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An oral cancer biobank initiative: a platform for multidisciplinary research in a developing country

Rosnah Binti Zain · Vimmitra Athirajan · Wan Maria Nabillah Ghani · Ishak Abdul Razak · Raja Jalaludin Raja Latifah · Siti Mazlipah Ismail · Atiya Abdul Sallam · Anita Zarina Bustam · Zainal Ariff Abdul Rahman · Adam Hussien · Norain Talib · Sok Ching Cheong · Amin Jallaludin

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Abstract Identification of diagnostic markers for early detection and development of novel and therapeutic agents for effective patient management are the main motivation for cancer research. Biological specimens from large cohort and case-control studies which are crucial in providing successful research outcomes are often the limiting factor that hinders research efforts, especially in developing countries. Therefore, the Malaysian Oral Cancer Database and Tissue Bank System (MOCDTBS) were established to systematically collect large number of samples with comprehensive sociodemographic, clinicopathological, management strategies, quality of life and associated patient follow-up data to facilitate oral cancer research in Malaysia. The MOCDTBS also promotes sharing among researchers and the development of a multidisciplinary research team. The following article aims to describe the process of setting-up and managing the MOCDTBS.

Keywords Oral cancer · Biobank · Malaysia · Multidisciplinary team

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R. B. Zain (✉) · V. Athirajan · W. M. N. Ghani ·
I. A. Razak · R. J. Raja Latifah · S. M. Ismail ·
A. A. Sallam
Oral Cancer Research and Coordinating Centre, Faculty of Dentistry, University Malaya, 50603 Lembah Pantai, Kuala Lumpur, Malaysia
e-mail: rosnahmz@um.edu.my

R. B. Zain
Department of Oral Pathology, Oral Medicine and Periodontology, Faculty of Dentistry, University Malaya, Kuala Lumpur, Malaysia

I. A. Razak
Department of Community Dentistry, Faculty of Dentistry, University Malaya, Kuala Lumpur, Malaysia

S. M. Ismail · Z. A. A. Rahman · S. C. Cheong
Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, University Malaya, Kuala Lumpur, Malaysia

A. Z. Bustam
Dean's Office, Faculty of Medicine, University Malaya, Kuala Lumpur, Malaysia

A. Hussien
Department of Restorative Dentistry, School of Dental Sciences, Universiti Sains Malaysia, Kubang Kerian, Kelantan, Malaysia

N. Talib
Oral Health Division, Ministry of Health, Putrajaya, Malaysia

S. C. Cheong
Oral Cancer Research Team, Cancer Research Initiatives Foundation, Kuala Lumpur, Malaysia

A. Jallaludin
Department of Otorhinolaringology, Faculty of Medicine, University Malaya, Kuala Lumpur, Malaysia

Introduction

Increasing efforts have been made worldwide to study the underlying mechanism of cancer and its association with genetic, environmental and lifestyle factors. The understanding of these affords an opportunity to use this information to derive biomarkers for diagnosis, prognosis and therapeutics, which are expected to improve patient management. However, limitations due to specimen resources hinder the successful translation of research outcomes into clinical practice. Therefore, there is a need for a biobank to organise specimen and data collection to overcome these limitations. A biobank is generally defined as a place where biological specimens are collected, stored, processed and disseminated together with associated clinical data (Simon et al. 2007; Molnar and Bencsik 2006 and Watson et al. 2010). These specimens and comprehensive sociodemographic, clinicopathological, management and follow-up data are vital for research undertaken in the biomedicine and biotechnology disciplines. The establishment of biobanks are largely driven by the need to overcome some of the multi-factorial influences of diseases by ensuring that the sample size is met, a criteria that is often not achievable within individual projects.

Biobanks pool biological specimens and data at one central location to enable a systematic collection of large number of cases which can be used for research. More importantly, this enables follow up clinical data associated with these specimens to be collected and utilized for the analysis of long term treatment evaluation, intervention strategies and to assess quality of life and survival rates of patients. To date, there are several successfully established biobanks worldwide. Among the prominent biobanks are the UK Biobank (United Kingdom), Victorian Cancer Research Tissue Bank (Australia), Canadian Tissue Repository Network (Canada) and Singapore Biobank (Singapore).

