. In relation to cancer registries, this is the subject of the next chapter.

CHAPTER THREE: Cancer Registries: Exploring Some Legal Considerations

3.1. Introduction

In all legislations concerning cancer registries there are two particular concepts that are of great importance. The first is Privacy, and the second is that of Data Security.[10] As in South Africa, different countries have a variety of legislations which relate to cancer registries. In this chapter, I will look at some of these different legislations then comment on our South African laws. The legal frameworks impacting on cancer registration in South Africa include the Constitution, the National Health Act, the Promotion of Access to Information Act, Common Law, as well as Data Privacy legislation which is still being developed.[11]

[10]Data security is an enormous area and, because of the word-restriction, I will not discuss it in this research report. There are several guidelines e.g. the Anderson's Guidelines (Denley, Smith, 1999:1329) and the Caldicott Guidelines (1997) that are most comprehensive concerning this topic.

[11] I will make only some comments concerning the proposed Data Security legislation.

3.2. Privacy

According to the Privacy International Report (PIR) (2003), privacy has ‘roots deep in history’, which include Biblical references, as well as protection of privacy in early Hebrew culture, classical Greece and ancient China. These focused on the right to solitude.

Privacy is a basic human right recognised in the UN *Declaration of Human Rights* (1948), the *International Covenant on Civil and Political Rights* (1966) and in many other international and regional treaties and documents.

For example, Article 12 of the 1948 *Universal Declaration of Human Rights* states:

> *‘No-one should be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks on his honour or reputation. Everyone has the right to the protection of the law against such interferences or attacks’*

According to the SA Law Reform Commission Report on Privacy and Data Protection (2009), Privacy is a valuable and advanced aspect of personality. In South

Africa, Neethlingôs Law of Personality as presented in the South African Law Reform Commissionôs Report (2009: 76) proposes a definition of privacy as follows:

> *Privacy is an individual condition of life characterised by exclusion from publicity. This condition embraces all those personal facts which the person concerned has determined himself to be excluded from the knowledge of outsiders and in respect of which he has the will that they be kept private.*

Privacy as a concept flows from the right to be left alone, which is a part of the idea of respect for persons. Privacy is a natural right which provides the foundation for the legal right. It is an important right as it is a necessary condition for other rights like freedom and security of person.[12]

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[12] Some different examples of privacy in legislation follow: *The Council of Europe's Convention for the Protection of Human Rights and Fundamental Freedoms,* Article 8, 1950, states:'(1) Everyone has the right to respect for his private and family life, his home and his correspondence. (2) There shall be no interference by a public authority with the exercise of this right except as in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health of morals, or for the protection of the rights and freedoms of others.' The Preamble to the *Australian Privacy Charter* (1994) states the following:

There is also a relationship between privacy, freedom and human dignity. The duty to respect a personôs privacy is a *prima facie* duty. It is not an absolute duty that does not allow for exceptions. The right to privacy is thus confined by social responsibility.

However, privacy is difficult to define and there is no single definition that is universally accepted. As an example, the *Calcutt Report* (1990) from the UK noted that ónowhere have we found a wholly satisfactory statutory definition of privacyô They settled on the following definition in their first report on privacy:

> *Privacy is 'the right of the individual to be protected against intrusion into his personal life or affairs, or those of his family, by direct physical means or by publication of information'*.

Alan Westin in his 1967 work *Privacy and Freedom* (PIR 2003), defined privacy as

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"A free and democratic society requires respect for the autonomy of individuals, and limits on the power of both state and private organizations to intrude on that autonomy. Privacy is a key value which underpins human dignity and other key values such as freedom of association and freedom of speech. Privacy is a basic human right and the reasonable expectation of every person".

ôthe desire of people to choose freely under what circumstance and to what extent they will expose themselves, their attitudes and their behavior to others.ô

Edward Bloustein as quoted in the PIR (2003) views privacy as an interest of human personality. ôIt protects the inviolate personality, the individualôs independence, dignity and integrityô Thus we can see that there are many different definitions of privacy but all derive from the idea of respecting persons.

