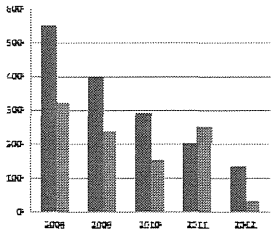


## Biggest Loser

### No. of Participants

# measurements 1/1/2008-8/15/2012

NCD outreach data, opportunity sample

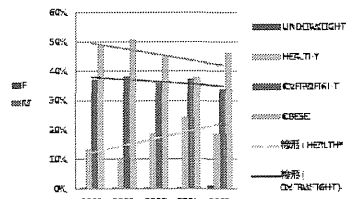


### BMI

% in WHO BMI categories

1/1/2008-8/15/2012

NCD outreach data, opportunity sample



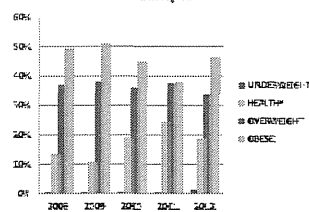
## Biggest Loser

### BMI

% in WHO BMI categories

1/1/2008-8/15/2012

NCD outreach data, opportunity sample



## School Gardening Project

- Purpose:
- To increase physical activities
- To increase fruits and vegetables intake
- To increase parents involvement

## Results

- Water only policy – about 90% of all Elementary School.

## Palau Obesity Project 2010-11

- Palau Obesity Project was possible through a grant from the Government of Israel. \$10,000
  - MOH and State Legislatures
  - Given small resources to come up with one project in the state to reduce childhood obesity.
  - 15/16 projects were on health promotion and only one was on health protection. Only one state legislature was willing to deal with health policies. All wanted to do health promotion which is the job of the health sector.



## Example of Health Protection

- Enacted and need further improvement
  - Tobacco Control Act
  - Breastfeeding Act
  - Health Care Fund
  - 34<sup>th</sup> PNC
- Needed
  - Alcohol Control Act
  - Food Content Act (Salt, sugar, fat, MSG etc)
  - Water Flouridation
  - Helmet and Seatbelt and others
- Needed Transformational Policies
  - Health in All Policies (HiAP)
  - Health Foundation
  - Healthy Settings and others



### Conclusion

1. **We will be in an NCD Crisis within the next 5 years. This will threaten the MOH budget, HCF especially Tertiary Health Care and will begin to threaten Primary Health Care.**
2. **Younger and younger people will be effected with many of them pushed into poverty.**
3. **We will lack the human capacity to appropriately deal with this crisis.**
4. **The gains in health, mainly in the Communicable Diseases, Family Health and Environment Health will be lost due to this crisis as resources are reshuffled.**
5. **At this time we lack the will to take a critical look and respond appropriately.**
6. **If, we do not follow through with some of the initiated strategies going forward, we will definitely be in a social crisis.**



Kom kmal mesulang!

[ncdpalau4@gmail.com](mailto:ncdpalau4@gmail.com)



# Public Health Research and Public Health Issues Republic of Palau

Nagoya and Osaka Universities  
January 20 – 27, 2013

Presenter:  
Berry Moon Watson, MPH  
Interim Director  
Bureau of Public Health

## Purpose of the Presentation

- ◆ Provide currently known health facts about Palau
- ◆ Provide insights into known Palau health Outcomes
- ◆ Provide current research findings about Palau people's health
- ◆ Provide recommendations about what should be targets of future health research in Palau
- ◆ Generate discussion on "the next step"

## Republic of Palau Profile

- ◆ Land Mass = 189 sq. miles with 7 populated islands out of over 200 islands
- ◆ Population ~ 21,000
- ◆ Population By Ages
- ◆ Teen Pregnancy Rate
- ◆ Fertility Rate
- ◆ Birth Rate
- ◆ Death Rate
- ◆ Infant Mortality Rate
- ◆ Maternal Mortality Rate

## Knowledge Base Development

- ◆ Palauans are 7<sup>th</sup> heaviest people in the world (*WHO*)
- ◆ Obesity and other NCD's are Leading causes of premature Deaths.
- ◆ Obesity and Overweight is a burden prior to and during pregnancy.
- ◆ Obesity/Overweight begins in early years of life.
- ◆ Injuries 5<sup>th</sup> leading cause of death

## Knowledge Base Development (Cont.)

- ◆ Palauans (Micronesians) carriers of the "Thrifty Gene"  
– Genetically susceptible for Overweight/Obesity.  
Women are the carrier and transmitter of this gene.  
(*Japan/Palau Study*)
- ◆ Mental Health Issues (post-partum depression) affect about 3% of mothers (*PPRAS*)
- ◆ Elderly population affected by depression (*Dr. Osarch*)
- ◆ Behavioral Patterns – "what health facts we know does not necessarily dictate our positive actions to improve our health" (*TTS*)

## Knowledge Base Development (Cont.)

- ◆ Dental caries in children one of the highest in the world (*I. Appanaitis/Watson*)
- ◆ Vegetables/Fruits make up around 10% of daily meals of children (*SHS-2011*)
- ◆ Some children as early as primary school spill sugar and protein in their urine (*SHS-2011*)
- ◆ Youngest adult on-set diabetic is 15 years old Palauan female
  - ◆ Concern is the passing of diabetes recessive gene to the next generation

## What should be the next step in improving understanding toward improving health outcomes for Palauans

- Understanding socio-economic patterns that make people behave the way they do.
- Understanding legislative actions and policies that influences behavioral patterns that affects health
- Understanding decision making skills that influences health outcomes
- Health vs. life/death perceptions – cultural and contemporary.

