Quality Mental Health Research in the Philippines

Conceptualization, Design, and Methods

A Manual on Mental Health

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DOST - PCHRD

Philippine Council for Health Research and Development

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ACRONYMS

FGD	Focus Group Discussion
ASEAN	Association of South-East Asian Nations
MH	Mental Health
MH-TWG	Mental Health Technical Working Group
NCMH	National Center for Mental Health
NMHRA	National Mental Health Research Agenda
NUHRA	National Unified Health Research Agenda
PCHRD	Philippine Council for Health Research and Development
PCMH	Philippine Council for Mental Health
PICOT	Patient/Population, Intervention, Comparator, Outcome, Time
SDGs	Sustainable Development Goals
SNS	Social Networking Sites
UNDESA	United Nations Department of Economic and Social Affairs
WAPR-Phil	World Association for Psychosocial Rehabilitation - Philippines
WHO	World Health Organization

FOREWORD

Over the last four decades, the Philippine Council for Health Research and Development (PCHRD) has evolved and grown to keep its relevance while staying true to its commitment as the lead coordinating body for health research and development initiatives in the country. The Council is honored to welcome mental health as a timely addition to its research priority areas under the National Unified Health Research Agenda (NUHRA), with the recent enactment of the Philippine Mental Health Law.

Recognizing the pressing need to put focus on mental health research is a significant step in improving the quality of life of our fellow Filipinos. But as with all the other priority areas, initiating a new program entails defining its set of concepts and priorities, and we are grateful for the expertise put forth by our Filipino researchers from the World Association for Psychosocial Rehabilitation-Philippines (WAPR-Phil) in the development of the National Mental Health Research Agenda (NMHRA) 2019-2022.

To ensure that we harness proposals that are consistent with the language and mindset for mental health (MH) research based on the Mental Health Law, the PCHRD and its Mental Health Technical Working Group (MH-TWG) conducted the "Capacity Building in Technical Writing for Mental Health Research Development" last 24 November 2020 and 5 December 2020. The writeshop equipped project teams from various research organizations and academic institutions with the necessary skills and knowledge that will prepare them in developing proposals on mental health.

This manual is a compilation of the essential discussions exchanged between the lecturers and participants from the mental health writeshop. The purpose of this document is twofold: first, to serve as a working manual to guide mental health researchers in the submission of their proposals to PCHRD and other research organizations and second, to record the rich discourse on mental

health concepts and research framework generated from the writeshop.

The PCHRD acknowledges the commitment and hard work of the MH-TWG and the lecturers in coming up with this manual: to Dr. Ma. Carmen L. Tolabing, who led the conduct of the writeshop and her team who shared their expertise in mental health research, Dr. Lourdes L. Ignacio, the chair of PCHRD MH-TWG as well as the TWG members: Dr. Arsenio Sze Alianan, Jr., Dr. Carl Abelardo T. Antonio, Dr. Ma. Cecilia G. Conaco, Dr. Michael L. Tan, and Dr. Manuel F. Bonifacio.

I salute all those whose hard work contributed to the creation of this important document. These successes are the result of hard work in adverse times.

Finally to the readers, we hope to help you find the right paths to fully understanding the language of mental health research in the Philippines. We hope reading this manual will help you in your mental health research endeavors, and we look forward to your contributions and feedback.

Maraming salamat at magandang agham sa inyong lahat!

Jaime C. Montoya, MD, MsC, PhD, CESO II
Executive Director III
Philippine Council for Health Research and Development
Department of Science and Technology

INTRODUCTION

Mental health is one of the research priorities in the National Unified Health Research Agenda (NUHRA) 2017–2022. At that time, there was no mental health research framework upon which the Philippine Council for Health Research and Development (PCHRD) could anchor its decisions to support studies in mental health. Hence, it supported the conduct of the project: "Defining the Research Agenda in the Philippines" proposed by a non-government organization, the World Association for Psychosocial Rehabilitation–Philippines (WAPR-Phil).

The completion of this project launched the PCHRD publication in October 2019, of a National Mental Health Research Agenda (NMHRA) in the Philippines for 2019–2022. It also organized a Mental Health Technical Working Group (MH-TWG) to act as technical reviewers to the research proposals submitted immediately after a call for proposals was launched nationwide. These were proposals to be provided financial support for the following year, 2020. An impressive number of 37 proposals from various parts of the country were submitted for review by April 2020. Though caught by the limitations of the pandemic that struck the country, the MH-TWG went ahead and undertook the expected review of these proposals. These reviews showed that the proponents were quite limited in their grasp of mental health concepts, and the range of mental health programs and strategies for intervention, especially as these have to be consistent with the provisions of the recently legislated Philippine Mental Health Law of 2018. The research proponents also showed limitations in their capacities for technical writing in mental health research.

A decision to conduct a writeshop on 24 November and 5 December 2020 was made by the MH-TWG with selected proponents, who have submitted their research proposals but these were not right away approved because there were revisions that needed to be addressed. The writeshop on "Capacity Building in Technical Writing for Mental Health Research" was organized under the

chairmanship of one of its members, Dr. Ma. Carmen Tolabing of the College of Public Health of the University of the Philippines, and was conducted virtually.

The general objective was to develop a technically sound research proposal that will have an impact on mental health research and development. The specific objectives were:

- to understand mental health concepts and the framework for mental health research and development;
- to identify and describe the research problem in mental health and highlight its impact on mental health research and development;
- to develop the basic skills in the conduct of a research proposal on mental health, particularly on: (1) describing the MH research problem; (2) synthesizing and writing the literature review; (3) developing the conceptual framework; (4) designing the research matrix (i.e., qualitative and/or quantitative methods); (5) planning for data collection; (6) planning for data analysis.

The writeshop was structured around three activities: didactic lectures; workshops, and plenary and parallel sessions. The participants were divided into groups of three and each group was facilitated by a pair of facilitators (i.e., subject matter expert, a mental health expert and a research methods expert).

The MH-TWG has decided to publish the proceedings of this writeshop to serve as a manual to guide research proponents in the formulation of quality mental health research in the Philippines. It was agreed that all the lectures during this two-day webinar-writeshop would be the main chapters of this manual.

It is recognized that the production of this manual is an initial venture to write a manual on mental health research in the Philippines. Hence, it is considered as a "work in progress" in developing quality mental health research in our country.

This manual would not have been possible without the excellent leadership of the chair of this writeshop, Dr. Ma. Carmen C. Tolabing, and her colleagues at the College of Public Health; namely, Professors Carl Abelardo T. Antonio, Louella Patricia D. Carpio, Kim Carmela D. Co, and Derick Erl P. Sumalapao who delivered lectures, authored the corresponding chapters in this manual and facilitated the writeshop sessions. We would also like

to acknowledge the contribution of Dr. Michelle G. Ong, Professor of Psychology, College of Social Sciences and Philosophy, UP Diliman, who authored the module on Qualitative Research Design, which was not covered in the writeshop activity.

We are grateful for the encouragement and support of the members of the MH-TWG (2020): Professors Manuel F. Bonifacio, Ma. Cecilia G. Conaco, and Arsenio Sze Alianan, Jr., in discussing the post-writeshop results and in deciding that we publish this "pioneering" manual on mental health research in our country.

Many thanks are also extended to the members of the PCHRD Mental Health Team, Paul Ernest N. de Leon, Marianne Joy G. Laya, Bianca Joyce T. Sornillo, Lemuel D. Lozada, and to the other PCHRD staff who were involved during the writeshop activity—Grace Ann A. Cenon, Yasmin Janina A. Serrano, Patricia Mae M. Parilla, Alyana Kaye M. Bacarra, and Ronald Ryan D. Lolong—for their valuable administrative support and assistance, especially as we go through getting these tasks done and completed in the midst of the pandemic.

Mabuhay tayong Lahat!

Lourdes Ladrido-Ignacio, M.D.
Professor *Emeritus* in Psychiatry, University of the Philippines
Chair, PCHRD Mental Health Research Advisory Group

READING GUIDE

Before proceeding, please be reminded that the contents of this manual are narratives of the discussions during the writeshop: "Capacity Building in Technical Writing for Mental Health Research Proposal Development", which was held as part of the activities for the 2020 National Science and Technology Week.

The discussions in each chapter should be supplemented by the corresponding slide presentations used during the writeshop, which you may access here: https://tinyurl.com/MHManual.

Worksheet activities are also included at the end of each chapter which may be useful in the development of your research proposal. Other relevant documents can also be downloaded from the link provided above.

Mental Health Technical Assessment Form

NUHRA 2017-2022

NHMRA 2019-2022

2017 National Ethical Guidelines for Health and Health-related Research

Chapter 1

Introduction to Mental Health Research

›› A. Definitions, Concepts, and Framework

By Arsenio Sze Alianan, Jr., PhD*

The World Health Organization (WHO) defines health as "…a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (WHO, 2018). This definition clearly includes mental and social well-being as integral components of health in general. In fact, the WHO states that "mental health is a state of well-being in which an individual realizes his or her own abilities, can cope with the normal stresses of life, can work productively and is able to make a contribution to his or her community" (WHO, 2018).

Goal Number 3 of the United Nations' Sustainable Development Goals is to "ensure healthy lives and promote well-being for all at all ages" (UNDESA, 2015). Apart from aiming to decrease non-communicable diseases and premature mortality, this goal runs parallel to the WHO definition of health, which capitalizes on its fundamental link with wellbeing through the lifespan. Indeed, this goal pushes the agenda of mental health among its member states and the whole world, stressing its importance in sustainable development.

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* Assistant Professor, Department of Psychology, Ateneo de Manila University and Member of the PCHRD Mental Health Research Advisory Group.

Being a member state and a signatory of the said development goals, the Republic of the Philippines enacted into law Republic Act (RA) 11036, also known as "An Act Establishing a National Mental Health Policy for the Purpose of Enhancing the Delivery of Integrated Mental Health Services, Promoting and Protecting the Rights of Persons Utilizing Psychiatric, Neurologic, and Psychosocial Health Services, Appropriating Funds Therefore, and for Other Purposes" or simply as the Mental Health Law.

> Republic Act 11036—or the Mental Health Law—describes itself as "an act establishing a **national mental health policy** for the purpose of enhancing the **delivery of integrated mental health services**, promoting and protecting the **rights of persons** using psychiatric, neurologic and psychosocial health services, appropriating funds therefore and for other purposes (*emphasis added*)." It uses a more expanded definition that includes **resiliency** as an integral component of mental health.

This rights-based law enshrines mental health in the public health policy and government service delivery agenda. A copy may be downloaded through the following website: <https://www.officialgazette.gov.ph/2018/06/20/republic-act-no-11036/>

As a way of situating mental health research in the Philippine context, a selection of provisions of the Mental Health Law shall be highlighted here. One such provision is the creation of the Philippine Council for Mental Health ((PCMH), an advisory body attached to the Department of Health. The Council further established the framework for a national mental health strategic plan. A brief description of the six goals of the Mental Health Law sets the tone for the discussion of the following chapters of the law:

- Chapter IV - Mental Health Services
- Chapter V - Promotion of Mental Health in Educational Settings and the Workforce
- Chapter VI - Capacity Building, Research and Development
- Chapter IX - Mental Health of Drug Dependents.

Implications of these provisions are then discussed.

This law affirms that the mental health of every Filipino is a basic human right that the state must protect and maintain. Policies and services necessarily encompass the spectrum of promoting mental health and wellbeing, prevention of mental illness, and provision of timely and efficacious treatment. The law acknowledges the neurodevelopmental, psychological, and sociocultural influences of this spectrum, which must be taken into account when crafting policies and providing services pertaining to mental health. All these policies and services are shaped and informed by research evidence, and promulgated across sectors of society.