In law, privacy can be divided into:

- Information Privacy: this covers the collection and handling of personal information
- Bodily Privacy: this is concerned with the protection of the physical body against invasive procedures
- Privacy of communications: this covers security and privacy of all forms of communication
- Territorial privacy: this deals with setting limits on intrusion into various environments ï for example the domestic environment and work place

3.3. Privacy Legislation

Nearly every democratic country in the world explicitly recognises a right to privacy in their constitutions. The legal right to privacy is also protected in most democratic societies under Private Law. Some of the legislations that protect privacy are e.g. the USAôs *Privacy Act,* UKôs *Data Protection Act,* Australiaôs *Privacy Charter* containing 18 privacy principles, and the Organisation for Economic Co-ordination and Developmentôs (OECD) *Guidelines for the Protection of Privacy and Transborder Flow of Personal Data.*

The move to legislate privacy began as far back as 1970 in some countries. The rapid development of informational technology has created a need for further legislation, as the amount of information potentially available in the public domain is ever-increasing. This has led some countries to revise existing legislation and introduce new directives.

In 1981 the Council of Europe passed the directive on the õProtection of Individuals with regard to the processing of personal data and on the free movement of such dataö The Directive also requires

that data being transferred to countries outside the European Union be covered by privacy laws.

Privacy International (PI) wrote a report entitled ñPrivacy and Human Rights, an International Survey of Privacy Laws and Practiceò (2003). In the report they note that the power, capacity, and speed of information technology is accelerating rapidly. With it the extent of privacy invasion or the potential thereof, there is a corresponding increase in the development of further information safeguards. The report also notes that other trends contribute to privacy invasion. These include amongst others 1) globalisation as it has removed the geographical limitations to the flow of data and 2) convergence because data systems are interoperable with multiple systems

Privacy is an old concept, but it is also a concept which has seen more and more challenges as technology progresses. In many ways the world as we know it has become larger and at the same time it has become smaller. Safeguards for privacy have to be addressed and constantly revisited in order to maintain adequate protection for all.

3.3.1. Privacy legislation and research

Privacy legislation is well-intended and this has resulted in formal Privacy Acts in most countries. However, in many of these Acts, medical research has not been specifically addressed. Trevena, et al (2006:476) note that well-intended privacy legislation may not have been implemented in line with community views, especially as regards the use of personal information for health research. The challenge is to balance the privacy rights of individuals with the requirements of research intended for population/public benefit.

For example, Iverson, et al. (2006:168) discuss their struggle in obtaining access to registry data for epidemiological research in USA Gulf War veterans. Concerning this, the USA *Data Protection Act* was applied in a restrictive manner and data controllers created significant obstacles to their research. They noted that data controllers and such committees often assume that information-based research requires the same review procedures and strict principles as is applied to interventional research (ibid:170). This approach does not take into account, the different

sorts of risks involved. They argue that although informational privacy is important,

> *'it is not nearly as fundamental as the right not to be assaulted against your will by a medical researcher as may occur in an interventional study* (ibid).

The question over whether informational privacy is less important than bodily integrity can be debated, but the point is made that the ó proportionality principle is misapplied if the risks associated with epidemiological research are equated with interventional researchô (ibid: 168).

Trevena, Irwig and Barratt (2006:473) conducted a trial to assess the impact of *Australian Privacy Law* on research. Potential research participants were randomised between an opt-in versus an opt-out consent process. They found that opt-in recruitment methods markedly decreased the proportion of patients recruited into the trial compared to an opt-out consent method. In addition, opt-in participants were more likely to include active preventive health seeking participants as well as those who had a higher risk of developing disease. Moreover, the opt-in method

tended to under-recruit patients from lower educational background. They conclude that this type of selection bias is unacceptable and renders any research, emanating from this type of study design useless (ibid).