## Discussion:

- STEP-wise Survey will provide us with many health information about our population
- What we don't know is “what makes the population tick”
- We have programs that provides intervention through:
  - Prevention/promotion/primary (evidence-base?)
  - Medical care (evidence-base?)
- Information that guides us to move from “what's know” to what we want Palau “to be” is lacking:
  - Empowering of people/communities

MESULANG  
(THANK YOU)

## PALAU INSTITUTIONAL REVIEW BOARD

APPLICATION FOR IRB APPROVAL OF HUMAN SUBJECTS RESEARCH

P.O. Box 6027

Koror, Republic of Palau 96940

Tel.: (680) 488-4773 Fax: (680) 488-4701

Date : September 12, 2012Title of Study: Multi-Disciplinary Study for Promoting Non-Communicable Disease (NCD) Control  
in Republic of PalauName of Principal Investigator: Atsuko AoyamaMailing Address: 65 Tsurumai-cho, Showa-ku, Nagoya, Japan 466-8550Phone: +81-52-744-2108 / 2128 Email Address: atsukoa@med.nagoya-u.ac.jpCell Phone: +81-52-80-5328-3502 Fax #: +81-52-744-2131

**Names of Other Investigators or Study Coordinator (if any) – List all other project personnel including co-investigators, and anyone else who has contact with subjects or identifiable data from subjects. Include email address for each who should receive electronic copies of IRB correspondence to PI):**

Name of Co-Investigator/Others: Hiroyasu IsoEmail Address: iso@pbhel.med.osaka-u.ac.jpName of Co-Investigator/Others: Hiroshi YatsuyaEmail Address: h828@med.nagoya-u.ac.jpName of Co-Investigator/Others: Kaori HonjoEmail Address: khonjo@glocol.osaka-u.ac.jpName of Co-Investigator/Others: Takashi MitaEmail Address: mita@glocol.osaka-u.ac.jpName of Co-Investigator/Others: Yorah DemeiMailing Address: NCD Unit, Bureau of Public Health Services, Ministry of HealthPhone: 680-488-4612 Email Address: ncdpalau4@gmail.comName of Co-Investigator/Others: Berry Moon WatsonMailing Address: Health Planning and Research Division, Ministry of HealthPhone: \_\_\_\_\_ Email Address: berrymoonwatson.88@gmail.comName of Co-Investigator/Others: Temmy TemengilMailing Address: International Health Coordinator, Ministry of HealthPhone: 680-488-2553 / 2552 Email Address: temengil@gmail.comName of Co-Investigator/Others: Patrick U. TelleiMailing Address: Palau Community CollegePhone: 680-488-1669 Email Address: tellei@palau.eduName of Co-Investigator/Others: Julie TelleiMailing Address: Palau Resource InstitutePhone: 680-488-1669 Email Address: ngetelngal@gmail.com

**Collaborating centers, institutes or departments:**

Name: NCD Unit, Bureau of Public Health Services, Ministry of Health

**Collaborating centers, institutes or departments:**

Name: Health Planning and Research Division, Ministry of Health

**Collaborating centers, institutes or departments:**

Name: Palau Community College

**Collaborating centers, institutes or departments:**

Name: Palau Resource Institute

**Name of funding source or sponsor (please do not abbreviate):**

Not Funded \_\_\_ Federal \_\_\_ State \_\_\_ Industry \_\_\_ Foundation \_\_\_ Private \_\_\_

Other (specify): Health and Labour Sciences Research Grants (Research on global health issues) sponsored by the Ministry of Health, Labour and Welfare, Government of Japan

**For industry sponsored research (if applicable):**

Sponsor's master protocol version #: \_\_\_\_\_ Version Date: \_\_\_\_\_

Investigator Brochure version #: \_\_\_\_\_ Version Date: \_\_\_\_\_

Any other details you need documented on IRB approval:

**Brief Summary.** Provide a brief non-technical description of the study, which will be used in IRB documentation as a description of the study:

NCDs are recognized as a priority health issue in Palau, thus several studies, including WHO STEPS Survey targeted to the population between 25 and 64 years of age and various school based studies, have been implemented. However, data and information on prevalence of NCD risk factors, including hypertension, raised cholesterol, diabetes, obesity and overweight, alcohol and tobacco consumption, unhealthy diet, and physical inactivity, of the population between 18 and 24 years of age are mostly missing.