Six Goals of the Mental Health Law

- Strengthen effective leadership and governance in mental health;

- Develop and establish mental health services that are both comprehensive and available to everyone in the country;

- Protect rights and freedoms of persons with mental health conditions (service user);

- Strengthen information systems, evidence and research;

- Integrate mental health services in basic health services; and

- Promote mental health in educational institutions, workplaces,and communities.

Chapter IV of the Mental Health Law emphasizes the need to provide services that are evidence-based and pro-poor. The community-based mental health care paradigm was espoused, whereas more specialized care shall be made available in regional, provincial and tertiary hospitals. Specialized care includes neurological, psychiatric, and psychosocial services.

Chapter V details the involvement of educational and work settings in the promotion of mental health. This addresses developmentally appropriate and lifelong mental health education and promotion.

Capacity building and research and development are covered in **Chapter VI**. In the area of capacity building, school personnel and barangay health workers are expected to be equipped with basic skills in mental health promotion and prevention of mental illness. Cognizant with the community-based mental health care paradigm, appropriate school personnel and barangay health workers are also expected to provide basic interventions for common

mental health issues. The law also endorses strengthening research evidence in shaping policies and service provision. Dissemination and application of research findings are thus necessary in this endeavor.

The law makes a special mention on identifying drug dependents as mental health service users in **Chapter IX**. This allows for the protection of their rights to timely and efficacious assessment and intervention services.

The goals and selected provisions discussed herein have three broad implications:

First, mental health and illness is a spectrum, ranging from full mental health to mild, and severe mental illness. The old adage "an ounce of prevention is worth more than a pound of cure" is enshrined in its emphasis on prevention of mental illness and education of the public, and the provision of psychosocial services. In espousing community-based mental health, services are decentralized and take on a primary health care orientation that is humane and rights-based.

Second, mental health encompasses neurodevelopmental, psychological and sociocultural influences. This acknowledges the multifactorial and multidimensional nature of the spectrum of mental health, and the need for similarly multi-disciplinary services and interventions.

Third, mental health is everybody's business, necessitating multi-agency and inter-agency involvement. This cuts across the education, workplace, research and knowledge generation, and legal sectors of society.

In summary, wellbeing and mental health are integral parts of overall health. The Mental Health Law enshrines the Philippines' need to protect and promote mental health among its citizens. This law cuts across all levels of governance and various sectors of society. It supports the notion that mental health will contribute to the country's sustainable development.

Download/scan here:

Note: Please refer to the presentation entitled "**Introduction to Mental Health**" by Dr. Arsenio Sze Alianan, Jr. that was used during the writeshop.

https://tinyurl.com/MHManual

>> B. The Conceptual Framework for Mental Health in the Philippines

By Lourdes Ladrido-Ignacio, MD[†]

The Director General of the World Health Organization, in calling for programs that would upscale mental health services, articulated the fact that mental health conditions continue to be prevalent, persistent and burdensome worldwide. This global mental health situation, which the Philippines, share is aggravated by the continuing occurrence of extreme life experiences caused by disasters (natural and man-made), violence in the home and in the streets, etc.

The Philippines, being geologically and geographically vulnerable to these adversities, has to cope with the overwhelming and devastating destruction that have generated aggravating mental health and psychosocial consequences among the people. The current impact of the pandemic, the uncertainty and isolation it has imposed on everyone, has apparently pushed them to the limits of their endurance. All these have posed major mental health challenges in the county.

The passage of the Philippine Mental Health Law (RA 11036) in 2018 provides the opportunity for the country to address these global and national mental health challenges It is important that those participating in the development of mental health programs in the Philippines read the provisions of this Law.

RA 11036 affirms the right of all Filipinos to mental health as well as the fundamental right of people for quality mental health services.

Mental Health, as articulated in the Mental Health Law, is defined as "The state of well-being in which an individual realizes one's own abilities and potentials copes adequately with the normal stresses of life, displays resilience in the face of extreme life events, works productively and fruitfully, and is able to make a positive contribution to the community" This definition is essentially consistent with the WHO definition of mental health except for the addition of the line "displays resilience in the face of extreme life events".

[†]   Professor Emeritus in Psychiatry, University of the Philippines; and chair, PCHRD Mental Health Research Advisory Group.

The uniqueness of the definition of Mental Health in the Philippine MH Law is further strengthened when one looks at the highlights of this Law. These are the following provisions:

1. **It is rights based**. This articulates the promotion of mental health, and maximizes the mental health and psychosocial well-being of every Filipino as his fundamental human right. There are provisions that would address the current mental health situation, where the rights of anyone who suffer from conditions considered "mental" and subjected to discrimination and dehumanization, are addressed.

2. **Institutional reforms for better governance and leadership in mental health**. Although the Department of Health assumes the chairmanship of the policy making and implementing body, the Philippine Council for Mental Health, the Law recognizes the Philippine Local Government Code and the leadership role of local government units in the delivery of mental health services in the communities. The PCMH is composed of members from six government agencies and three civil society organizations, giving this a multi-dimensional multi-sectoral leadership.

3. **Deinstitutionalization and emphasis on strengthened integrated community mental health services**. This is a shift in emphasis from the prevailing hospital-based (basically mental hospitals) services to strengthened community mental health services.

4. **Expansion of programs, with the integration of the mental health programs in non-health institutions (i.e., educational institutions, workplaces, and the general community).** Schools and work-places are recognized to have significant roles in mental health promotion programs to sustain the mental health of the majority of the population, like the young students in schools at various levels, and those working adults who through their productive lives are expected to make positive contributions in their communities and the country as a whole.

5. **Improvement of mental health information**, which is evidence based and of institutional capacities.

Philippine Council for Mental Health

The Law provides for the creation of a Philippine Council for Mental Health (PCMH) as the policy and implementing body for its full and effective implementation. The PCMH has finalized a national strategic plan for mental health. The features of this plan are:

1. Whole of government, whole of society approach

2. Mental health programs' emphasis on promotion and prevention as crosscutting the major programs on:

   a. Governance and leadership

   b. Mental health management information systems

   c. Comprehensive integrated, quality and accessible services for continuing care for mental and neurological disorders and psychosocial problems

All these carry the perspectives of being rights based, of providing balanced care and effective recovery.

The PCMH is composed of members from six government agencies and three from civil society organizations. It is chaired by the Secretary of Health but its composition is right away looked at as multisectoral and multi-dimensional. The PCMH has organized technical working committees to implement its plan. Among these committees is the Technical Committee on Training Education and Capacity Building.

The Technical Committee, in addressing the need for the full implementation of the MH Law, has recognized that a reorientation of the concept of mental health is necessary. The prevailing concept of mental health in the country needs to be reframed from its limited focus on the individual alone, which is basically a clinical illness bio-medical orientation to a wider focus on the majority of the population ("the healthy who are well") to promote and sustain their health including their mental health and to reduce their risk to ill-health. In this

perspective, there is the vital recognition that the individual and his environment are interconnected.

> The Technical Committee on Training Education and Capacity Building has emphasized the need for clear language and concept of mental health since it is recognized that there currently is a "babel of tongues" in relation to mental health. Hence, a conceptual framework for mental health in the Philippines was drawn.

Biopsychosocial-Spiritual Framework

The Conceptual Framework for Mental Health in the Philippines was adopted by the PCMH as Resolution 2020-003. This articulates the reorientation of mental health in the country and is multidimensional in its view of the individual as interconnected, to the external environment and a Spirit Within.

This broadened view is the biopsychosocial-spiritual framework.

1. The **biological (physical) dimension** focuses on the brain which serves as the system that integrates an individual's bodily functions and his/her ability to interact with the environment to maintain life. This basically addresses the perspective of the **brain and the self.** Somehow, this captures what is commonly referred to as the "body-mind unity".

2. **The psychological dimension addresses the individual's personality,** which is the combination of his instinctual urges, limits of control, thought processes, emotional expressions, actions and behaviors. The development of personality patterns in the individual proceeds along with his normal physical growth and development through his life course (from infancy to senescence) and is influenced

by environmental events. The **Self** is recognized as the integration of the individual's personality pattern and his environment.

In understanding the **Self,** three important components must be understood: (a) self-identity; (b) self- esteem; (c) self-worth. These are what differentiate individuals from each other.

3. The **social dimension** articulates the fact that the external environment of the individual, the societal system (society) is to be understood as distinct from him. Although interconnected with the individual, it has characteristics that are distinct from the individual. Society is not just the sum total of individual characteristics. In this dimension, there are five important considerations:

   a. **Social relationships** as the core in the individual's connectedness to each other and their environment.

   b. **Social institutions**—the structure/organization of society for it to provide the necessary social support for the individuals within it. Each of these institutions exists as "functional prerequisites in society" necessary to meet the needs of the people for stability and meaning in their lives. These institutions are political, educational, economic health, social welfare, and family and religious institutions.

   The truism that there is no health without mental health should further be understood as health (mental health) that is closely linked to social integration—the integration of all the social institutions in the community which provides the necessary social support for the individual. "No man is an island".

   c. **Social determinants** of mental health have recently gained attention in understanding the social dimension of mental health.

There have recently been identified five important determinants: demographic (age, sex, ethnicity), economic, neighborhood, environmental change, socio-cultural factors.

Since this has been a recent development, there is a need for research studies in the Philippines to address these very important issues.

d. **Social attitudes**—stigma, discrimination, prejudice, etc. still prevail.

e. **Social Suffering** is presently understood as the **collective phenomenon** among those with concerns for mental health. This concept puts into focus that the suffering felt is not confined to the individual alone; it is shared by those in his immediate social unit, family, and his greater community.

The pandemic that the world, including us in the Philippines, has undeniably caused this collective phenomenon: Social Suffering.

4. **Spiritual dimension i**s a recent development in the conceptualization of mental health in the Philippines. While there has been articulated a biopsychosocial conceptual framework, the recent impact of extreme life events notably the present pandemic, has generated in the Philippines the belief that the spiritual dimension in an individual's life as he/she goes through these experiences cannot be ignored.

Spirituality is distinct from religion. This dimension addresses the recognition of a feeling, an experience, a belief of something greater than the self, something more to being human but to which is experienced a connection that becomes a source of inner strength, guidance and meaning in life. It is recognized as a universal human experience. This experience is identified as the recognition of a Spirit Within, which an individual is aware of as an integral part of his Being/ Life and which provides inner guidance and strength,

in his search for meaning and peace, especially crisis. Spirituality is acknowledged as among the top coping mechanisms of the Filipino.

The diagram below shows the biopsychosocial spiritual framework for mental health in the Philippines.
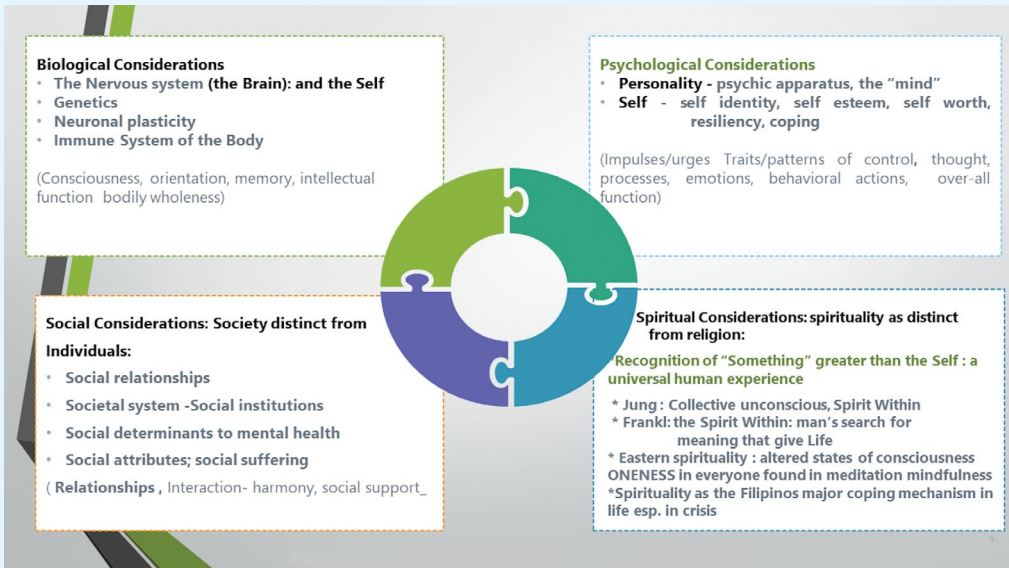
Figure 1. The Biopsychosocial-Spiritual Framework

Conclusions

The biopsychosocial-spiritual framework that has been adopted by the PCMH in its Resolution 2020-003 (February 2021):

- Is a reminder that mental health is an integral component of the WHO definition of health, which is the state of the physical, mental and social well-being of man. Hence, the truism that "there is no health without mental health".