Sullivan (2008:1) notes that the impact of legislation in the USA has resulted in a downturn in cancer research macro-productivity. He also notes that the need to comply with all the legislative requirements, from local and national research requirements, as well as federal law, has substantially increased the mean cost per article on cancer research published in the USA. In his keynote comment in the *Lancet Oncology*, Sullivan writes,

> *... We have the perverse situation where the emphasis in cancer is now on translational and clinical research, while the regulatory burden on the areas crucial to this endeavour – i.e. clinical trials, use of human tissues, and use of data – is increased exponentially* (ibid).

He also notes that there are many directives that have added layers of complex and often contradictory regulations to cancer research; these have led to a decrease in data collection by registries and have negatively impacted on secondary, epidemiological and population research.

In the UK, Canada and Europe, individual research ethics boards have interpreted these regulations differently and this has created further confusion and frustration for researchers (Sullivan 2008:2). Current cancer research requires international collaboration and multicentre studies. Every country has its own privacy legislation and every centre has its own individual ethics committee, from which approval for research must be obtained. This means that there are numerous regulations that the same multicentre study has to fulfil and this creates a definite barrier to collaboration. For such reasons it is appropriate to suggest that cancer research should be subject to proportionate, fit-for-purpose regulations and that researchers, regulatory policy-makers and patient groups should drive the process for harmonisation and de-regulation.

In keeping, I will now look at two examples showing some problems and responses to different data and privacy protection legislation affecting cancer registration.[13]

3.3.2. The UK experience

The United Kingdom has had vigorous and extensive debate regarding the UK Cancer Registry. The General Medical Council (GMC) advised doctors to seek patients consent for the disclosure of data to cancer registries. This has emanated from both the ethical requirements of good medical practice and also what is required under their *Data Protection Act* and *Common Law of Confidentiality*. According to the GMCôs Chairman Sir Cyril Chantler (2001:8),

> *... patients want an open and honest relationship with their physicians, and they have a right, legally and ethically, to expect their data to be treated as private and confidential.*

[13] In the European Union, Data Privacy Laws, under the title of the "European Union's Directive on the Protection of Individuals with regard to the Processing of Personal Data and Free Movement of Such Data", (termed 'The Directive'), are stringently applied to all scenarios including those involving medical research. In the USA the "Health Insurance Portability and Accountability Act" (HIPAA) of 2006 provides the legal requirements governing the collection, transmission and access to data. Over thirty countries have enacted data protection statutes.

Debate in the UK has extended over whether Parliament should make the necessary changes in the law, to make cancer a notifiable condition.

Whilst the 1998 UK *Data Protection Act* strengthened the law protecting an individualôs privacy and enforced stricter controls on the use of personal data, the 2001 *Health and Social Care Act* made provision for the disclosure of patient identifiable information in certain circumstances, including medical research (Robling et al. 2004:104).[14] The UK has seen a number of pieces of legislation that impact on the cancer registry (Haynes et al. 2007:302). These include the *Data Protection Act* of 1998 (which establishes a series of data principles which prescribe how data must be processed, maintained and transferred), Section 60 of the *UK Health and Social Care Act* of 2001, the UK *Common Law of Confidentiality* and the UK *Human Rights Act* of 1998.

[14] Similar issues have occurred in the USA, where, despite cancer registration being legislated as mandatory, there are conflicts with the "Health Insurance Portability and Accountability Act" (HIPAA) laws, as well as growing concerns as to whether patient consent should be sought. The balance has to be created between the need for confidentiality and informed consent and the requirements for research and public health surveillance.

The UK *Data Protection Act* specifically covers medical research and preventive medicine and allows for the creation of a disease register with the necessary controls in place. However, the UK *Common Law of Confidentiality* states that patient identifiable data should not be provided to third parties, regardless of their compliance with the *Data Protection Act.*

Section 60 of the UK *Health and Social Care Act* of 2001 now provides for the processing of patient identifiable data despite the common law of confidentiality (ibid:303). Under this Act, regulations may be made which permit the processing of patient information for medical purposes deemed necessary or appropriate to improve patient care or which are considered to be the publicôs interest.