This research aims to: (1) study epidemiological situation of NCDs of the young adults between 18 and 24 years of age; (2) examine people's life-style, social backgrounds, and cultural belief which may affect their health status; and (3) identify various risk factors which needs to be taken into account to develop effective control measures. The study group will also analyze the original data of the WHO STEPS survey.

**Purpose:**

- To study epidemiological situation of NCDs among people living in Palau.
- To examine people's life-style and social backgrounds.
- To identify various risk factors of NCDs.
- To recommend effective NCD control strategies and interventions.

**Participants/Subjects** (inclusion/exclusion criteria; special populations; recruitment inducements and costs to subjects):

(1) Field epidemiological study

- Since the recent WHO STEPS Survey targeted the population between 25 and 64 years of age, this field study targets the young adults between 18 and 24 years of age.
- Target population: young adults between 18 and 24 years of age living in Palau, excluding pregnant and breastfeeding women (approximately 4,000)
- Study population: 15–25 % of the people between 18 and 24 years of age in Koror city (approximately 600–1,000).

(2) Sociological study

- Key informant interviews: 10–20 community leaders, health workers, etc. living in Palau.

- Focus group discussions: 5–8 people in each group, 4–8 groups of various categories: *e.g.* young /old, men/women, tobacco users/ non-users, obese/non-obese, *etc.*, in total 20–60 people living in Palau.
- (3) Epidemiological study based on the data of the recent WHO STEPS Survey
- Analyze the original data of the recent WHO STEPS Survey of 2,800 people (a little over 10 % of the target population) between 25 and 64 years of age living in Palau.

**Procedures (methods):**

(1) Field epidemiological study

- Cross sectional study to obtain base line data.
- Physical examination and blood tests follow the WHO STEPS Survey protocol.
- Structured questionnaire of the WHO STEPS Survey protocol will be slightly modified to adjust to the young adults
- Logistic regression analysis:  
Dependent variables: obesity; hypertension; diabetes; hyperlipidemia.  
Independent variables: social, economic and psychological factors; life style; daily habits.

(2) Sociological study

- Key informant interviews to community leaders, health workers, *etc.*
- Focus group discussions of several category groups of people, following a semi-structured topic guide, facilitated by a well-trained facilitator.
- Obtain qualitative data, such as traditional belief relating to diet and physical activities; knowledge, attitude and behavior for health; relationship with family and community, *etc.*
- Qualitative analysis of English text data and identify NCD risk factors.

(3) Epidemiological study based on the data of the recent WHO STEPS Survey

- Statistically analyze the original data of the recent WHO STEPS Survey of 2,800 people between 25 and 64 years of age living in Palau.

(4) Policy recommendation for controlling NCDs

- NCD control strategies and interventions will be developed based on the study results

**Benefits to subjects and/or society:**

- Participants will contribute to learning more about NCD situation in Palau and developing better control strategies.
- If some participants are found to be suffering from untreated NCD, medical advice will be given to them.
- Participants will not get any direct benefits, and they will not be paid for participation in this field study.
- Participants are free to take part in this study or not. No penalties or loss of benefits will occur if they refuse to take part. They may withdraw at any time, even if they decide to take part in this study.

**Full description of risks and measures to minimize risks:**

- Participants have to spend time to take examinations and to respond questionnaires.
- Participants will feel slight pain while taking blood samples
- Trained staff of the Ministry of Health will carry out the questionnaire survey and blood testing, so that the risks can be minimized.

- No serious physical and psychological damages are expected to be caused by the study.

**Logistics** (proposed calendar of the study, including any needs such as local staff, costs to be borne by subjects, if any):

Sept 2012	Discussions for planning the study (in Palau) Submission of application for IRB approval
Sept – Nov 2012	Preparation of draft questionnaires adjusted to young adults Preparation of logistics of field epidemiological and sociological studies.
Nov 2012	Discussions for preparing the field epidemiological study (in Palau) Implementation of sociological study [local staff needed]
Dec 2012 – Jan 2013	Further preparation of the field epidemiological study Data analysis of sociological study Analysis of WHO STEPS Survey data
Jan 2013	Discussions of study planning and data analyses (in Japan)
Feb – Jul 2013	Further preparation of the field epidemiological study Data analysis of sociological study Analysis of WHO STEPS Survey data
Aug – Nov 2013	Implementation of the field epidemiological study [local staff needed] Discussions of the results of data analyses (in Palau)
Dec 2013 – May 2014	Data analyses
Jun 2014 – Oct 2014	Preparation and submission of academic papers
Nov 2014	International conference on NCD control strategies (in Japan)
Dec 2014– March 2015	Preparation of policy recommendations

**Data Considerations:**

**Confidentiality of the data:** Describe procedures for maintaining confidentiality of the data you will collect or will receive. Describe how you will protect data from access by those not authorized. How will data be transmitted among research personnel? Where relevant? Describe procedures for maintaining confidentiality of the data you will collect or will receive. Describe how you will protect the data from access by those not authorized. How will data be transmitted among research personnel? Where relevant, discuss the potential for deductive disclosure (i.e., directly identifying subjects from a combination of indirect ID's).