- Is an articulation of the reorientation of the concept of mental health in the Philippines. This is an expanded concept from the prevailing limited focus on the individual alone and the perspective biomedical clinical to a broadened perspective that addresses the interconnectedness of the

individual and his environment. This environment is understood as the external environment of the society that provides him social support and stability where he lives in but also an internal environment in him experienced as the Spirit Within, that can be a source of inner guidance, strength, meaning, and peace.

- The adoption of this broadened framework has been the product of a convergence of various studies in the neuroscience, genetics, psychological, behavioral and the social sciences as well as those pursuing studies on the relevance of spirituality in the life of a human being.

- The Philippine Mental Health Law has provided for the creation of a Philippine Council for Mental Health to fully implement its provisions, acknowledging the need for this broadened framework for mental health for its effective implementation.

The Council is composed of members from government and civil society organizations, representing a multisectoral group and ensuring the participation of a wider sectoral group in the provision of mental health programs. This signifies the fact that mental health is expected to be everybody's business, and not just the responsibility, as has prevailed, in one sector only (health) and within it, a specialty group (psychiatrists).

While the framework presents each of the four dimensions in an individual, it is expected that its application to mental health programs must be integrated and holistic.

There is a **need to adopt this reorientation** in the concept of mental health to fully implement the Philippine Mental Health Law. In doing so, we do not need to seek new landscapes but simply to have new eyes.

Download/scan here:

Note: Please refer to the presentation entitled "**The Conceptual Framework for Mental Health in the Philippines**" by Dr. Lourdes L. Ignacio that was used during the writeshop.

https://tinyurl.com/MHManual

>> C. The National Mental Health Research Agenda 2019-2022

By Lourdes Ladrido-Ignacio, MD

The Philippines seeks to achieve Health for All. Cognizant of the fact that there is no health without mental health, it passed the Philippine Mental Health Act in July 2018.

The completion of the implementing rules and regulations of the Mental Health Act, especially the articulation of its implementing body, the Philippine Council for Mental Health, of its national strategic plan for mental health influenced the development of the National Mental Health Research Agenda (NMHRA).

This development has further found support in global developments in mental health, notably the publication in October 2018 of the Lancet Commission on Global Mental Health in support of the United Nations' Sustainable Development Goals (SDGs) for its member countries. These concurrent events signal the need to reframe the current mental health situation in the country. There is an agreement that the vital need to undertake the necessary studies on Mental Health cannot be ignored any longer.

The NMHRA evolved through a participatory and multisectoral bottom-up approach. This involved a series of stakeholder consultations in the four project sites (Metro Manila, Iloilo, Baguio, and Davao) and focus group discussions among experts in these areas. Concurrent to these, online and grey literature in the project sites were reviewed. In the review of the literature, the WHO's Two-dimensional Approach Matrix (2D CAM) was used. This yielded the knowledge gaps in the field of mental health, especially in the conduct of research.

This agenda setting process resulted in a national mental health research agenda that is expected to be the priorities for research in the Philippines in the next five years (2019–2022) and possibly, even beyond. Out of the issues raised during this process, three themes emerged. These were framed into outcome statements to be consistent with the results-oriented framework used by the national budgeting system of the Philippines.

Outcomes	Key Indicators
Outcome 1: Improved Mental Health Information System	Prevalence and burden of disease assessed
	Risk factors and determinants known and understood
	Evaluation studies on interventions
Outcome 2: Strengthened Leadership and Governance	Community based mental health services established nationwide
	MH integrated in primary health care; institutional capacities and competencies developed
	Investments in MH improved
	Digital technologies enhanced and harnessed
Outcome 3: Accessible, Affordable, Responsive and Holistic Mental Health Services	Provision of accessible patient-centered, recovery oriented holistic treatment and care
	Balanced care for mental disorders

Cross-cutting Issues in the Mental Health Research Agenda

Cross-cutting issues in the agenda set forth for each of the outcomes were identified. The diagram below illustrates these issues in the mental health research agenda. These are:

1. Emphasis on promotion of mental health and well-being
2. Cultural relevance and appropriateness
3. Task sharing
4. Life course perspective
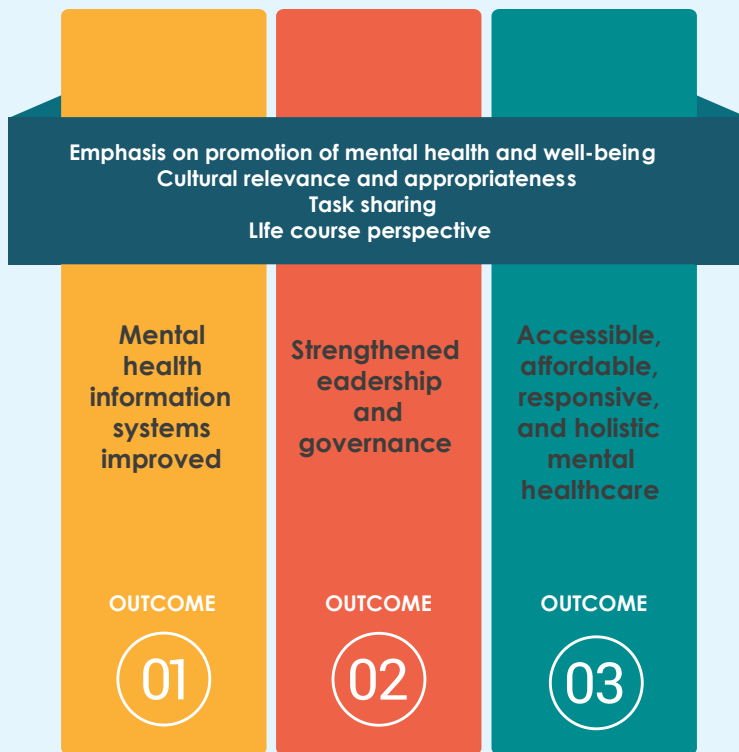
Figure 2. Cross-Cutting Issues in the Mental Health Research Agenda

Note that a major component of this Manual's section on the National Mental Health Research Agenda are two documents that should be revisited for the specifics on these outcome statements, their key indicators and especially the identified research priorities as articulated in the stakeholder consultations, focus group discussions with experts, and the review of 732 scholarly and media articles on mental health.

These documents are the following:

- Booklet on the NMHRA 2019-2022
- Lourdes L. Ignacio's power point slides on the NMHRA presented during the PCHRD writeshop on Nov 24, 2020

Download/scan here:

https://tinyurl.com/MHManual

Note: Please refer to the Powerpoint presentation entitled "**National Mental Health Research Agenda 2019-2022**" by Dr. Lourdes L. Ignacio that was used during the writeshop.

References ("Definitions, Concepts, and Framework" Subsection)

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Chapter 2

Describing a Mental Health Research Problem

By Ma. Carmen C. Tolabing, BSPH, MPH, DrPH [‡]

Research is a scientific inquiry to generate new knowledge and contribute to the evolving body of knowledge. There are many areas of research, one of which is health research. Health research is an applied form of research that is carried out to address a health problem or contribute to its solution. Davies defines health research as follows:

> The process for obtaining systematic knowledge and technology which can be used for the improvement of the health of individuals and groups. It provides the basic information on the state of health and disease of the population; it aims to develop tools to prevent and cure illness and mitigate its effects and it attempts to devise better approaches to health care for the individual and the community. (Davies, 1991)

The research process involves four phases: identification of the research problem; planning the research; research implementation; and dissemination and utilization of research results.

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>> A. Identifying and Formulating the Research Problem for Quantitative Research

As health research aims to address a health problem, it is common for a research problem to be derived from the statement of a health problem. Formulation of the research problem includes narrowing down a health problem in researchable terms. This involves a process that will lead from the statement of a health problem, to the formulation of a research problem.

The research problem may be a health concern, an issue that needs to be resolved, or a question put forth in scientific literature that needs to be answered through scientific inquiry. The research problem defines the research project; thus the wording is critical. The process on how to write a clearly worded research problem and research objectives is described below.

Stating the Research Problem

A characteristic of research is that it demands a clear statement of the research problem (Sanchez et al., 1989). A good research question is very important because it is the basis for the formulation of the research objectives, data collection methods, and research design.

One of the challenges in research is formulating the research problem in a form that will allow a solution. Thus, the goal in developing a research problem is to state it in researchable, clear, and specific terms. In quantitative research, the research problem statement should be stated in one of three ways: a quantity to estimate, a characteristic to describe, or an association to be established (Sanchez et al, 1989).

The process of developing a research problem involves three steps.

The **first step** is to state the problem in a researchable format which lends itself to investigation. It involves specifying the characteristic (study variable) that will be measured and the unit from which or on whom measurements will be made. The research problem statement should not be confused with the health problem as they are not the same although they are closely related since the research problem in health research is derived from a health problem.

Health Problem Vs Research Problem Statement

A **health problem** is a statement about a problem situation or deficiency in something. The statement that **"There are reports that people with mental health needs are unable to avail of professional mental health services in Region X"** is a health problem statement and not a research problem. It does not specify what needs to be investigated and on whom data will be obtained. It only states a deficiency.

Compare the above problem with this statement; "What are the factors that contribute to non-availment of professional mental health service among people who need it in Region X?" The latter statement is an example of a **research problem statement** since it has specified both elements required for a researchable statement: study variable (factors affecting professional mental health service); and study unit (individual needing professional mental health).

Another research problem that can be derived from the health problem above is "What is the frequency of availment of professional mental health service among individuals who need such service" The **study variable** is availment of professional mental health service and the **study unit** is the individual needing professional mental health service.

The **second step** is analysis of the research problem. The purpose of the analysis is two-fold: first, to determine feasibility and significance of the research problem; and second, to dissect and clarify the problem. Dissecting the problem means breaking it up into different related components. This is particularly important if the research problem is broad as it helps define and clarify the scope of the research.

The **third and final step** is to state the research question and the sub-questions completely and in clear and specific terms. For a research problem that is broad and complex, sub-questions have to be formulated and these are derived from the identified components of the problem. The elements of a research problem statement are: **specific variables,** a **study unit** (study population), **setting**, and **time** if applicable.

For intervention studies, the PICOT format (i.e., P-patient/ population, I-intervention, C-comparator, O-outcome, and T-time) is useful in stating the research questions (Haynes, 2006).

If the research problem involves association, such as risk factor identification or assessment of effects of interventions, a research hypothesis is formulated at this step of the process. A **research hypothesis** is a statement of the expected relationship between two variables. Like the research question, the research hypothesis should be stated in clear and specific terms. Ideally, the hypothesis should have five elements to make it testable: c**ause, dose response, time response, outcome,** and the **population** to whom the hypothesis will apply.

> The process of stating a problem in a researchable format involves narrowing down the health problem in researchable terms. A researchable problem statement is one that indicates the need for a scientific inquiry for its solution. The statement of the health problem needs to be transformed into a problem statement that focuses on quantifying or describing a particular characteristic or analyzing a characteristic in relation to another characteristic.