The UK *Common Law of Confidentiality* is based on case law and hence is open to interpretation. The UK *Human Rights Act* 1998 states that ôeveryone has the right to respect for his private and family life, his home and his correspondenceô and that ôthe protection of personal data, not least medical data, is of

fundamental importance to a personôs enjoyment of his or her right to respect for private and family lifeô

However, this right is not an absolute right. The UK *Human Rights Act* further provides for the possibility that the interests of a patient and community, in terms of protecting the confidentiality of medical information, may be outweighed by other interests like the protection of health.

In 2001 British hospitals began to suspend the flow of data to cancer registries (Barrett et al. 2006:1069). This was followed by an outcry from cancer registries and epidemiologists and a call for clarity in reading the conflicting Acts. As Brewster et al (2001:146) so aptly states:

> *The British Public now faces a stark choice. On the one hand, total personal autonomy, informed consent before any data is shared, and the loss of unbiased information about the burden of cancer in the community and the outcome of cancer treatments and cancer screening programmes; on the other hand,*

legislation to guarantee the availability of unbiased, population based health information and the obvious benefits that flow from this to current and future cancer patients and to the wider public.

The UK then established the Caldicott Commission (1997) to assess and develop guidelines around data collection and privacy. The *Caldicott Commission's General Principles of Good Practice* provide six principles by which one should abide by as regards data collection. They are:

- Principle one is that there must be justification for the use and transfer of patient identifiable data.
- Principle two requires that patient identifiable data should be used only where it is absolutely necessary.
- Principle three requires that the absolute minimum necessary patient identifiable data should be used.
- Principle four states that access to patient identifiable data should be on a strict need to know basis.

- Principle five requires that all those who have access to patient identifiable data should be aware of their responsibilities and obligations to respect patient confidentiality.
- Principle six requires that one understands and complies with the laws for the use of patient identifiable dataô(Haynes et al 2007:305) .

3.3.3. The Canadian experience

The Canadian government passed the *Personal Information Protection and Electronic Documents Act* in 2000. This was designed to specifically address important privacy and confidentiality issues in medical research (Gershon and Tu, 2008:178).

Similar to the UK experience, the privacy legislation has had a negative effect on observational research, in the situation where a waiver of informed consent is sought. Most privacy legislation specifically addresses when waivers may be obtained.

However, as Gershon and Tu (ibid) note, due to a conservative interpretation of this legislation, many research boards and data custodians have refused to grant waivers and that there are an increasing number

of trials where this has resulted in decreased participation, selection bias, incomplete research, and dismantled disease registries.

These two examples have shown that whilst privacy-related legislations are enacted with good intention, they are not necessarily grounded in the type of research and related activities involved in cancer registries and registration. Because of this, more or more-clearly defined parameters are needed.

3.3.4. South African laws, privacy and cancer registries

In terms of the South African Constitution, every person has personality rights, such as the right to physical integrity, freedom, reputation, dignity and privacy. The South African Law Reform Commissionôs Report Project 124 of 2009 lists privacy and data protective legislation and codes of conduct which are present in South Africa. They are as follows:

- Constitution of South Africa Act 108 of 1996
- The Promotion of Access to Information Act 2 of 2000
- The Electoral Act 73 of 1998

- Electronic Communications and Transactions Act 25 of 2002
- Banking Codes of Conduct
- Various best practices - Marketing Federation of South Africa
- Case law on bodily privacy, privacy of communication, territorial privacy[15]

Concerning privacy, the South Africa Constitution (Act 108 of 1996) Section 14 provides that:

> *...everyone has the right to privacy, which includes the right not to have –*
>
> *9 (a) their persons or homes searched;*
>
> *(b) their property searched;*
>
> *(c) their possessions seized; or*
>
> *(d) the privacy of their communications infringed*

Importantly, privacy is not an absolute right, but may be limited in terms of law of general application and has to be balanced with other rights in the constitution (SA Law Reform Commission Project 124, 2009:81). Privacy can be limited in accordance with the

[15] No case law on information or data privacy is mentioned in the report.

limitation clause of the Constitution contained in Section 36.