- The data and information of the participants will be kept confidential. Participants' names will not be kept with the information during the analysis.
- Data will be coded in Palau. Original data and the code numbers of the participants will be securely stored at the Ministry of Health, Republic of Palau.
- Copies of the coded data will be shared with study group members in Japan. The copied data will be stored in password-locked flash memories and securely stored in locked cabinets in a locked room.
- Computers used for the analyses are not connected to the network.
- Only the results of the analyses will be published, and each participant cannot be identified.

<p><b>Data sharing:</b> With whom will <i>identifiable</i> (contains any of the 18 identifiers listed in question A.4.9 above) data be shared outside the immediate research team? For each, explain confidentiality measures. Include data use agreements, if any.</p>	<p><b>Data security for storage and transmission:</b> Please check all that apply.</p> <p><i>For electronic data:</i>  <input type="checkbox"/> Secure network  <input checked="" type="checkbox"/> Password access</p>
---	---



<input checked="" type="checkbox"/> No one <input type="checkbox"/> Coordinating Center <input type="checkbox"/> Statisticians <input type="checkbox"/> Consultants <input type="checkbox"/> Other researchers: <input type="checkbox"/> Registries: <input type="checkbox"/> Sponsors: <input type="checkbox"/> External labs for additional testing: <input type="checkbox"/> Journals: <input type="checkbox"/> Publicly available dataset: <input type="checkbox"/> Other:	<input type="checkbox"/> Encryption <input type="checkbox"/> Other (describe): <input checked="" type="checkbox"/> Portable storage (e.g., laptop computer, flash drive) <i>Describe how data will be protected for any portable device:</i> password locked  <i>For hardcopy data (including human biological specimens, CDs, tapes, etc.):</i>  <input type="checkbox"/> Data de-identified by research team (stripped of the 18 identifiers listed in question A.4.9 above) <input checked="" type="checkbox"/> Locked suite or office <input checked="" type="checkbox"/> Locked cabinet <input checked="" type="checkbox"/> Data coded by research team with a master list secured and kept separately <input type="checkbox"/> Other (describe):
<p><b>Post-study disposition of identifiable data or human biological materials.</b> Describe your plans for disposition of data or human biological specimens that are identifiable in any way (directly or via indirect codes) once the study has ended. Describe your plan to destroy identifiers, if you will do so.</p> <ul style="list-style-type: none"> <li>▪ Blood samples will be discarded immediately after testing at the study cite.</li> <li>▪ All the original data, information, and questionnaires will be discarded properly after completing the study.</li> </ul>	

**Commitment to Good Practices in Palauan communities:**

I certify that, as a researcher involved in Palauan communities, I have considered the following “good practices”:

- To respect the culture, traditions and knowledge of Palauans;
- To conceptualize and conduct research with the Palauan community as a partnership;
- To consult members of the community who have relevant expertise;
- To involve the community in the design of the project;
- To examine how the research may be shaped to address the needs and concerns of the community;
- To make best efforts to ensure that the emphasis of the research, and the ways chosen to conduct it, respect the many viewpoints of different segments of the community question;
- To provide the community with information respecting the following:
  - Protection of the Palauan community cultural estate and other property;
  - The availability of a preliminary report for comment;
  - The potential employment by researchers of members of the community appropriate and without prejudice;
  - Researcher’s willingness to cooperate with community institutions;
  - Researcher’s willingness to deposit data, working papers and related materials in an agreed-upon repository.
- To acknowledge in the publication of the research results the various viewpoints of the community on the topics researched; and
- To afford the community an opportunity to react and respond to the research findings before the completion of the final report, in the final report or even in all relevant publications.

Considering the Palauan peoples’ right to react to the research findings, I will give such matters due consideration. If disagreement persists, I shall afford the group an opportunity to make its views known, or will accurately report any disagreement about the interpretation of the data in their reports or publications.

\_\_\_\_\_  
Signature of Principal Investigator

\_\_\_\_\_  
Date

**Principal Investigator:** I will personally conduct or supervise this research study. I will ensure that this study is performed in compliance with all applicable laws, regulations and institutional policies regarding human subject research. I will obtain IRB approval before making changes or additions to the project. I will notify the IRB of any other changes in the information provided in this application. I will provide progress reports to the IRB at least annually, or as requested. I will report promptly to the IRB all unanticipated problems or serious adverse events involving risk to human subjects. I will follow the IRB approved consent process for all subjects. I will ensure that all collaborators, students and employees assisting in this research study are informed about these obligations. All information given in this form is accurate and complete.