Describing the Research Problem (Statement of the Research Problem)

The next step after formulating the research question is to describe it. The description, also known as the **Statement of the Research Problem** is a concise explanation of what is to be researched about and its context. It is usually written in one to two paragraphs.

For the purpose of this Manual, the best practice is to discuss the following four points when describing the research problem (Sacred Heart University Library, 2008):

- First, describe the desired situation or what is known about the subject of the research.

- Second, explain the current situation and how it falls short of the desired or what should be known. The discrepancy between the desired and the current or between what is known and what is unknown represents the gap in knowledge.

- Third, explain how the research results will contribute to moving the current situation to the desired or how it will bridge the knowledge gap.

- Fourth, conclude the statement by stating the research question (or hypothesis if applicable) .

The statement of the research problem forms part of the introduction section of the research proposal and is usually placed at the end of the section. Alternatively, the statement can be placed as a stand-alone section depending on the proposal format.

>> B. Formulating the Research Objective

The research objective is set after a good research question has been formulated. A research objective is a statement that defines the desired goal of the research. In setting the research objective, the researcher needs to refer to the main research question and sub-questions. This is because the objective refers to the way by which the research question can be answered. The research question is transformed from an interrogative form to a declarative sentence starting with action phrases. Examples of action phrases are: "to determine", "to describe", "to examine", and "to compare".

The research objective should be stated properly. A well-stated objective possesses the following qualities: specific, measurable, attainable, realistic and time-bound (Sanchez et al, 1989).

SMART Objectives

Qualities	Definition
Specific	The following are indicated: 1) Study variable 2) Study unit 3) Setting and time, if applicable
Measurable	Study variable is measurable; that is, it can be collected by observation, query, or review of records In quantitative research, the variable is expressed in some statistical and epidemiologic measures such as frequency, proportion, prevalence, incidence, average/mean, risk, association, etc.
Attainable	Collected data will provide answer to the research question
Realistic	Practical method for measuring the variable is available, accessible, and affordable
Time-bound, if applicable	Relevant time is indicated, such as follow-up time in incidence studies or time elapsed between exposure to a factor and development of outcome in association studies

Objectives can be divided into two categories. The **general objective** gives the overall goal of the research while the specific objectives are statements about the specific outcomes expected.

The **specific objectives** should all contribute to the attainment of the general objective. The general objective is generally derived from the statement of the main research question while the specific objectives are based on the components of the research question or sub-questions.

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Note: Please refer to the presentation entitled "**Formulating and Describing the Research Problem**" by Dr. Ma. Carmen C. Tolabing that was used during the writeshop.

Activity A. Research Problem Identification and Clarification

Worksheet A-1

1. State the **health problem** that you would like to address through your proposed health research project.

2. Narrow down the health problem in # 1 into specific terms and transform it into a research problem.

    2.1 State the specific health problem that will be addressed by your research project.

    2.2 Transform the health problem into a research problem statement.

3. State the **research problem** that you will address in your research project.

Worksheet A-2

4. Analyze the research problem:

    4.1 Feasibility, significance, ethical consideration

        4.1.1 Is it feasible to conduct the research? Please explain.

        4.1.2 Is the research significant? Please explain.

            a. How can results contribute to the evolving body of knowledge about mental health?

            b. How can the results contribute to the solution of the identified health problem?

            c. How can results impact on: practice of mental health profession (clinical or public health): promotive, preventive, curative, rehabilitative care?

d. How can results of the study contribute to the overall performance of mental health interventions?

e. How can results affect a policy-making activity?

4.1.3 Is it ethical to conduct the proposed research?

4.2 Dissect the problem into related component (Related components will serve as sub-problems)

5. State the problem and sub-problems in clear and specific terms (in question format)

Type of Research	Related Components
Descriptive type of research	Patient (population)
	Study variable
	Setting (time if applicable)
Analytic research/association studies (Non-intervention and intervention)	Patient (population)
	Study variables (intervention and comparator)
	Outcome (effect outcome and safety outcome)

Worksheet A-3

6. Describe the research problem (1-2 paragraphs)

6.1 State what the desired situation/what is known about the research problem is.

6.2 State what the current situation/unknown about the research problem is.

6.3 State how the research results will move the current situation to the desired situation.

6.4 State the main research question.

Worksheet A-4

7. Formulate the research objectives (SMART format).

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Chapter 3

Synthesizing and Writing the Literature Review

By Carl Abelardo T. Antonio, MD, MPH, IPFPH, FRSPH, AFCHSM, MIHM§

This chapter discusses general pointers in preparing literature reviews specifically intended for grant proposals, although some of the ideas may find applicability for other research proposals (i.e., academic research). An underlying assumption here is that researchers already have an existing (draft) literature review document on hand. Hence, the main outcome of this chapter is that researchers should be able to critique and propose ways to improve the literature review for their current mental health proposal.

A **literature review** is a synthesis, critique, and interpretation of studies done on a particular topic. Despite the simplicity of this definition taught in research methods courses across different levels of education, however, there is very little focus on how to operationalize this idea of literature reviews. Hence, in most cases, literature reviews tend to become an extended bibliography of studies assembled from a cursory search of conveniently accessible documents. This situation poses a challenge, however, as the literature review, which forms part of the conceptualization stage of the research process, is an integral step that permeates and influences most, if not all, of the components of research

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(i.e., topic selection and research question formulation, study design and methods). It should also be noted that literature reviews prepared for grant proposals are usually more focused (i.e., directed to the primary research question and will typically include recent evidence) and shorter in length (i.e., typically 0.5 to 3 pages) when compared with those prepared for academic research.

Given this evolving understanding and appreciation of literature reviews, there has emerged a whole branch of science that develops and refines approaches to literature reviews. This includes systematic reviews and meta-analysis, overview of reviews, and a whole range of qualitative evidence synthesis approaches (e.g., ecological triangulation, meta-narrative). In general, however, all of these different approaches share a common set of procedures. The first phase consists of defining eligibility criteria for literature, identifying sources of literature, developing a search strategy, and implementing the strategy to identify relevant studies. This will be followed by an iterative phase of reading included studies, extracting relevant information (usually thematically organized), and analyzing included literature. All the information from different studies is then synthesized and written in narrative form.

A few work examples by the author are summarized in the matrix on page 29.

When searching the literature, researchers should first consult evidence synthesis papers on the topic before perusing individual empirical papers as these works already highlight the state of science and the knowledge gap on a particular topic. If empirical papers will need to be perused, the search should include relevant databases for mental health (e.g., PsycINFO) in addition to multidisciplinary databases (e.g., MEDLINE, CINAHL Complete, Cochrane Library). Regional (e.g., ASEAN Citation Index, WPRIM) and local databases (e.g., HERDIN Plus) databases; online local/institutional journals that may not be indexed in any database; and Google Scholar should also be consulted to increase yield for relevant research done in the Philippine setting.

Type of Review	Reference
Narrative review	Rivera AB, Antonio CT. "Mental health stigma among Filipinos: Time for a paradigm shift". *Phil J Health Res Dev.* 2017;21(2):20–24.
Scoping review	Antonio CT, Li CMJ. "Definition and conceptualization of collaboration in drug rehabilitation: Systematic synthesis and comparison using a scoping review approach". *Acta Med Philipp.* Under review.
Systematic review and meta-analysis	Antonio CT, Cochon KL, Rocha-Tulagan II, Amit AL, Torres CH. "Levetiracetam versus other anti-epileptic drugs for treating partial onset seizures with or without secondary generalization in patients 16 years of age and older with newly diagnosed epilepsy: A systematic review and meta-analysis". Final Technical Report. Quezon City: Pharmaceutical Division, Department of Health; 2018. 81 p.
Mapping review	Antonio CT, Torres CH, Liao SS, Torres AH, Saguros SA. "Illicit drug research in the Philippines: A systematic mapping review". Manuscript in preparation.
Policy document review	Antonio CT, Li CMJ, Siu JYM, Guevarra JP, Leabres JM, Vista SD, Estacio LR. "Treatment and rehabilitation for illicit drug users in the Philippines: A review of policy and service arrangement". *J Public Health Dev.* Under review.

In terms of synthesizing the literature, researchers may use the following thematic areas as a guide:

- Concepts (i.e., key ideas under study and the corresponding definition);
- Theories (i.e., theoretical frameworks or paradigms used by other researchers in studying a particular topic;
- Variables (i.e., categories of concepts, objects, or factors being measured, including how these are operationalized);
- Methodologies and methods (e.g., study design, instruments for data collection); and
- Empirical evidence (i.e., what other researchers reported on a particular topic).

Researchers should keep in mind that the principal aim of the literature review section of a grant proposal is to demonstrate that a project warrants funding that could have been otherwise allocated elsewhere. The burden is on the researcher to demonstrate that a knowledge gap in the current body of empirical evidence exists, and that the study design and methods being proposed are based on the state-of-the-art and state-of-the-science approaches. All of these will be supported by an adequate literature review.

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Note: Please refer to the presentation entitled **"Synthesizing and Writing the Literature Review"** by Dr. Carl Abelardo T. Antonio that was used during the writeshop.

Activity B. Synthesizing and Writing the Literature Review

Worksheet B-1

1. Assess the literature review of your current mental health proposal guided by the questions listed below, and develop a plan to improve the literature review.

2. Present an updated literature review (work in progress acceptable, if already available).

Guide Question	Elements to Look For
Does the literature review (LR) provide materials that demonstrate that the proposed research contributes something new to our understanding of the topic or the world?	• Organized and comprehensive search for literature, including local literature, considered in the review • Clear statement on the existing state of evidence and the knowledge gap • Critical appraisal/critique of prior research (i.e., strengths and weaknesses/limitations)
Does the LR provide materials that justify the approach to the topic, and the selection of methods?	• Review of theories, methodologies, methods, and tools used in prior research.
Does the LR present a synthesis of the relevant literature?	• Results of individual studies are combined and not treated separately (may be accompanied by table showing detail for individual studies).
Is the LR clearly and concisely written?	• Focused on addressing the primary or secondary RQ

Chapter 4

Developing the Conceptual Framework

By Louella Patricia D. Carpio, MD[¶]

The framework is a blueprint of a study. This provides the logical structure that guides the development and conduct of the study. It should emanate from a thorough literature review and should adequately support the research problem or the study hypothesis.

Conceptual frameworks relate the concepts or variables used in organizing the knowledge espoused by the researcher. This also presents an integrated way of looking at the research problem and implies the proposed relationships of the main variables of a study.

The **conceptual framework** should be differentiated from a **theoretical framework.** Though both are based on abstract concepts or constructs, the conceptual framework is a structure developed by the researcher to explain the phenomenon being studied. On the other hand, a theoretical framework is based on a set of existing theories which have been tested and validated by other scholars. In addition, a theoretical framework is in the form of a model that pivots the results of studies or theories. Though there is a progressive relationship between the two, it should be noted that not all conceptual frameworks progress to theories.

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To illustrate the utility of conceptual frameworks:

A case scenario was depicted to construct a conceptual framework and define study variables within the framework. The study scenario attempts to determine if there is a relationship between using social networking sites and psychological functioning.

Research variables are defined as any person, place, or time characteristic that is being measured or described. It should be noted that a variable should have more than one value. For the case scenario, the described study variables included *age, sex, socioeconomic status, parental education, use of social networking sites (SNS)* and *psychological functioning.* Age, for example, can be defined as the respondents' reported age in years while sex is the reported biologic sex. Both quantities have more than one value as *sex* can vary as either male or female while *age* can be a number from 0 to infinity.

In quantitative analytic studies, the independent variable/s, dependent variable/s, and confounding variable/s should be identified.

- The **independent variable** is hypothesized to be a factor contributing to the development of the outcome;
- The **dependent variable** is the outcome.
- **Confounding variables** are extraneous variables that are associated with both the independent and dependent variables. These may confound the relationship between the dependent and independent variables so these must be identified.