Section 36 allows for the limitation of rights in the South Africa Constitution, Act 108 of 1996ôs *Bill of Rights,* provided that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom. The nature of the right, importance of the purpose of limitations, nature and extent of limitation as well as the relation between the limitation and its purpose also need to be taken into account.

South Africa currently does not have a general data protection law. The South African Law Reform Commission is working on a Data Privacy Act. According to their 2009 report concerning the proposed Data Privacy Act,

> *... any data privacy legislation will therefore have to find a balance between the data subjects fundamental right to privacy as set out in section 14 of the Constitution on the one hand, and on the other hand, other persons' legitimate*

needs to obtain information about the data subject…

In this we can see that a balance must be found between the right to privacy and any oppositional rights or interests. According to Mervyn Dendy (2009:1), the approach of the Constitutional Court, in the context of privacy, is that,

... it is only the inner sanctum of a person, such as his family life, sexual preference and home environment that is shielded from erosions by the conflicting rights of the community. 'Privacy is acknowledged in the truly personal realm, but as a person moves into communal relations and activities such as business and social interactions the scope of personal space shrinks accordingly.

As with confidentiality, we can see that there is a potential conflict between the rights of the individual and the good or need of the community.

Data Protection laws are required to regulate the collection, storage, use and transmittal of personal

information Preliminary proposals of Law Commission, as set out in its Issue Paper, are summarised as follows (Michalson 2004):

1. Privacy and data protection should be regulated by legislation
2. General principles of data protection should be developed and incorporated in the legislation
3. A statutory regulatory agency should be established
4. A flexible approach should be followed in which industries will develop their own codes of practice in accordance with the principles set out in the legislation) which will be overseen by the regulatory agency.

The SA Law Commission highlights the following in its summary of proposals in their 2009 ñReport on Privacy and Data Protectionò:

- Privacy is a valuable aspect of personality.
- Data protection forms an element of safeguarding a personôs right to privacy.
- Data protection provides for the legal protection of a person in instances where his or her personal information is being collected, stored,

used or communicated by another person or institution.

- The Constitutional right of privacy is not absolute, but may be limited in terms of law of general application and has to be balanced with other rights.
- Competing rights would include the administration of national social programmes, maintaining law and order, and protecting the rights, freedoms and interests of others, including their commercial interests.

As privacy is enshrined in the South Africa Constitution (Act 108 of 1996) there may be challenges to any laws or regulations which are seen to interfere with these. The decision to make cancer a notifiable condition, under statutory regulations, may therefore be challenged on the basis of an infringement of privacy.

3.3.5. Public health, individual rights and constitutionality of cancer registries

In the USA, McLaughlin et al (2010:1295) recently reviewed a challenge to the constitutionality or not of cancer registries. This was based upon two aspects:

1) ‘the vagueness of statutory aims to pursue public health versus individual privacy interests of cancer patients’ and 2) ‘the alleged indignity of one’s individual medical information being transmitted to government authorities’

The Cancer registry statutes, in states covered by the National Cancer Institute’s SEER programme and the US Centers for Disease Control and Prevention’s National Programme of Cancer Registries, all stated specific public health benefits and provide limits and safeguards on the government’s possession of private medical information.

McLaughlin et al (2010:1296) considered the question of whether cancer registries are unconstitutional around the five conditions described by Childress et al. (2002:170), which provide a ‘rough, conceptual map to the terrain of public health ethics’ These conditions include

1) public justification that includes transparency and public accountability;

2) the least infringement on individual autonomy through selection of methods and procedures; and

3) effectiveness, necessity and proportionality in that benefit will outweigh infringed interests.

Mclaughlin et al (2010:1299) found that there was minimal infringement of privacy together with high public value in the establishment of cancer registries. The effectiveness was shown by the significance and uses of cancer data. The condition of necessity was fulfilled as there are no alternatives to population-based registers to provide complete and accurate epidemiologic data. The final condition of proportionality is also achieved as the benefits of cancer registration outweigh the moral considerations associated with infringed rights. These are important considerations to recall when discussing South Africa's new National Cancer Registry.