Oral cancer is commonly defined as malignant neoplasm which involves the lip, tongue, mouth (oral cavity) [ICD-10: C00-06], oropharynx [ICD-10: C09-C10], excluding the salivary glands [ICD-10: C07-C08] and other pharyngeal sites [ICD-10: C11-C13] (Warnakulasuriya 2009). Compared to other cancers, cancer of the oral cavity has clearly defined sub-sites with each sub-site been associated with different aetiological factors and genetic behaviours. For example, tongue cancer has been observed to be more aggressive (American Cancer Society 1997; Schwartz et al. 2000) and was associated with different risk factors compared to buccal mucosa (Liao et al. 2010). Therefore it is evident that a biobank dedicated specifically to cancer of the oral cavity is required so that large number of specimens from each different sub-site can be studied in great detail to address the heterogenic behaviour of this disease.

In Malaysia oral cancer is not as common as breast or prostate cancer, however it is one of the most common causes of death due to cancers. Therefore, there is a need to pull together all resources of specimen and data collection such that large number of specimens/data can be collected for statistically meaningful studies. Furthermore, surgery is the first line of treatment for oral cancer, thus affording the opportunity to collect biological materials as compared to other cancers such as nasopharyngeal carcinoma where radiation is the most common treatment choice.

The idea of a biobank sparked from the realisation by a group of researchers that oral cancer data in Malaysia are scarce and these are often collected at an ad-hoc basis by individuals or small groups of researchers, making it unrealistic to generalize the research findings. In order to cope with the increasing demand of human oral cancer specimens with accompanying data for research and to conform with the latest standards in cancer research where high quality of data and specimens are a pre-requisite, a Malaysian Oral Cancer Database and Tissue Bank System (MOCDTBS) was established. This system was set up to provide a standard approach on data and specimen collection and to organise a systematic method of processing, storing and disseminating biological specimens and associated data.

The MOCDTBS concept

The MOCDTBS symbolizes the outcome of partnership and collaborative efforts nurtured between academic institutions, government and non-government organisations (Zain et al. 2009) with University of Malaya (UM) spearheading this effort. Other partners in the partnership include 6 major Ministry of Health (MOH) referral hospitals throughout the country, Cancer Research Initiatives Foundation (CARIF) and

Universiti Sains Malaysia (USM) where clinicians, pathologists, oncologists, epidemiologists and scientists from these centres work together towards the development and maintenance of this system.

This system is novel in terms of availability of an extensive range of genetically varied biological specimens due to the acquisition of samples from various ethnic groups in Malaysia. The availability of a variety of genetic data on oral cancer is a significant advantage of this system that has contributed towards the undertaking of many research projects in various disciplines in this field. Additionally data and specimen are also collected from various major referral centres all over the country such that the real oral cancer scenario in Malaysia could be captured. This is in contrast with other biobanks, which are often more focused on a certain catchment area for recruitment of respondents; for example the Victorian Cancer biobank which collects specimens from public and private hospitals in metropolitan Melbourne and Geelong (http://www.viccancerbiobank.org.au/) and the Oxford Biobank stores where specimens are collected from healthcare facilities within the vicinity of the collection centre (http://www.oxfordbiobank.org.uk/index.html/).

The MOCDTBS is managed by the Oral Cancer Research & Coordinating Centre (OCRCC), Faculty of Dentistry, University of Malaya, however every member of this partnership provide expertise in various fields for the development of MOCDTBS. The Cancer Research Initiatives Foundation (CARIF) played a substantial role in the initial set-up of procedures for specimen collection, processing and served as a banking facility. The Oral Health Division, Ministry of Health Malaysia, University of Malaya and Universiti Sains Malaysia provided expertise in the management of oral cancer patients. Together, these experts from various specialties have devised a systematic process for the collection of data and specimen that are associated with patient management such that important data and biological specimens can be collected and stored for research purposes.

The activities of the biobank are governed by a Central Advisory Committee (CAC) consisting of representatives from each institution of this partnership. The CAC is set-up to review the feasibility of applications for data and specimen request/usage and to decide whether data and specimens can be disseminated. The committee also reviews project applications to avoid overlap of research areas, and also govern policies on authorship and other relevant matters. This concept of a body to govern all activities of a biobank is also observed in other biobanks such as the Scientific Advisory Group formed for the Singapore biobank (http://www.stn.org.sg/) and the International Scientific Advisory Board for the UK biobank (http://www.ukbiobank.ac.uk/docs/UKBProtocolfinal.pdf).