In the case scenario, *Use of SNS* was identified as the independent variable and measured as the number of hours spent on social media websites. In contrast, *psychological functioning* was identified as the dependent variable. The identified confounding variables include *age, sex, socioeconomic status,* and *parental education.*

It is imperative to identify the relationships of the concepts or variables in constructing the conceptual framework. The schema of a conceptual framework in an analytic study is illustrated in **Figure 3.** The main relationship being investigated is the relationship of the independent variable with the outcome variable, and an arrow from the hypothesized factor to the outcome depicts the causal hypothesis being investigated. On the other hand, confounders point to both the independent and

dependent variables because these affect both variables. The arrows show the direction of the study while all key concepts and variables should be placed in the framework. It should be noted that there should be no double-headed arrows and that the flow of the framework cannot be circular. All the arrows that depict relationships should also be adequately supported by the literature review. On the other hand, if the study is descriptive in objective, then all the variables that describe the phenomenon of interest should be included and point towards the outcome to be described.
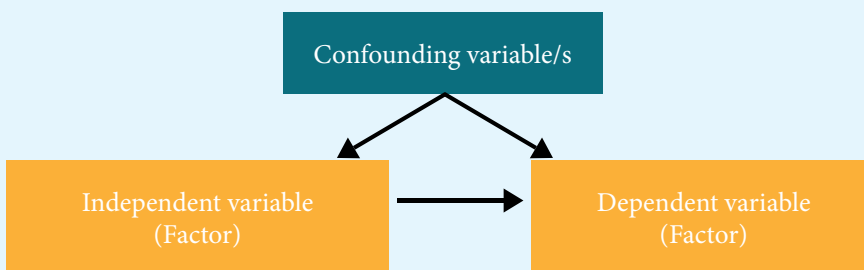
Figure 3. Basic Schema of a Conceptual Framework

Reconsidering the case scenario on whether SNS use affects psychological functioning, the conceptual framework was simplified in Figure 4. This relates that the variable use of SNS is hypothesized to affect *psychological functioning* and that *age, sex, socioeconomic status* and *parental education* affects this relationship.
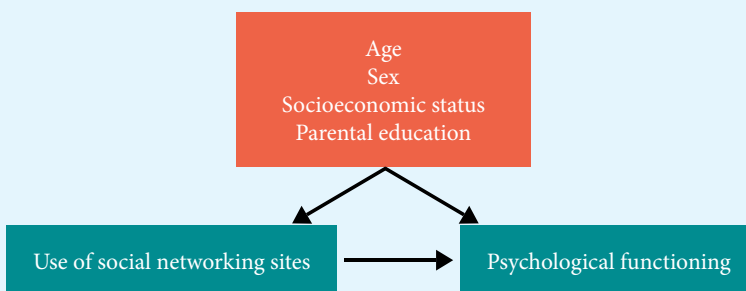
Figure 4. Conceptual Framework of the Case Scenario

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Note: Please refer to the presentation entitled **"Developing the Conceptual Framework"** by Dr. Louella Patricia D. Carpio that was used during the writeshop.

Activity C. Developing the Conceptual Framework

Worksheet C-1

1. Specify your study objectives.

2. List your study variables.

3. Identify the outcome of interest and the variables to be described if descriptive.

4. Identify the primary exposure variable/s, outcome variable/s of interest and confounders, if analytic.

5. Illustrate the relationships of the variables through blocks and arrows.

Chapter 5

Designing the Research

>> A. Quantitative Research Designs

By Kim Carmela D. Co, RN, MSc[**]

The research methodology describes the "HOW" of the study—specifically how the study objectives will be answered. The **study design** sets up the framework for the collection and analysis of data to attain the study objectives. The priority in selecting the study design should be appropriateness to attain objectives with the least limitations. There may be different designs that can be appropriate to answer the study objectives, and in that case, the choice of design can be based on feasibility. **Feasibility** includes considerations of ethical practices, time, manpower, resources and availability and accessibility of the study population or the data to answer the research objectives.

When describing the specific research design in the protocol, the investigator should also describe why it was selected, which includes the advantages and limitations of the design and the feasibility considerations. Including a schematic diagram with dates of data collection can help clarify the study design.

Based on the objective being answered, research designs can be largely classified into two: descriptive and analytic studies.

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Descriptive studies aim to describe the target population, either through quantitative methods, qualitative methods, or mixed methods. For example, when describing a specific population, like persons with mental health disorders, descriptive studies can involve explaining the clinical outcomes or their lived experiences, or determining the prevalence of a specific characteristic in that population. Descriptive studies can also involve describing the policies being implemented or synthesizing the available literature to answer the research problem.

Meanwhile, **analytic studies** aim to determine associations or a cause-and-effect relationship. Different designs can provide different levels of evidence, and generally designs that can provide higher levels of evidence would entail more time and resources to conduct. It should be emphasized that the level of evidence is not just dependent on the design, but also on how the actual study was designed and implemented. **Systematic reviews** that are done well can provide a high level of evidence, but requires that a lot of studies have been done already before it can be conducted. **Randomized controlled trials** are considered the gold standard for providing evidence for treatment effects, but take a lot of resources to implement. Descriptive studies can also be used to provide evidence for cause-effect relationships but the evidence will be weak, if they are used alone. Thus, descriptive methods can be incorporated in analytic studies to provide context for the cause-effect being studied.

For Example:

If the objective is to determine the effectiveness of an intervention for relief of anxiety, the study should utilize an analytic design. In experimental studies, investigators give the intervention to study participants, while in observational analytic studies, the investigators simply observe which of the participants received the intervention.

There are different variations of **experimental designs,** depending on the number of groups and types of intervention, and whether the intervention groups will be randomly assigned. For **observational studies**, the specific design depends on the variables being studied: (1) whether the exposure or outcome variable is rare in the target population; (2) how long it takes for the outcome to occur from the time

of exposure; and (3) whether the data on the exposure and outcome variables will be measured at the same time or at different times.

The protocol should also include the target population, participant selection, and recruitment.

- The **target population** specifies the population that the investigators want to make conclusions about, which can be defined using person, place, and time characteristics.

For Example:

The target population can be defined as "Persons diagnosed with Major Depressive Disorder in Hospital X". It may be important to specify Hospital X because the patients diagnosed in Hospital X might be different from Hospital Y in terms of socio-economic status, severity of condition, and other characteristics. The target population informs the scope and eligibility criteria of the study, and the investigator can control how wide or narrow it is, depending on how generalizable the results should be.

- Meanwhile, the **study population** is the population from which the participants will be recruited from, defined using eligibility criteria (inclusion and exclusion criteria). As much as possible, the study population should be the same as the target population. If some members of the target population are excluded or inaccessible and cannot be included in the study population, it may introduce bias to the study findings.

For Example:

In a study to determine the prevalence of mental health conditions among adolescents in the Philippines, the target population should be all adolescents in the Philippines. However, if a school-based study was used to implement it, then adolescents who are not in school would automatically be excluded from the study population, which may have an impact on the prevalence estimates (for example, if those with mental health conditions are more likely to drop out from school).

- The protocol should also describe **how study participants will be selected** from the study population. This can mean including everyone who passes the eligibility criteria (total enumeration), or only including a subset (sampling). If sampling will be done, the protocol should detail how many will be included, and how the study participants will be selected. The sample size can be pre-determined for quantitative studies, but for qualitative studies, participant recruitment can be continued until the point of data saturation.

- Lastly, the protocol should include details on the **recruitment process** if primary data collection will be done, including the source of study population members, how the invitation will be sent, and how the recruitment and informed consent process will be conducted. For studies that will utilize secondary data, there should be details on where the data will come from and how it was collected.

The contents of the research design in the protocol may be different for specific designs.

For example, for systematic reviews or policy reviews, the methods of the proposal should include how references were searched for and selected and how the information will be retrieved and synthesized.

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Note: Please refer to the presentation entitled **"Designing the Research - Quantitative Studies"** by Prof. Kim Carmela D. Co that was used during the writeshop.
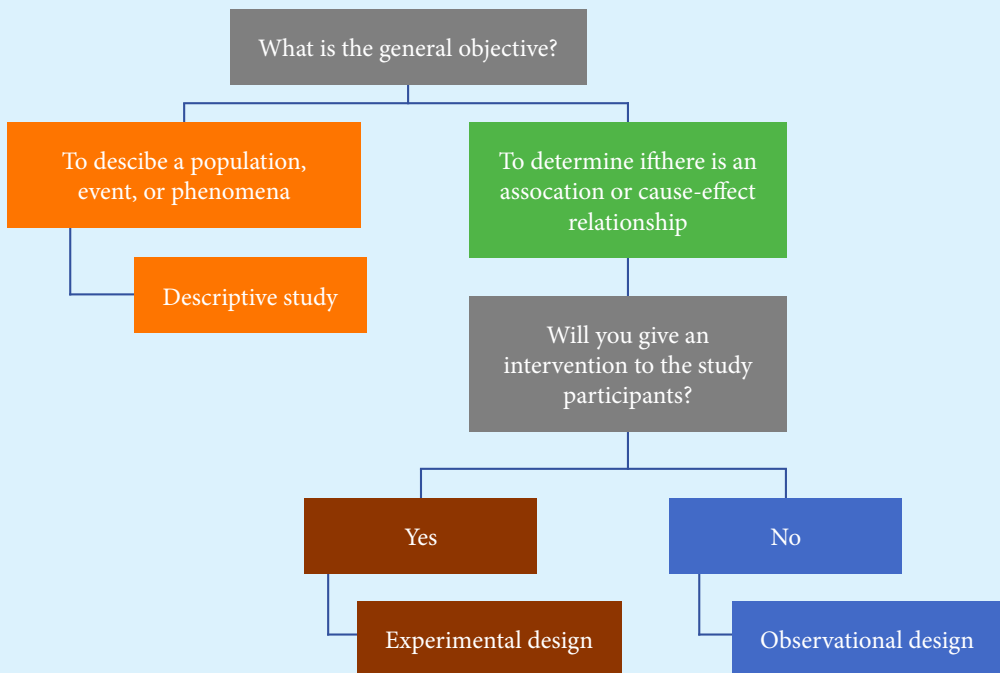
Activity D. Designing the Research for Quantitative Studies

Worksheet D-1

1. Describe the study design to be used.

   1.1. Specify the research design.

Select an appropriate type of research design (refer to Figure 5):

Figure 5. Flowchart for Selecting the Type of Research Design

Is the general objective **descriptive** or **analytic**?

If the objective requires an analytic study design, will the study involve giving an intervention to the study participants?

If YES	If NO
Experimental design	**Observational design**
How many groups and types of intervention will be given?	Is the exposure or outcome variable rare in the target population?
If with more than one intervention, how will the groups be assigned (i.e. randomized or not)?	How long does it take for the outcome to occur from time of exposure? Will you be collecting data about the exposure and outcome variables at the same time or at different times?

    1.2. Explain the rationale for the choice of research design.

    1.3. Describe the advantages and disadvantages of this design.

2. **Define the target population** (Which population do you want to make conclusions about?)

3. **Define the study population** (Which population will you select participants from?)

    3.1. Specify the eligibility criteria for participants (inclusion/exclusion criteria). Include person, place, and time characteristics as appropriate.

    3.2. Provide rationale for the eligibility criteria.

4. How will you select participants to include in the study?

    4.1. Identify a potential sampling frame of participants.

    4.2. Include a step-by-step process of how participants will be selected.

5. Is there a pre-specified number of participants that will be included in the study?

   5.1. If yes, how many? Provide rationale, sample size computation and references, as appropriate.

   5.2. If no, describe until when participant recruitment will be done.

*Note: If your design is a systematic review, for items 3-5, change "participants" to "studies", and describe how you will select studies instead.