\_\_\_\_\_  
Signature of Principal Investigator

\_\_\_\_\_  
Date

**Conflict of Interest Questions and Certification**

The following questions apply to all investigators and study staff engaged in the design, conduct, or reporting results of this project and/or their immediate family members. For these purposes, “family” includes the individual’s spouse and dependent children. “Spouse” includes a person with whom one lives together in the same residence and with whom one shares responsibility for each other’s welfare and shares financial obligations.

<p>A.3.1 Currently or during the term of this research study, does any member of the research team or his/her family member have or expect to have:</p> <p>(a) A personal financial interest in or personal financial relationship (including gifts of cash or in-kind) with the sponsor of this study?</p> <p>(b) A personal financial interest in or personal financial relationship (including gifts or cash or in-kind) with an entity that owns or has the right to commercialize a product, process or technology studied in this project?</p> <p>(c) A board membership of any kind or an executive position (paid or unpaid) with the sponsor of this study or with an entity that owns or has the right to commercialize a product, process or technology studied in this project?</p>	<p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> Yes</p>	<p><input checked="" type="checkbox"/> No</p> <p><input checked="" type="checkbox"/> No</p> <p><input checked="" type="checkbox"/> No</p>
<p>A.3.2 Has the University or a University-related foundation received a cash or in-kind gift from the sponsor of this study for the use or benefit of any member of the research team?</p>	<p><input type="checkbox"/> Yes</p>	<p><input checked="" type="checkbox"/> No</p>
<p>A.3.3. Has the university or has a University-related foundation received a cash or in-kind gift for the use or benefit of any member of the research team from an entity that owns or has the right to commercialize a product, process or technology studied in this project?</p>	<p><input type="checkbox"/> Yes</p>	<p><input checked="" type="checkbox"/> No</p>

If the answer to ANY of the questions above is yes, the affected research team member(s) must complete and submit to the Ministry of Health the form accessible at <http://pirb.webs.com>. List name(s) of all research team members for whom any answer to the questions above is yes:

**Certification by Principal Investigator:** By submitting this IRB application, I (the PI) certify that the information provided above is true and accurate regarding my own circumstances. I understand that as Principal Investigator I am obligated to ensure that any potential conflicts of interest that exist in relation to my study are reported as required by the Palau IRB.

\_\_\_\_\_  
Signature of Principal of Investigator

\_\_\_\_\_  
Date

**Checklist of Items to Include with Your Submission (2 copies of each):**

Check	Item
	1. This application. One copy must have original PI signatures.
	2. Research Protocol (Research Project)
Included  Not Applicable	3. Consent (official Palauan translations if needed) and assent forms, fact or information sheets; include phone and verbal consent scripts.
Included  Not Applicable	4. All recruitment materials including scripts, flyers and advertising, letters, emails.
Included  Not Applicable	5. Questionnaires, focus group guides, scripts used to guide phone or in-person interviews, etc
Included  Not Applicable	6. Investigator Brochure if a drug study

A6.4.2 INVESTIGATOR CONFIDENTIALITY STATEMENT

PALAU INSTITUTIONAL REVIEW BOARD

INVESTIGATOR CONFIDENTIALITY STATEMENT

P.O. Box 6027

Koror, Republic of Palau 96940

Tel.: (680) 488 2552/2553

Fax: (680) 488 1211

---

I, Atsuko Aoyama, of Nagoya University, Japan, hereby declare

*(full name)*

*(state, country)*

that I will maintain absolute confidentiality throughout the duration of my study, Multi-Disciplinary Study for Promoting Non-Communicable Disease (NCD) Control in Republic of Palau (Title and PIRB number) . I will not disclose any information I obtain from any participant to anyone without prior permission of the participant.

Signature: \_\_\_\_\_

Print Name: Atsuko Aoyama

Date:     /     /    

Witness

Signature: \_\_\_\_\_

Print Name: \_\_\_\_\_

Date:     /     /

A6.4.3 STAFF RESPONSIBILITIES

**PALAU INSTITUTIONAL REVIEW BOARD**

**RESPONSIBILITIES OF STAFF IN HUMAN SUBJECTS RESEARCH**

P.O. Box 6027

Koror, Republic of Palau 96940

Tel.: (680) 488 2552/2553

Fax: (680) 488 1211

---

**Title of Research Project:** Multi-Disciplinary Study for Promoting Non-Communicable Disease (NCD) Control in Republic of Palau

**Principal Investigator:** Atsuko Aoyama

As a member of this research team I understand that I share responsibility for the protection of human subjects. By signing this statement, I am indicating my understanding of these responsibilities and I agree to the following:

- If I am involved with the consent process, I understand that the process is to be conducted as approved by the Institutional Review Board. By means of the consent process, I will ensure that prior to their agreeing to participate, potential subjects will understand that participation is voluntary, will have been given all pertinent details about the study and will have the opportunity to ask questions, and that they will understand what will be asked of them in the conduct of this research.
- I understand that names and any other identifying information and all other information about study participants are completely confidential. I agree not to divulge, publish, or otherwise make known to unauthorized persons or to the public any information obtained in the course of this research project that could identify the persons who participated in the study.
- I understand that any violation as described above may be grounds for disciplinary action, and may include termination of employment.
- I agree to notify my supervisor immediately should I become aware of any violation of ethical principles or regulatory requirements for the protection of human subjects, whether this be on my part or on the part of another person. These might include breach of confidentiality, failure to properly obtain or document informed consent, or deviation from the approved study protocol.