Structure of the MOCDTBS

The MOCDTBS essentially consists of a database and a specimen bank. The workflow of this system is illustrated in Fig. 1 where UM, USM CARIF and hospitals under the MOH serve as collection centres for data and specimens from patients diagnosed with oral malignant and pre-malignant lesions and healthy individuals visiting the healthcare facility and/or the general population. A standard protocol for collection, processing and storage of data and specimen were established based on the best practice guidelines by the International Society for Biological and Environmental Repositories (ISBER 2008) to be practiced at each collection centres. At every participating hospital-based centre, a research coordinator (RC) was hired to coordinate and manage all the activities of that centre and to communicate with the OCRCC which serves as the central collection centre. Clinicians and RCs who are responsible for collecting data and specimens are calibrated through training workshops to ensure that data and specimen are collected in a systematic and standardized manner. In addition, this training workshop is also organised periodically for updates.

Standard operating procedures

Database

In every case, individuals will be given a patient information sheet followed by verbal explanation by the surgeon on the nature of research carried out, type of biological materials required and importance of these materials for research. These patients will need to sign a consent form if they agree to participate and provide data and specimens for research. Data collection begins when informed consent is obtained from

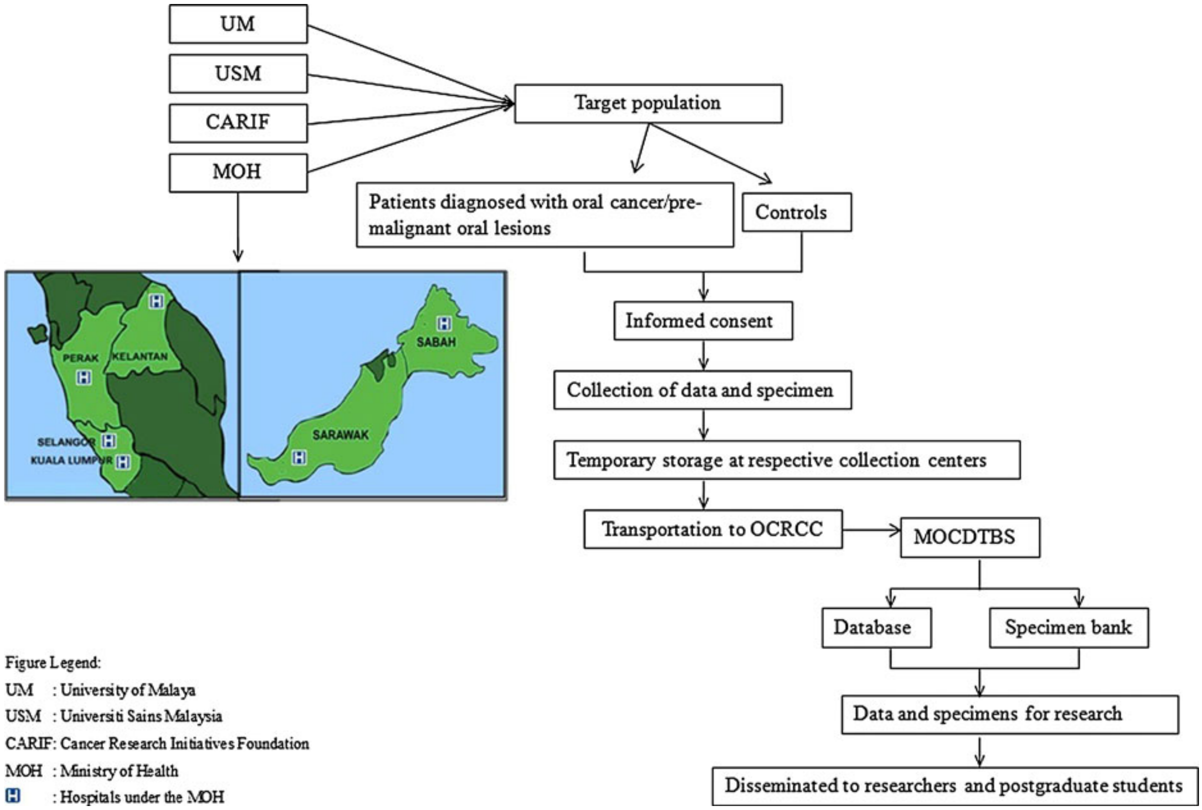

Fig. 1 Workflow of structure and function of MOCDTBS

patients who were histologically diagnosed with cancer of the oral cavity or pre-malignant oral lesions. Consented patients will be given a biobanking code to preserve anonymity. Data is collected via interview with the patient using a set of questionnaire developed based on the National Advisory Dataset by the British Association of Head and Neck Oncologists (2003) and adapted to the local setting according to requirements and resources available in Malaysian hospitals. Clinical data were obtained from the clinicians based on clinical charts and pathological reports. Details of treatment methods such as surgery, chemotherapy and radiotherapy were collected from respective specialists assisted by the RCs. The data that was obtained were then digitalized using custom-designed computer software that was made available on a laptop at every participating centre. The complete dataset includes parameters on sociodemographic, risk habits, clinicopathological details such as site and TNM staging, details of management strategies, quality of life measures and dietary intake. These data were then sent electronically to the MOCDTBS operating centre at the OCRCC, Faculty of Dentistry, University of Malaya where a project manager is tasked to collect, collate and store these data in a systematic manner for easy retrieval.

Specimen bank

Specimens are collected either during biopsy, surgery or follow-up. Specimens are coded based on the biobanking code that is assigned to each individual to ensure that anonymity is preserved. Specimens collected and stored in this biobank are tissues, blood, saliva, buccal cells and formalin fixed paraffin embedded tissues (FFPE).