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>> B. Qualitative Research Designs

By Michelle G. Ong, Ph.D. [††]

Research design is about clarifying the logical connections between your research questions and the process by which you will attempt to generate answers to those questions. This involves making explicit your assumptions about research and knowledge and articulating WHY you are viewing the topic specifically from the perspective that you have taken.

Qualitative research requires thinking qualitatively—it will require a more interpretive/phenomenological or critical stance that does not assume the existence of an objective reality where universal laws *may* be discovered. It involves a non-linear process, where decisions about everything from the research questions to the data collection method, number of participants, and method of analysis may change as additional data is collected and analyzed. They will often use a non-probability sampling method as the objective seldom involves being able to generalize to a population but rather to understand experiences or meanings which may have relevance for others. Text (which can be words, images, and even objects with meaning), rather than numbers, will form the data.

In qualitative research, theory can function as a framework to help describe or explain the phenomena or may actually be the output of the study. Subjectivity is not a problem but a key feature and strength. Qualitative research is best for providing a detailed picture of social phenomena, investigating processes, meanings, constructions, and identifying what and how factors become relevant.

As mental health is an issue and experience that can be very unique and deeply personal to those directly affected by it, qualitative research has the potential to contribute significantly toward expanding, deepening, and complicating our knowledge of mental health in the Philippines. In mental health research, questions about peoples' experience, understandings and perceptions, practices/accounts of practice, influencing factors, and representation, construction, and language practice can provide important insight for clinicians, patients, families

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and communities, and policymakers. Answers to such questions can help improve policies, public awareness and acceptance, family and community support, and treatment outcomes.

> Qualitative research can generate knowledge which can complement and enhance findings from quantitative research; it can also generate new knowledge, perspectives and theories that challenge the results of quantitative research.

Qualitative Data Collection Methods

There are many different options for collecting qualitative data. Broadly they may be classified as falling under two large categories—those where interaction with participants is a main feature and those where there is little to no interaction with participants.

The two most well-known data collection methods involving interaction with participants is the q**ualitative interview and focus group discussions (FGD).** The main difference between the two is that interviews allow for more in-depth and detailed discussion of an individual's personal experiences, perspectives, meanings, whereas focus groups are best when one is interested in general understandings and perceptions, representation, construction, and language practice. One can ask people about their personal views, practices, opinions in an interview, and participants can have the opportunity to discuss these in detail. The interaction with other participants that is possible in an FGD allows the researcher to observe or collect a range of views (not necessarily personal—people can bring up what they see in popular media or what they hear from others that they do not necessarily subscribe to or practice themselves); to understand the relation of those different ideas to each other (e.g. which is more dominant or mainstream), and to see how they are justified or made sense of in a social context. Both these methods require the skill of the researcher/interviewer or facilitator to elicit good

quality data. As such, they can be intimidating to the novice qualitative researcher.

Textual data collection methods, in contrast, require less intervention and interaction with a researcher but have the same potential to produce rich qualitative data for analysis. Qualitative surveys, story completion tasks, and researcher-directed diaries require materials and instructions to be prepared by the researcher beforehand and then given to participants to accomplish. These methods require the researcher to design the materials/instructions so that they are engaging for the participants; otherwise, there is the risk participants will produce data that is not too useful for the project. In the absence of interaction with a researcher/interviewer in the accomplishment of these data collection activities, participants must be highly motivated to invest time and energy into answering the survey, completing a story, or making a diary entry.

Collecting **pre-existing textual data** (for example, from social media, from public documents, from traditional media such as news reports) avoids all these challenges by needing no participants! There is a large amount of pre-existing textual data that can yield important knowledge on mental health; the challenge is in selecting the right type for one's purpose, good sampling, and making sure proper permissions (if necessary) are obtained.

All data collection methods have their pros and cons. Some methods are more suited to certain types of questions or purposes than others. The choice of data collection method must take into account the research objectives, the theoretical and methodological framework, as well as practical concerns and constraints (such as funding, time, challenges with participant recruitment, and researcher skill or experience).

Ensuring the Quality of Qualitative Research

Good qualitative research requires a consideration of questions of appropriateness, adequacy or sufficiency, and ethics. In the previous sections, the issue of appropriateness has been discussed to some degree (where **appropriateness** pertains to the decision to use qualitative research and qualitative data collection methods by taking into consideration the research objectives, existing literature, relevant theory/theories, and practical issues). This section focuses now on adequacy or sufficiency, and research ethics.

In qualitative research, representativeness is not often the main criteria for good sampling. After all, one will sometimes use qualitative research precisely to understand those unusual or rare cases that defy the general trend— for example, individuals who recover from a mental health condition without undergoing established or known treatment protocols.

Purposive sampling's aim is to recruit the best participants for the study according to specific criteria as determined by the objectives or the theoretical framework. As in the example above, an interest in rare cases or conditions might require purposive sampling. **Snowball sampling** is typically employed in situations where the population of interest is difficult to reach and would be best accessible to other members in the group. Remember that size alone does not determine a good sample! The final size can be determined by theoretical and methodological concerns as well as practical concerns. The criteria for selection/participation must have a logical basis; they can be based on the theoretical framework, or follow criteria well-established in the literature, or based on an identified gap in the literature your research would like to address.

Research is often judged for its quality based on reliability, validity, and generalizability. Qualitative research has a similar set of criteria but with a different conceptualization or emphasis.

- **Trustworthiness** is about the researcher being able to demonstrate that the data and the analysis were generated

systematically and verified (either by participants or by other research).

- **Ecological validity** highlights the utility or applicability of the findings to real-world problems and settings.

- **Transferability** of the findings of a qualitative study is made possible by the researcher's provision of a detailed description of the specific contexts, participants, settings and circumstances of the study, so that readers or end-users may assess the applicability of these findings to their own context.

> *No matter the adherence to [research] quality criteria, no matter the adequacy and excellence of the sample employed, no research can be good research if it is not done ethically.*

A few of the techniques researchers may use for ensuring or improving the quality of their work include: member checking, triangulation, and using a research journal.

Member checking is where findings are presented back to participants for comment. This is especially useful for research that aims to represent the views of participants, particularly when they are marginalized groups. This helps avoid misrepresenting or misinterpreting them. **Triangulation** can mean the use of different sources of data, different data collection methods, different approaches or theories (i.e., a multi-disciplinary team) so as to provide a richer or broader view that can then help strengthen the researcher's analytic claims.

A **research journal**, which is a documentation of the researcher's observations, insights, dilemmas, decisions made, and analytic notes while going through the entire research process (from conceptualization to data collection to analysis) is invaluable for ensuring quality. It is an accounting of the research process and provides an opportunity for reflexivity, for writing up a detailed report of the research process, and thus, for ensuring the trustworthiness of the research.

No matter the adherence to these quality criteria, no matter the adequacy and excellence of the sample employed, no research can be good research if it is not done ethically. Researchers must ensure that the general principles for ethical research (protection from harm, respect for individual dignity, right to self determination, right to privacy, protection of confidentiality, honesty and integrity) are respected throughout the process. Qualitative research can require thinking more deeply about these principles as the methods employed and the resulting analysis can sometimes introduce ethical challenges that would not be present in quantitative research, or in methods that do not involve participants. For example, how do we protect individuals' identities and dignity when extensive, detailed, very personal stories are included in your research report?

For those who will use online modes of data collection, which is fast becoming a popular mode of data collection out of necessity, additional ethical challenges include:

- Establishing participant identity: How do we know we are really communicating with the person we are supposed to be communicating with?

- The effects of visual anonymity: There is a tendency for greater disclosure in conditions of visual anonymity (e.g. email- or chat-based communication). How do we manage disclosure so that it is at a level which is safe for both the participant and the researcher?

- Maintaining confidentiality: As everything that is online is potentially searchable, easily reproduced and shared, and no communication platform is 100% secure, how do we protect confidentiality?

- Managing online relationships: Given the ambiguity in online communication, how do we ensure that both participant and researcher remain professional and that their boundaries are respected by the other?

All in all, qualitative approaches can be productive for mental health researchers; they come with their unique strengths and their own set of challenges. A good research proposal using a qualitative design must ensure that questions of appropriateness, adequacy, and ethics are considered, and that the decisions to use certain methods of data collection, sampling, and analysis are well-justified and can be seen to satisfy the objectives of the project.

Download/scan here:

https://tinyurl.com/MHManual

Note: Please refer to the presentation entitled **"Using a Qualitative Research Design for Health Research"** by Dr. Michelle G. Ong.

Activity E. Designing the Research for Qualitative Studies

Worksheet E-1

1. Looking at the types of questions qualitative research can be good for, think of questions based on any one of the four outcomes of the Mental Health Research Agenda. Explore the potential of research questions regarding experience, understandings and perceptions, practices/accounts of practice, influencing factors, and on representation, construction, and language practice for contributing to the mental health research agenda.

2. What is your research topic?

3. Is it possible to use a qualitative design for this topic? Revisit the questions most suited to qualitative research and see if such questions can be asked in relation to your topic.

4. What methods for data gathering do you plan to use? What sampling strategy? Why?

5. Do you have any specific practical and ethical concerns?

References

Clarke, V., & Braun, V. (2013). Successful qualitative research: A practical guide for beginners. London: Sage Publications.

Forrester, M.A. (Ed.) (2010). Doing qualitative research in psychology: A practical guide. London: Sage Publications.

Neuman, W. (2014). Social research methods: Qualitative and quantitative approaches. Boston: Pearson.

Chapter 6

Plans for Data Collection

By Ma. Carmen C. Tolabing, BSPH, MPH, DrPH

Accurate data collection is essential in maintaining the integrity of research results. There are three main methods of data collection:

- Query
- Observation
- Review of records

Each method has its strengths and limitations which can affect the quality of collected data. Errors in data collection is one of the sources of inaccuracies in results of health research. These errors can be due to several factors—namely, the data collection instrument, the data collector, and the study participant. Errors in the data collection process may be made intentionally or inherent in the method of data collection. Thus, data collection should be carefully planned and the anticipated inaccuracies recognized so that measures to minimize them are in place, including quality assurance and quality control.

Data Collection Instruments

One of the main activities in planning the data collection process is the development of data collection instruments such as a questionnaire, field note and checklist, and abstraction form. The type of instrument depends on the method of data collection.

The key steps involved in developing a data collection instrument for quantitative research include:

- Identification of variables
- Operational definition of study variables
- Development of the data collection instrument
- Pretesting of instrument
- Instrument validation

There are guidelines in the development of data collection instruments and these are specific to the type of instrument.

A protocol for administering the instrument should likewise be developed and training of data collectors conducted. An existing instrument may be used instead of creating a new one provided written permission for its use is sought from its developer. There are legal and ethical considerations in using an existing instrument. In addition, if the instrument was developed and validated in another country or setting, it should be localized and the local version validated.

Writing the Plan

The data collection plan should be described in detail in the methods section of the research proposal, which includes the operational definition of study variables, source of data and method of data collection, description of the data collection instrument, data management plan, as well as quality assurance and quality control procedures. The instrument should be attached to the research proposal.

If there are multiple methods of data collection, a methods matrix will help ensure completeness and clarity of the process of measuring the different variables. The matrix outlines the method of data collection and data sources or respondents for each study variable. In addition, the potential errors of measuring the study variables should be identified and the corresponding ways to minimize them described.

The researcher should be able to demonstrate well how to address the inherent limitations of the data collection instruments and the anticipated errors in data in the collection process.

Download/scan here:

https://tinyurl.com/MHManual

Note: Please refer to the presentation entitled "**Plan for Data Collection**" by Dr. Ma. Carmen C. Tolabing that was used during the writeshop.