---

Signature

---

Date

---

Printed Name

---

Signature of PI

---

Date

---

Atsuko Aoyama

---

Printed Name

A6.5.1 SHORT CONSENT FORM

PALAU INSTITUTIONAL REVIEW BOARD

SHORT FORM VERSION FOR INFORMED CONSENT TO PARTICIPATE IN  
A RESEARCH STUDY

P.O. Box 6027

Koror, Republic of Palau 96940

Tel.: (680) 488 2552/2553

Fax: (680) 488 1211

---

**Title of Study:** Multi-Disciplinary Study for Promoting Non-Communicable Disease  
(NCD) Control in Republic of Palau

**IRB Study #** \_\_\_\_\_

**Principal Investigator:** Atsuko Aoyama

**Documentation of verbal presentation of English-language consent form**

*(Translate this text into the lines provided):* By signing below, I voluntarily agree to participate in this research study. The study and consent form have been verbally explained to me in a language I understand. I have had the opportunity to ask all my questions about this study. I have received answers to all my questions.

---

Signature of Research Subject

---

Date

---

Printed Name of Research Subject

---

Signature of Witness (oral interpreter may sign as witness)

---

Date

---

Printed Name of Witness

---

Signature of Person Obtaining Consent

---

Date

---

Printed Name of Person Obtaining Consent

# Multi-Disciplinary Study for Promoting Non-Communicable Disease (NCD) Control in Republic of Palau

## Outline of the Research Plan

### 1. Introduction

Non-communicable diseases (NCDs) are globally recognized threats to social and economic development, as shown in the Political Declaration of the High-level Meeting on the Prevention and Control of NCDs adopted by the United Nations General Assembly in 2011. It is becoming a new priority and additional burden on health in low and middle income countries, where urbanization and lifestyle changes are advancing rapidly.

Republic of Palau is an island country located in the western Pacific Ocean. Gross national income (GNI) per capita was estimated to be US\$ 7,250 (2011), thus Palau is classified as an upper middle income country. Total population was 20,609 (2011), of which 70 % are indigenous Palauans, and some of the people have Asian ancestry, including Japanese. Urban population reached 83 % of total population, and is expected to increase 1.4 % annually. Basic social indicators have been improved significantly: *e.g.*, life expectancy at birth was 69 years (2005); gross primary school enrollment rate was 101 % (2007); and access to improved water was 96 % (2010). [Data source: World Development Indicators. The World Bank]

While infectious diseases have been successfully controlled, burden of NCDs is increasing in Palau, where obesity and overweight are prevalent. If the population of 65 years and over (only 6.5 % in 2011) increase, health expenditure (already as high as 11.2 % of GDP in 2009) is expected to increase along with the increase of the burden of NCDs. Currently NCDs are leading causes of deaths in Palau, as well as in other Pacific island countries. Thus, the State of Health Emergency on NCDs has been declared in 2010 by the Pacific Island Health Officers Association and endorsed by the Micronesian Chief Executives, Micronesian Presidents, Association of Pacific Island Legislatures, Micronesian Traditional Leaders Council and Micronesian Chief Justices.

NCDs are recognized as a priority health issue in Palau, thus several studies, including WHO STEPS Survey targeted to the population between 25 and 64 years of age and various school based studies, have been implemented. However, data and information on prevalence of NCD risk factors, including hypertension, raised cholesterol, diabetes, obesity and overweight, alcohol and tobacco consumption, unhealthy diet, and physical inactivity, of the population between 18 and 24 years of age are mostly missing. It is urgently needed to study baseline data of above risk factors to understand the situation and magnitude of NCDs in Palau, and to develop effective NCD control strategies and interventions.

This research aims to: (1) study epidemiological situation of NCDs of the young adults between 18 and 24 years of age; (2) examine people's life-style, social backgrounds, and cultural belief which may affect their health status; and (3) identify various risk factors which needs to be taken into account to develop effective control measures. The study group will also analyze the original data of the WHO STEPS survey.

### 2. Objectives

- To study epidemiological situation of NCDs among people living in Palau.
- To examine people's life-style and social backgrounds.
- To identify various risk factors of NCDs.
- To recommend effective NCD control strategies and interventions.