Tissues surplus to diagnostic requirements are snapped frozen and kept in liquid nitrogen, while blood, saliva and buccal cells are centrifuged before being stored in −20°C freezers temporarily at respective collection centres prior to storage at the main storage centre at OCRCC, Faculty of Dentistry, University of Malaya. At the main storage centre, RNA and DNA are extracted routinely from the white blood cell component of the blood, frozen tissues sections, saliva and buccal cells using extraction kits according to the manufacturer's protocol and are subsequently tagged and banked accordingly. The banking of FFPE specimens are routinely done for specimens from University of Malaya, while access to archive FFPE tissues from other participating centres would be available upon request. Tissue microarrays (TMA) are made from the FFPE samples on project basis as and when required and once these are made they are also available to other researchers who request for them.

Informatics system

Informatics system and data management were derived according to the ISBER's best practice guidelines for banking where each patient registered in the system will be assigned a unique code. Specimens collected from the same individual will also be consistently labelled with this code. This code will be used as an identifier for future data/specimen retrieval. Apart from the electronic informatics system, collection forms are filled upon specimen collection to manually record incoming specimens.

Tracking of specimens is an important requirement based on the best practice proposed by ISBER. Almost all biobanks worldwide have established a tracking system to keep track on specimens collected. In MOCDTBS, when specimens reach the operation centre, the bank manager will register and assign a location for these samples using a specimen tracking software. The specimen tracking software is able to keep record on the availability, quantity and movement of the specimens. This system is available in a read-only format and only authorised personnel will be able to make changes to the system.

Periodic internal audits on the merged data collected from the various centres are conducted to ensure data integrity while audits on specimen were carried out to validate the location and availability of the specimens based on the system.

Access to the service

To obtain data and specimen from the MOCDTBS, applicants need to first obtain ethical approval from institutional review board, in this case the University's Medical Ethics Committee (MEC). MEC members consist of dentists, clinicians, public health specialists, pharmacologists, lawyers and members of the public, for example, a school teacher. Upon receiving ethical approval from MEC, applicants will have to forward their application for data/specimen to the CAC. CAC will then decide whether to approve the data/specimen request. Upon obtaining approval from CAC, applicants will have to fill in a pro-form made available at OCRCC. In the pro-form, applicants will state the specific variable of data and/or type and amount of specimen required. In the event of conflicting interests, researchers are informed and advised to revise their research proposal. Requests are usually not rejected directly to encourage research in the field of oral cancer in Malaysia. So far, approximately 90.5% of the applications were approved where only 9.5% of the projects were returned for revision.