3.4. Concluding remarks

South African legislators and the SA Law Reform Commission would do well to give consideration to the issues around medical data, its protection, as well as

its legitimate use and its use in research, to guide and inform better health care for all. As I have shown we should take cogniscence of what has occurred in other countries particularly the clashes between the laws governing privacy and medical research, especially in the context of epidemiological studies.

Whilst we need to ensure that privacy is not sacrificed in the name of science, we need to make certain our citizens may also truly benefit from science while being accorded the highest individual privacy-protection possible. We also need to ensure that all documents from professional bodies, as well as the Law itself, speak the same language and, importantly that all role players have a common understanding of the regulations.

Despite the opinion of some who believe that society must choose between science and privacy, ócancer registration does not imply choosing the benefits that follow from advancement of medicine over and above oneôs freedom from arbitrary and unnecessary intrusions on privacyô(McLaughlin, et al. 2010:1298). With McLaughlin, et al. we can argue that cancer registration that has a clearly defined purpose and the

required procedural safeguards can coexist with the constitutional right to freedom from arbitrary interference with oneôs privacy.

More importantly, it succeeds in balancing the right to privacy as stated in Article 12 of the *Universal Declaration of Human Rights* with various other rights that are stated in the *International Covenant on Economic, Social and Cultural Rights* 1994. These rights include the right of everyone to the enjoyment of the highest attainable standard of physical and mental health; the right to benefit from the efforts of government in regard to the prevention, treatment and control of epidemic, endemic, occupational and other diseases and finally the right of everyone to enjoy the benefit of scientific progress and its application.

CHAPTER FOUR: Recommendations and Conclusions

The burden of cancer that Africa faces now and will continue to face in years to come is daunting. Diagnostic, surveillance and preventive policies for cancer will require information that is reliable, consistent and comprehensive. This can only be achieved through the National Cancer Registry.

I have shown the importance of clear codes of conduct based on sound ethical guidelines. The IARC, as well as other established cancer reporting confidentiality guidelines may serve as reference guidelines for the South African confidentiality document.

The registry should function as a central database and other independent or special-interest registries, like the SA Childrenõs Cancer Study Group, should forward all their data to the NCR. The new registry, as indicated, represents an all-inclusive registry as no distinction between patients in the private medical sector and the public sector is made. Moreover, by extending the type of diagnoses to include clinical and

laboratory biomedicine the new NCR shows foresight in the realisation that cancer may be diagnosed through a variety of scientific means.

The draft regulations relating to cancer registration propose the establishment of three registries: the National Cancer Registry, the National Childhood Cancer Registry and the Population Based Registries. The regulation details the reporting structure, which is primarily the Director General. Concerning the overall transferring of information to healthcare professionals administrators, and the public, details concerning e.g. the functioning of the different types of registries, issues of confidentiality, informed consent and regulations concerning safe-data transfer should be transmitted openly to all.

An analysis of the current functioning of existing cancer registries, as well as other disease specific registries, will assist in evaluating the current thinking and functioning of registries in South Africa. This will provide insight into physicianôs views on confidentiality and informed consent. The public also needs to be consulted, possibly via existing cancer support

organizations as well as at a broader based community level. [16]

The issue of confidentiality needs input from ethicists, physicians, lawyers and wider consultation with the public. As part of the registry process, studies should be done in order to assess the publicôs view. Several studies have been performed in high-income countries and the Western world, but if replicated in South Africa, this would lead to greater knowledge. This is because Africa tends to view these issues in the spirit of Ubuntu and the community sees itself as a whole. This is different from the Western view where the individualised doand a rights centred view is more dominant.