### 3. Scopes, methods, and data sources

#### 1. Field epidemiological study on NCDs

- Cross sectional study to obtain base line data of the target population.
- Since the recent WHO STEPS Survey targeted population between 25 and 64 years of age, this field study targets the young adults between 18 and 24 years of age.
- Target population: young adults between 18 and 24 years of age living in Palau, excluding pregnant and breastfeeding women (approximately 4,000)
- Study population: 15–25% of the people between 18 and 24 years of age in Koror city (approximately 600–1,000).



- All interviewers have been already trained so no need for recruitment.
- Physical examination: and blood tests follow the WHO STEPS Survey protocol
- Structured questionnaire of the WHO STEPS Survey protocol will be slightly modified to adjust to the young adults
- Logistic regression analysis:  
Dependent variables: obesity; hypertension; diabetes; hyperlipidemia.  
Independent variables: social, economic and psychological factors; life style; daily habits.

## 2. Epidemiological study based on the data of the recent WHO STEPS Survey

- Analyze the original data of the recent WHO STEPS Survey of 2,800 people (a little over 10 % of the target population) between 25 and 64 years of age living in Palau.

## 3. Sociological study on risk factors

- Key informant interviews to 10–20 community leaders, health workers, *etc.* living in Palau.
- Focus group discussions of several category groups of people, following a semi-structured topic guide, facilitated by a well-trained facilitator: 5–8 people in each group, 4–8 groups of various categories: *e.g.* young /old, men/women, tobacco users/ non-users, obese/non-obese, *etc.*, in total 20–60 people living in Palau.
- Obtain qualitative data, such as traditional belief relating to diet and physical activities; knowledge, attitude and behavior for health; relationship with family and community, *etc.*
- Qualitative analysis of English text data and identify NCD risk factors.

## 4. Policy recommendation for controlling NCDs

- NCD control strategies and interventions will be developed based on the study results

## **4. Ethical considerations**

- This research plan has been reviewed and approved by the Bioethics Review Committee, Nagoya University School of Medicine.
- The research plan will obtain the approval of the Institutional Review Board (IRB), Ministry of Health, Republic of Palau.
- Written informed consent will be obtained from all study participants.
- The data and information of the participants will be kept confidential. Participants' names will not be kept with the information during the analysis.
- Original data and code numbers will be securely stored at the Ministry of Health, Republic of Palau.
- Participants will be given medical advice, in case they are found to be suffering from untreated NCD.

## **5. Tentative time frame**

Sept 2012	Discussions for planning the study (in Palau)
	Submission of application for IRB approval
Sept – Nov 2012	Preparation of draft questionnaires adjusted to young adults
	Preparation of logistics of field epidemiological and sociological studies.
Nov 2012	Discussions for preparing the field epidemiological study (in Palau)
	Implementation of sociological study
Dec 2012 – Jan 2013	Further preparation of the field epidemiological study
	Data analysis of sociological study
	Analysis of WHO STEPS Survey data
Jan 2013	Discussions of study planning and data analyses (in Japan)
Feb – Jul 2013	Further preparation of the field epidemiological study
	Data analysis of sociological study
	Analysis of WHO STEPS Survey data
Aug – Nov 2013	Implementation of the field epidemiological study
	Discussions of the results of data analyses (in Palau)
Dec 2013 – May 2014	Data analyses
Jun 2014 – Oct 2014	Preparation and submission of academic papers
Nov 2014	International conference on NCD control strategies (in Japan)
Dec 2014– March 2015	Preparation of policy recommendations

## 6. Team composition

(Core team members are listed. Other members including graduate students may participate in the study.)

[Joint Study Team of Nagoya University and Osaka University, Japan]

Nagoya University

Atsuko Aoyama	Professor	Team Leader
Hiroshi Yatsuya	Visiting Professor	NCD risk factor analysis

Osaka University

Hiroyasu Iso	Professor	Co-team leader
Kaori Honjo	Associate Professor	Epidemiological study
Takashi Mita	Associate Professor	Sociological study

[Research Team of Ministry of Health, Republic of Palau]

Ministry of Health, Republic of Palau

Yorah Demei	NCD Unit Administrator
Berry Moon Watson	Health Planning and Research Division Administrator
Temmy Temengil	International cooperation coordinator

Palau Community College

Patrick Tellei	President
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Palau Resource Institute

Julie Tellei

## 7. Budgets and other inputs

Major funding source:

Health and Labour Sciences Research Grants (Research on global health issues), sponsored by the Ministry of Health, Labour and Welfare, Government of Japan.

Roles and inputs:

[Roles of Joint study team, Japan]

- Planning the field study and preparing draft of adjusted questionnaires in collaboration with Palauan team
- Procuring reagents and consumables for physical examination and blood tests
- Allocating budget for travel costs between Japan and Palau for Japanese team members and invited Palauan researchers.
- Conducting key informant interviews, focus group discussions in collaboration with Palauan team.
- Collecting other relevant data and information. in collaboration with Palauan team.
- Data inputs and data analyses in collaboration with Palauan team.
- Analyzing the original data of the recent WHO STEPS Survey in collaboration with Palauan team.
- Jointly publishing academic papers in English.