Consent

With the increasing number of biobanks worldwide, a few issues with regards to ethics for biobanking had been raised and consent is the main concern. Although it was found that the public has good perception and high trust with research carried-out at universities or hospital-based facilities (Lindbald et al. 2005), they still feel that legal and social protection for privacy and confidentiality of donors are inadequate (Merz et al. 1997). Two main issues have been identified in obtaining consent for biobanking. First is whether the use of broad consent is ethically valid and second is whether a new consent is required for every new research utilising specimens obtained from the bank. Through literature research, it was concluded that a broad consent for specimen collection and storage is ethically valid if the following 3 criteria is fulfilled: (a) the privacy of donors are protected (b) the right to withdraw consent are granted (c) new studies are approved by ethics review board individually (Hansson et al. 2006). The MOCDTBS complies with all the requirements mentioned above to ensure validity of the consent used when recruiting participants. The individual's information and privacy are protected where a unique identification code will be assigned to maintain anonymity and confidentiality and only this code will be used for retrieval/utilization of data and specimens for research. This system also allows participants to withdraw their consent at any given time where participants are also informed that their refusal to participate will not jeopardize the diagnosis and management of their disease. Any new studies using data or specimens from this system will require a separate ethical approval from the MEC, prior to requesting for data or specimen.

Scientific impact

Arising from the successful collaborative partnership between members, the MOCDTBS have accelerated oral cancer research in the past 5 years. A simple search on Pubmed revealed that the number of publications have increased by 57.6% within the last decade where 39% of research reports were produced utilizing resources from the MOCDTBS. For example, with frozen tissue specimens and associated data available from the MOCDTBS, Cheong and colleagues were able to demonstrate that gene expression changes in oral squamous cell carcinoma (OSCC) could be influenced by aetiological factors suggesting that these have to be taken into consideration in the identification of biomarkers (Cheong et al. 2009). Furthermore, with the banking of FFPE tissues, we demonstrated the feasibility of conducting microarray gene expression studies on FFPE tissues which now opens up further investigations into the use of these tissues for the identification of clinically relevant biomarkers (Saleh et al. 2010).

Clearly, the availability of a resource centre for tissues and data facilitated and accelerated research that has helped us to understand the genetics underlying oral cancer development both at a single gene level and at a genome/proteome-wide level (Kumar et al. 2005; Hamid et al. 2007; Dom et al. 2008; Hamid et al. 2009; Gan et al. 2011; Karen-Ng et al. 2011; Saini et al. 2011). In addition to molecular research, this biobank has also enabled epidemiological research such as investigation into the practice of risk habits that are associated with oral cancer (Ghani et al. 2011; Lee et al. 2011), and the effects of oral cancer on the quality of life of these individuals (Doss et al. 2011). Most importantly, we have recently successfully compiled for the first time in Malaysia, a preliminary 5 year survival data for Malaysian oral cancer patients. All these data generated from the systematic collection, processing and storage of data and specimen contributes to the body of knowledge on oral cancer, leading to development of more effective ways of patient management, which would eventually result in better patient prognosis.

Without the biobank, data collection would be on an ad-hoc basis, collected by different group of researchers with different criteria where data/specimen collection would not be standardised. Therefore, research findings are specific to that project and cannot be applied to the general population and will not be comparable to other studies. Furthermore, ad-hoc data are predominantly without long-term follow up which impedes the evaluation of treatment strategies, prognosis and survival. The MOCDTBS serves as a one stop centre for comprehensive data and specimen collection where availability of epidemiological and clinicopathological data can later be linked with molecular data obtained from research findings to provide better understanding of oral cancer.

Summary

MOCDTBS is a combination of disease-oriented and population-based bank dedicated to oral cancers, like the Biobanking and Biomolecular Resource Infrastructure (BBMRI) (Yuille et al. 2007). In addition, the MOCDTBS also functions as a traditional/centralised bank where data and biological specimens collected from peripheral centres are physically transported to and stored at the main operating centre.

In terms of biobanking operation, the MOCDTBS is comparable to other established biobanks such as the UK biobank and the Canadian Tissue Repository Network where the best practice guidelines for banking are adopted and implemented (Vaught et al. 2010). In particular, the recommended standard procedures are implemented to establish the infrastructure and specimen handling, information and data management and ethical guidelines.

As a biobank in a developing country, the main challenge faced is in terms of maintenance of the biobank. Substantial funding is required to sustain the current system. Furthermore, the management of MOCDTBS requires dedicated full-time personnel to effectively manage the bank.

Established through partnerships and collaborative efforts (Zain et al. 2009), this system is deemed to expand the horizon of oral cancer research in Malaysia by providing researchers with high quality data and specimens such that oral cancer research could lead to improvements in patient management and prognosis. Therefore, serious efforts need to be advocated to ensure the sustainability of this system.

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Conflicts of interest None declared.

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