Activity F. Plans for Data Collection

Worksheet F-1

1. Identify the research objectives.

2. List down the study variables.

3. Define the variables operationally.

4. List the categories of the variables and their operational definition.

5. Indicate method/s of data collection to be used and the corresponding data source.

7. Summarize item # 1-5 in a tabular format (Table F-1)

    Note: For analytic studies, divide Table F-1 into three types of variables:

    a. Independent

    b. Dependent

    c. Confounding

8. Describe the data collection instrument/s briefly and attach the instrument as an appendix.

Table F-1. Measuring Research Variables

Variable	Operational definition	Categories of the study variables and their definition	Method of data collection	Source of data	Potential error in measuring the variable

Chapter 7

Plans for Data Analysis

By Ma. Carmen C. Tolabing, BSPH, MPH, DrPH

The plan for data analysis in a research proposal depends on the type of study. For quantitative research, the plan specifies the statistical measures to be used to summarize and analyze the study variables. Statistical measures used in quantitative research are divided into two: Descriptive Statistics and Inferential Statistics.

- **Descriptive Statistics** includes measures to summarize and to present research data;
- **Inferential Statistics** covers methods to come up with a generalization about a target population based on data obtained from a sample.

Summary measures are in the form of a single value that describes how common or how spread the values of a study variable are. There are numerous summary measures and their use depends on the type of variable—that is, whether qualitative or quantitative, and if quantitative, the scale of measurement.

Summary measures for **quantitative variables** include:

- Measures of central tendency (mean, median, mode)
- Measures of location (decile, percentile)
- Measures of dispersion (range, standard deviation variance, etc.)

Meanwhile, measures for **qualitative variables** are the proportion, ratio, and rate.

Statistical inference is the process of making generalizations about a population based on results obtained from a sample. There are two types of numerical values when we talk of statistical inference: parameter and statistic.

- A **parameter** is a characteristic of the study population of interest which is obtained from a study of the entire population
- A **statistic** is the term for any numerical value that is obtained from studying a subset of the population of interest or a sample.

For example:

If the characteristic of interest is prevalence of depression, the prevalence value is referred to as a *parameter* if the entire population of interest was included in the study while the prevalence value is a *statistic* if it was a result of a study on a sample of the entire population.

There are two statistical inference methods:

The first method is **estimation.** It is a process by which a statistic, computed for a random sample in a research project, is used to estimate an unknown population parameter. The result of the estimation process is reported as a **confidence interval** of a parameter, together with a percentage that specifies how confident the researcher is that the parameter lies in the interval. The confidence percentage is called the confidence level (probability that a particular value lies within this interval is called a level of confidence). The **confidence interval** consists of an interval of numbers obtained from a statistic (research result).

The second method of statistical inference is **hypothesis testing**. A hypothesis is an assumption about the population parameter. In hypothesis testing, two types of hypothesis are formulated: statistical hypothesis and alternative hypothesis. These are two complementary statements. The statistical procedure will test the correctness of the **statistical hypothesis**, such that if the statistical decision is to reject it, then the conclusion is the statement of the **alternative hypothesis**. A result is considered statistically significant if the statistical hypothesis is rejected.

The plan for data analysis can be summarized in a data analysis matrix as shown below. This matrix lists the research objectives and the corresponding statistical measures needed to achieve each listed objective. One objective may require several statistical measures and these should all be listed down.

Specific objective	Statistical measure/s to be applied
1.	---
2.	---

In addition to the description of the different statistical measures, the section on **plan for data analysis** includes dummy statistical tables. **Dummy tables** are skeleton tables containing only the row and/or column headings. The dummy tables represent the way information will be presented for each research objective. These tables will be completed as soon as the data collection is finished.

Download/scan here:

Note: Please refer to the presentation entitled "**Plan for Data Analysis**" by Dr. Derick Erl P. Sumalapao that was used during the writeshop.

https://tinyurl.com/MHManual

Activity G. Plans for Data Analysis

Worksheet G-1

1. List down all the specific objectives of the study.

2. For each specific objective:

    2.1   Construct a dummy table summarizing the collected data needed to answer the indicated objective.

    2.2   Identify the appropriate graph in presenting the results of the given objective.

    2.3   Indicate the statistical tests to employ in the analysis of data for a specific objective.

Chapter 8

Synthesis of the Mental Health Writeshop‡‡

Carl Abelardo T. Antonio, MD, MPH, IPFPH, FRSPH, AFCHSM, MIHM

This chapter summarizes the main points of discussion, mentor/ resource person observation, and participant feedback during the technical writing activity. A total of five workshops were conducted in the course of the writeshop during which participants worked with their assigned subject matter and methods expert-adviser to improve the initial proposal that they submitted. Each workshop took place immediately after the corresponding lecture and was guided by a worksheet that participants had to complete and present during the plenary session. The trainers recognize that the design of a research proposal is iterative in nature. Thus, the division of the writeshop into five separate activities was an artificial set-up to ensure that each workshop was a manageable teaching-learning activity.

The first workshop was on describing a mental health research problem, which highlighted the importance of clearly articulating the main research question being addressed by the proposed research as this has an impact on other design considerations. A common observation was that research questions as originally formulated

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‡‡ Referring to the "Capacity Building in Technical Writing for Mental Health Research Development" writeshop organized by PCHRD and its Mental Health Research Advisory Group on 24 November 2020 and 5 December 2020.

tended to be too broad, and the main task during the workshop was to focus this research question into a manageable form (for some groups, this task extended throughout all of the other workshops and affected their ability to complete their other outputs). Relatedly, the participants also had to establish at this stage the social value and feasibility of the research question they had formulated.

Some key takeaways from the writeshop:

- Researchers should allot more time in defining their research questions.

- Research question is best formulated iteratively.

- Careful thought should be given to determining the link between research question and study design considerations.

This was followed by the session on **synthesizing and writing the literature.** An observation common to most of the proposals is that the literature review sections tended to be too long and extensively discussed historical and conceptual issues. As mentioned during the lecture, grant proposal literature reviews should be focused (i.e., only cite literature relevant to the research question) and concise (i.e., at most three pages). Further, inclusion of local literature (especially from institutional or professional non-indexed journals) was often missed by proponents. Thus, it is uncertain if the study being proposed for funding was already done previously and, if so, how the new project will differ from the ones previously conducted. Participants mentioned that the questions in the worksheet provided good guidance in assessing the adequacy of their original literature review.

The succeeding three workshops were focused on design considerations for the proposed research. The first decision point was on **defining the study variables and developing the conceptual framework.** The importance of having a well-defined research question and an adequate literature review were highlighted by the activity. The research question will help in identifying the central aspects or concepts that will be investigated and measured, while the literature review will assist in defining, operationalizing, and relating the concepts and variables of interest. As such, future writeshops should allot more time for the first two activities. One other challenge encountered during this specific workshop was that proposals that intended to review policies

did not fit exactly within the parameters and questions provided in the worksheet on "defining the study variables".

Next, participants focused on **their plans for data collection and for data analysis** and on **designing the research** (design elements). The worksheets for these activities proved to be most useful for groups that were conducting research using a quantitative approach and were intended for primary data collection. The next iteration of the activity should have provisions for proposals that follow the qualitative tradition, use mixed methods or evidence synthesis approaches, or are concerned with policy review.

By way of closing this section, it is emphasized that the research question is a central element of a research proposal, regardless of whether it is being prepared for an academic purpose or for securing grant funding. Because of the intimate link of the research question with study design considerations, careful thought and sufficient time should be allocated to this task. Defining the research question is best done iteratively, in consultation with experts in the field, and after consideration of the relevant literature review.

The workshops also highlighted the broad scope of mental health research, which was most evident with the differences in research approach proposed by the different groups. Hence, similar activities should consider diversifying the methodological approaches discussed with participants, expanding the coverage of the worksheets to beyond quantitative methods, and tailoring the workshops or worksheets based on the planned study designs of the protocols being discussed.

Annex I

PCHRD Proposal Evaluation Process

As part of the DOST Councils' efforts to harmonize the processing of research proposals submitted for possible funding, PCHRD is now holding an annual Call for Proposals.

Interested proponents are required to register to the DOST Project Management Information System which may be accessed here: http://dpmis.dost.gov.ph/. Proposal submission will be done primarily through the portal, and the following supporting documents are required prior   to proceed in the evaluation process:

1. Complete proposal following the DOST Forms 1 and 2 (detailed R&D program/project proposal)*/**;

2. Line-item Budget - detailed breakdown of the required fund assistance;

3. A counterpart fund - minimum of 15% counterpart contribution except for projects involving the public good;

4. Curriculum Vitae or Personal Data Sheet (PDS) of Project Leader and other co-researchers/implementers;

5. Endorsement signed by the agency/institution head;

6. Clearance from the DOST or the Funding Agency on previously-funded projects handled by the Project Leader;

7. Approval from the institution's ethics review board for research involving human subjects or in the case of animal subjects, approval from the Bureau of Animal Industry (BAI);

8. Clearance from the DOST Biosafety Committee shall be required for research proposals involving the use of GMOs under contained use;

9. For private sector/non-government organizations and start-ups: ***

    a. Up-to-date Securities and Exchange Commission (SEC) registration or Department of Trade and Industry (DTI) registration, or Cooperative Development Authority (CDA) registration certificate, or other authenticated copy of latest Articles of Cooperation and other legal documents;

    b. Co-signers Statement (if applicable);

    c. Copy of latest Income Tax Return;

    d. Mayor's permit where the business is located;

    e. Audited Financial Statements for the past three (3) years preceding the date of project implementation or in case of those with operation of less than 3 years, for the years in operation and proof of previous implementation of similar projects (or in the case of startups, at least for one (1) year;

    f. Document of showing that NGO/PO has equity to 20 percent of the total project cost, which shall be in the form of labor, land for the project site, facilities, equipment and the like, to be used in the project;

    g. Disclosure of other related business, if any;

    h. List and/or photographs of similar projects previously completed, if any, indicating the source of funds for implementation;

    i. Sworn affidavit of secretary of the NGO/PO that none of its incorporators, organizers, directors or officers is an agent of or related by consanguinity or affinity up

to the fourth civil degree to the official of the agency authorized to process and/or approved the proposed MOA, and release of funds;

j.   For CSOs, compliance to regulations as required by the General Appropriations Act (GAA) pertaining to fund transfers to Civil Society Organizations (CSOs); and

k.   For foundation, DOST certification as accredited by the Science and Technology Foundation Unit.

Proposal Evaluation Process
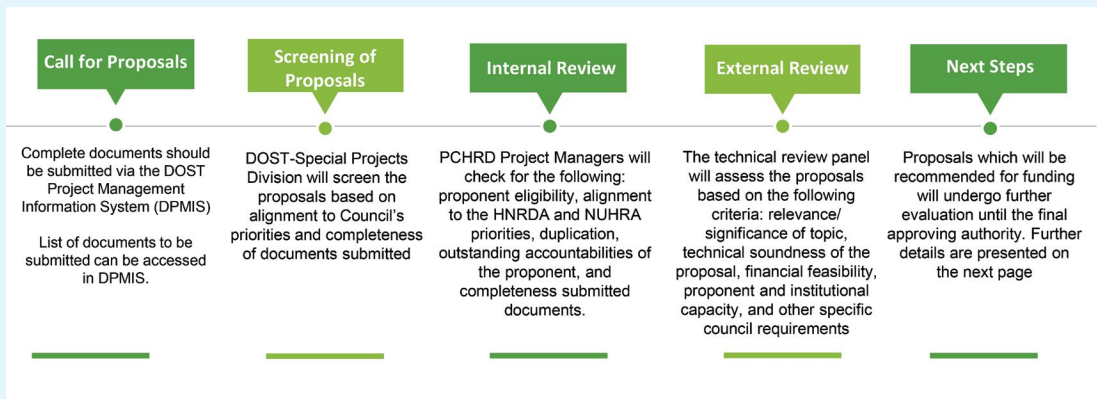
Figure 6. PCHRD Proposal Evaluation Process

Submitted research proposals will undergo a series of technical evaluation processes, the first of which are the internal and external technical evaluation with consultants. At this stage, proponents will receive feedback regarding the status of their proposals, which may either be:

- Recommended for Approval
  o   Proposals that fully met the criteria for evaluation or with only minor clarifications needed

- For Revision
  o   Proposals that have the potential to be approved once revised based on minor comments or recommendations
  o   Revised proposals will again undergo an internal and external technical review (if necessary)

- Disapproved
  - Grounds for disapproval:
    - ∗ Major technical and/or ethical issues in the proposal
    - ∗ Duplication with existing literature/projects
    - ∗ Proposal topic is not aligned with PCHRD priorities
    - ∗ Incomplete project documents
  - A summary of the recommendations made by the consultants may be requested by the proponents.
  - The project team may submit another proposal in the next call.