[Roles of MOH team, Palau]

- Obtaining IRB approval and other necessary permissions of local authorities.
- Sampling and recruiting the study population in collaboration with Japanese team.
- Conducting physical examinations, blood testing, questionnaire surveys in collaboration with Japanese team.
- Deploying MOH staff for the field study.
- Securing transportation within Palau, by sharing the costs with Japanese team
- Conducting a part of field interviews in Palauan and translating the records into English
- Securely storing the original data and coding numbers.
- Sharing the original data of the recent WHO STEPS Survey with Japanese team.

## INFORMED CONSENT FORM (1) – INFORMATION

### **Study Title: Multi-Disciplinary Study for Promoting Non-Communicable Disease Control in Republic of Palau**

#### **1. Summary**

Our study team is doing a research on the situation of non-communicable diseases (NCD) in Palau. This research aims to: (1) study epidemiological situation of NCD among local people; (2) examine people's life-style and social backgrounds which may affect their health status; and (3) identify various risk factors which needs to be taken into account to develop effective control measures.

We are asking you to participate in this study including questionnaires and physical examinations such as blood pressure and blood glucose test. If you participate in the study, you will help us learn more about NCD situation in your community and develop better control strategies. You will not get any direct benefits, and you will not be paid for participation in this study. However, we will give you medical advice in case you are found to be suffering from untreated NCD.

You are free to take part in this study or not. No penalties or loss of benefits will occur if you refuse to take part. You may withdraw at any time, even if you decide to take part in this study.

#### **2. Details of the study**

Study Title	Multi-Disciplinary Study for Promoting Non-Communicable Disease Control in Republic of Palau
Institutes	Nagoya University and Osaka University, Japan Ministry of Health, Republic of Palau
Team Leader	Prof. Atsuko Aoyama Department of Public Health and Health Systems Nagoya University School of Medicine
Team Members	Nagoya University Visiting Prof. Hiroshi Yatsuya Osaka University Prof. Hiroshi Iso Assoc. Prof. Kaori Honjo Assis. Prof. Takashi Mita
Local Collaborating Institutes	Ministry of Health, Republic of Palau Palau Community College Palau Resource Institute
Investigating issues	Non-communicable diseases (NCD) and their risk factors
Data and information to be collected	Physical data: height; weight; abdominal circumference; blood pressure; blood glucose, cholesterol, and triglycerides. Life-style and social backgrounds: past, present, and family history of NCD and other diseases; tobacco and alcohol consumption; diet habits; sleep; physical activities; age; sex; family structure; education; occupation; etc.

#### **(1) Study objective**

- 1) To study epidemiological situation of NCD among people living in Palau.
- 2) To examine people's life-style and social backgrounds.
- 3) To identify various risk factors of NCD.

4) To recommend effective NCD control measures.

**(2) Reasons you are chosen**

All people between 18 and 24 years old in the target areas are asked to participate.

**(3) Study methods**

[Methods]

1) Physical examination

Collect data such as height, weight, abdominal and hip circumference, and blood pressure

2) Blood sampling

Collect small amount of blood to measure glucose, cholesterol, and triglycerides.

3) Questionnaire

Collect the following information: past, present, and family history of hypertension, stroke, cardiac diseases, etc; tobacco and alcohol consumption; diet habits; sleep; physical activities; age; sex; family structure; occupation; education, etc.

4) Key informant interviews and focus group discussions

Collect qualitative data such as traditional belief relating to diet, physical activities; knowledge, attitude and behavior for health; relationship with family and community.

[Study period]

Whole study: August 2012 – March 2016

Data collection: Palau = November 2012, August – November 2013

We will not keep your name with the information while we analyze them.

**(4) Further questions**

You may ask further questions about the study protocol.

**3. Benefits and losses caused by participating in the study**

[Benefits]

1) You will contribute to learning more about NCD situation in your community and developing better control strategies.

2) If you are found to be suffering from untreated NCD, we will give you medical advice.

[Losses]

1) You have to spend time to take examinations and to respond questionnaires.

2) You will feel slight pain while taking blood samples.

**4. Consequences of not participating in the study**

No penalties or loss of benefits will occur if you refuse to take part.

**5. Privacy**

The data and information you provide us will be kept confidential. To protect your information, we will not keep your name with the information while we analyze them.

**6. Informing the results**

The kind of information we will look for in this study is not likely to tell you anything specific about your personal health. Thus, we will not inform you of the results of the examination, unless you are found to be suffering from untreated NCD.

**7. Publication of the study findings**

We will publish only the results of the analyses, from which each participant cannot be identified.

**8. Intellectual property right**

Researchers of the study team and their institutes will hold the intellectual property right which