The Health Professions Council of South Africa (HPCSA) should also work on guidelines that provide an understanding of the registry-research perspective. This should address issues such as confidentiality and the need, or not, for informed consent in registries, taking into account the various laws that impact on this. In addition as part of continuing education, healthcare professionals, such as doctors

[16] For example The Cancer Association of South Africa (CANSA) and the Childhood Cancer Foundation South Africa (CHOC).

and researchers should be engaged in the topic of their moral duty to act in the good of their patients. One way is by way of sharing information with them such as possible concerns about confidentiality, and privacy. Beyond the individual patient, an active and on-going national campaign for the purpose of educating the public about the National Cancer Registry is vital.

It is not feasible to obtain individual informed consent for cancer registration for the reasons I have raised in this research report. It is equally perceivable that informed consent need not be required if the research conducted is of an epidemiological nature. The challenge remains concerning how to process and respond to requests for data sets where the proposal involves research that is more ócliniclôin nature.

I suggest that these requests should all be centralized and addressed by the National Cancer Registry Board. There should be wider inclusion of public representation onto Research Ethics Committees and the National Registry Board. The current suggestion of including one person on the National Cancer Advisory Committee should be reconsidered (National

Health Act 2003, Govt Gazette 2009). We should be cautious and be careful not to allow the final decision or total control of the vetting function to lie solely with a Patient Advisory Group. Local Ethics committees will also need on-going education, to ensure that they clearly understand the legal aspects governing privacy, and make consistent and reasonable decisions.

South Africa should make representations at an international level, both to the United Nations and to the World Medical Association, to suggest that the relevant declarations be revised to take into account current challenges and conflicts that are inherent therein.

The National Cancer Registry should look to various guidelines to inform their Data Protection Practices, including the Caldicott Guidelines, Andersonsô Principles of Data.

The South African Constitution recognises the right to privacy. However, the Constitutional right of privacy is not absolute, but may be limited in terms of law of general application and must be balanced with other

rights. With the great advances in information technology, South African legislators and the SA Law Reform Commission would do well to give specific consideration to the issues around medical data. These include its protection, legitimate use and data protection in research.

The establishment of the National Cancer Registry and a thorough review of the ethical and legal considerations may provide a clear direction for other disease specific registries as well. I suggest that there should be a greater government impetus to legislate this type of data collection, be it either through research ethics committees at individual facilities or possibly a national coordinating or overseeing registry organization.

In this research report, I have attempted to discuss some of the complex legal and ethical issues faced in setting up the National Cancer Registry in South Africa. In Chapter One I have contextualized the burden of cancer in Africa and reviewed the current state of cancer registration in South Africa. I have provided sufficient reason as to why the re-establishment of the South African Cancer registry is

a necessity from a public health perspective. I have reviewed the data requirements as per the IARC guidelines, as these requirements determine some of the ethical and legal issues that require consideration.

In Chapter Two I have noted some of the challenges that existing registries face, and explored some of the ethical aspects pertaining to cancer registries. I have pointed out that confidentiality is a core component of the doctor-patient relationship and it can be protected and preserved in the cancer registry if the guidelines on confidentiality are held paramount in practice. Arguing that there is minimal infringement or harm to the patient can obviate the needs for informed consent in the cancer registry. I have shown that patients generally view registries in an altruistic light, and view cancer registration as a benefit to society in general. I have argued that as cancer registries provide epidemiologic research for the greater good to society, that autonomy can be limited in this context.

In Chapter Three I have explored some of the legal considerations that current legislation and case law may place on individuals and registries. I have focused on the concept of privacy, as it is privacy that

is most under threat with any legislation that aims at making cancer registration compulsory. Advances in medicine and information technology have necessitated legislation governing the protection of data and privacy. Several countries with established national cancer registries have had to review how this legislation should deal with the issues of privacy and data protection in the research context. Legislation has had to be clarified and amended to ensure that research, which would provide benefits for the wider community, can continue without undermining individual rights.

South Africa is still at an early stage in its new National Cancer Registry. I hope that this report will help to inform the various bodies that are considering how to frame laws and rules that will impact on such registries. The issues I explored have clearly justified the need for a National Registry for Cancer and that the positive benefits provided by such a registry can, on balance, be achieved with minimal infringement of individual rights and the hope for better healthcare for all South Africans.

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