Research proposals which will receive a *Recommended for Approval* rating will be further evaluated by the following approving authorities:

- PCHRD Executive Director
  - For PCHRD-funded projects with a requested budget of *less than PhP 5,000,000.00*

- PCHRD Governing Council
  - For PCHRD-funded projects with a requested budget of *PhP 5,000,000.00 and above*

- DOST Undersecretary for Research and Development
  - For DOST-funded projects with a requested budget of *PhP 5,000,000.00 and below*

- DOST Executive Committee
  - For DOST-funded projects with a requested budget of *more than PhP 5,000,000.00*

The final results of the evaluation process will be relayed to the proponents by an official letter from PCHRD or DOST.

* DOST Forms can be accessed in the DOST website: www.dost.gov. ph.

** Contents of the proposal will be directly inputted into the DPMIS but the accomplished forms will be possibly requested during the technical review.

*** Private Higher Educational Institutions accredited by the Commission on Higher Education and private research and development institutions with proven track record with DOST shall be exempted from these requirements.

Annex II

Mental Health Technical Assessment Form

TECHNICAL ASSESSMENT CHECKLIST FOR MENTAL HEALTH RESEARCH[§§]

SECTION	CHECKLIST ITEM	EVALUATION YES	NO	REMARKS
Title	Is the title clear?			
Introduction	Is the scientific background adequately described?			
Background	Is the health problem/burden of disease/condition of interest adequately described: morbidity measures, morbidity measures, BOD measures -DALYs?			
	For clinical trials: Are the following information provided: study outcomes, types of intervention, study population, and type of study designs used?			

SECTION	CHECKLIST ITEM	EVALUATION		REMARKS
		YES	**NO**	
Significance of the study	Is the research significance adequately described and convincing enough? *This section requires imagination and creativity. In terms of knowledge, show how the results will confirm, contradict, conflict or create new body of information in the field of mental health.*			
	a. Does it include how results can contribute to the evolving body of **knowledge**? Focus on knowledge *building / development - expand the horizon of knowledge in MH*			
	b. Does it include how results can impact on: • practice of profession (mental health professional practice: clinical/public health)? • MH policy?			
	c. Does it describe the multi-level implications to *education, training, practice viewed in terms of promotion, prevention, treatment and rehabilitation and transformation in MH intervention.*			
	d. Does it show how the study will contribute to the knowledge building needs of MH • How the results of the study will contribute to the overall performance of MH interventions. • What improvements, innovations and changes may be initiated using the results of the study? *This section can be summarized as (K) Knowledge (I), Information (M), Management (P), Practice (K I M P). These must show the impact of the research on the overall intervention management in MH. If possible the implications must indicate the challenges of the results to the overall management and practice of mental health. This will cover: Promotion, prevention, care, rehabilitation and transformation. It must be remembered that research in MH is action research.*			

SECTION	CHECKLIST ITEM	EVALUATION YES	NO	REMARKS
Objectives/ Research Questions	Are the specific objectives or hypotheses specific, measurable, attainable (and time-bound, if applicable)?			
	Are specific objectives relevant to the general objective and will they contribute to its attainment?			
	For intervention studies/clinical trials/ reviews Does the objective explicitly state the research question being addressed with reference to patient, intervention, comparator, and outcome of interest (PICO)?			
Literature Review	Is the current state of knowledge (what is known/what is unknown) adequately described?			
	Is the gap in knowledge clearly identified?			
	Is the literature review comprehensive and up-to-date?			
	Are the literature included directly relevant to the research question? Are local literature cited?			
Epidemiology of study variables	Is the epidemiology of all the study variables presented and adequately described?			
	For analytic studies: Aside from the study variables (e.g. independent and dependent variables), are confounding variables identified, described, and their epidemiology presented?			
Conceptual framework	Does the framework represent a good synthesis of the literature on the topic in relation to the research question?			
	- Does the framework situate the research problem in the current body of knowledge?			

SECTION	CHECKLIST ITEM	EVALUATION		REMARKS
		YES	NO	
	If the framework was drawn on existing models/theoretical framework, like behavioral models, are the study variables clearly identified in the model/framework?			
Methods				
1. Study design	Is the study design identified and appropriate to answer the research problem?			
	Is the research design cost-effective to answer the objectives of the study?			
	Is the study design described adequately (i.e. key elements of study design presented)?			
	For clinical trials: Is there an indication if the trial is parallel or factorial, and the allocation ratio used?			
Study population	Is the study population appropriate for the objective of the study and the research design?			
	Are the eligibility criteria for participation identified (i.e. inclusion/ exclusion criteria) ?			
	Is the rationale for the eligibility criteria explained?			
	Is the method of ascertainment of each eligibility criterion described?			
	Is the setting of the proposed study described?			
Recruitment process	For primary data collection (query and observation) - Is the method of recruitment adequately described?			
	- How will recruitment of respondents be done: in-person, posters, flyers, by phone?			
	- Who will do the recruitment? - Is there a possibility of undue influence?			

SECTION	CHECKLIST ITEM	EVALUATION YES	NO	REMARKS
Other considerations	Is the source population/sampling population (where the sample will be selected) adequately described?			
	For cohort studies: - Are the methods of follow up described?			
	- For matched studies, are matching criteria and the number of exposed and unexposed indicated?			
	For case-control studies: - Is the rationale for choice of cases and controls explained?			
	- Are matching criteria and the number of controls per case indicated?			
	For reviews: - Is a description of databases with dates of coverage, and plans for contact with study authors to identify additional studies included?			
	- Is a full electronic search strategy for at least one database, including limits to be used indicated?			
	For studies on instrument validation or diagnostic accuracy: - Is the reference standard and its rationale for use described?			
	- Are the technical specifications of materials and methods involved (including how and when measurements will be taken) indicated and/or references for index tests and reference standard cited?			
	- Are the definitions of and rationale for units, cut-offs, and/ or categories of the results of the index tests and the reference standard indicated?			

SECTION	CHECKLIST ITEM	EVALUATION YES	NO	REMARKS
Study variables	Are the major study variables identified?			
	For analytic studies: - Are variables such as independent variables, dependent variables, potential confounders, and effect modifiers clearly identified?			
	For clinical trials: - Are the interventions for each group described, including specific details to allow replication?			
	- Are the outcomes adequately explained, including how these will be measured and assessed?			
	For systematic reviews: - Are variables listed and defined, including any assumptions and simplifications made?			
	- Are the summary measures clearly defined per variable?			
2. Sampling				
Sampling method	Is the sampling method identified?			
	Are the following defined: target population, sampling population, sampling frame, sample?			
	Is the sampling procedure clearly described – step-by-step to allow replication?			
	Is the sample representative of the target population?			
Sample size	Is sample size justified?			

	For quantitative research
	 - Is the sample size computation correct?
	   - Are the statistical parameters used for the computation of sample size indicated?
	   - Are the references used for the parameter used in the computation of sample size cited?			

SECTION	CHECKLIST ITEM	EVALUATION		REMARKS
		YES	NO	
Other considerations	*For clinical trials:* Are interim analysis and guidelines for termination needed for the type of outcome? If so, are they specified?			
	For reviews: - Is the process for selecting studies (i.e. eligibility, screening, included in systematic review/ meta-analysis) indicated?			
	- Are the approaches to literature search (e.g. hand-searching, citation snowballing) described?			
3. Data collection methods	Is the data collection method adequately described to allow replication?			
	Is the data collection instrument identified and described?			
	Is the data collection instrument clear and complete (i.e. all study variables or their indicators are covered)?			
	For multiple methods of data collection, is the data collection matrix provided (for each objective, the corresponding variables, method of data collection and source of data identified)?			
	Is there an operational definition of study variables? *For studies that will use scales or index scores: Is the scoring system provided?*			
	Are all study variables relevant to the attainment of the objectives?			
	Are data quality control measures in place?			
	For secondary data collection (document/ records review) - Is the source document identified and described?			
	- Who collected or is collecting the data?			

SECTION	CHECKLIST ITEM	EVALUATION YES	NO	REMARKS

	- What is the nature of the data?
	  - registration system, surveillance, research data, etc?
	  - date of data collection or frequency of data collection – periodic, adhoc, etc?			

	- Is there a description of how the document or individual records (patient, employment records) will be accessed?			
	For clinical trial: - Is the method to be used to generate random allocation sequence given?			
	- Is the type of randomization described?			
	- Are the individuals who will generate the random allocation sequence, who will enroll participants, and who will assign participants to interventions identified?			
	- Are those who will be blinded after assignment to interventions indicated?			
	For studies on diagnostic accuracy: - Is the period of data collection (i.e. before or after the tests) described?			
	- Are information on the number, training, and expertise of persons executing and reading the index test and the reference standard given?			
	- Is there any description of whether or not the readers of the index test and the reference standard will be blinded to the results of the other test and of clinical information that may influence the reading of the test result?			

SECTION	CHECKLIST ITEM	EVALUATION		REMARKS
		YES	NO	
	For reviews: - Is the method of data extraction from reports and any processes for obtaining and confirming data from investigators explained?			
	- Are the methods of handling data, coding, and combining results of studies (including methods of consistency) described?			
	- Are the methods of addressing articles published in languages other than English given?			
	- Are the methods of handling abstracts and unpublished studies described?			
	For systematic reviews: - Are the methods to be used for assessing risk of bias in individual studies (including specification of whether this was done at the study or outcome level) and how this information is to be used in any data synthesis described?			
	- Are the methods used for assessing risk of bias that may affect cumulative evidence (e.g. publication bias, selective reporting within studies) explained?			
Bias and limitations	Are possible biases (selection bias, information bias) and confounding and their sources identified and the corresponding methods to minimize them described? Are the limitations of the study described?			
Data analysis	Are the descriptive statistical measures to be used identified?			
	Are inferential statistical approaches specified?			
	Is the data analysis matrix presented (statistical tools to be applied per research objective)?			

SECTION	CHECKLIST ITEM	EVALUATION		REMARKS
		YES	NO	
	Is there an explanation on how missing data will be addressed?			
	For association studies: Are measures to control for confounding described?			
	For cohort studies: Is there an explanation on how losses to follow-up will be addressed?			
	For qualitative research Is the plan for analysis adequately described			
Ethical Consideration	Is there an ethical consideration section in the proposal? Are all the elements of research ethics addressed in this section?			
	1. Is the recruitment process clearly described (how, where, who)?			
	2. Is the Informed consent form complete, clear, and appropriate?			
	3. Is the process of obtaining informed consent clearly described (how, where, who?)			
	4. Is the process for ensuring privacy and confidentiality of data, including data protection plan described?			
	5. Are all known and anticipated risks and discomforts related to participation of respondents and the corresponding measures to mitigate them adequately described?			
	6. What are the benefits of the study to the study participants, if any?			

SECTION	CHECKLIST ITEM	EVALUATION YES	NO	REMARKS
Attachments	Are the following documents, as well as others that are cited in the body of the proposal, attached to the proposal?			
	a. Sample size computation			
	b. Data collection instrument			
	c. Dummy tables			
	d. Sampling frame			
	e. Recruitment material (letter, flyer, script for in-person recruitment)			
	f. Informed consent form			
	g. others			

ACKNOWLEDGMENTS

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