Doris Howes Calloway

Contributions to US Department of Agriculture Human Metabolic Research

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When the US Department of Agriculture developed a new West Coast human nutrition research center in 1980, it turned to Dr Doris Calloway at the University of California at Berkeley, an internationally known and respected researcher in human nutrition, for expertise on controlled human nutrition metabolic research. This article highlights the importance and impact of Dr Calloway's leadership, expertise, and unique metabolic research methods in establishing human nutrition metabolic research at the US Department of Agriculture/Agricultural Research Service, Western Human Nutrition Research Center. It also provides a historical overview of the origins of the Western Human Nutrition Research Center and discusses the importance of a metabolic facility for human nutrition research. Nutr Today. 2022;57(5):288–294

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BEGINNINGS OF HUMAN NUTRITION METABOLIC RESEARCH AT UNIVERSITY OF CALIFORNIA AT BERKELEY AND US DEPARTMENT OF AGRICULTURE

Human nutrition research conducted under Dr Calloway's leadership at the University of California at Berkeley (UCB) Department of Nutritional Sciences between 1965 and 1977 resulted in significant advances in protein, energy, and mineral metabolism.[1] The research also led to the development of important national and international dietary standards and food and nutrition policies.[2] Much of this research was conducted in the metabolic research facility located on the top floor of the Nutritional Sciences building and often referred to as the "Penthouse" because of its panoramic views of the San Francisco Bay and Berkeley Hills. This metabolic unit was established in 1965 by Dr Calloway and her colleague, Dr Sheldon Margen, a professor and physician in the department.[1] This article is part of a series of publications that focus on Dr Calloway's research and the contributions of her research to contemporary scientific discourse around human nutrition, dietetics, and public health.[1,2]

An important byproduct of this body of research was knowledge and understanding on how to design and conduct controlled human nutrition metabolic studies. At the time, few other research facilities in the world had human nutrition metabolic units. The novel feeding regimens, unique biological sample collection techniques, and other protocols established for UCB human metabolic research were sought by and shared with many scientists throughout the world. Dr Calloway, as an internationally known and respected leader in human nutrition, provided guidance to some of the US Department of Agriculture (USDA) Human Nutrition Research Centers. A prime example is the guidance she provided when the human nutrition metabolic research unit (MRU) was established at the USDA's Western Human Nutrition Research Center (WHNRC), initially located at the Presidio of San Francisco, California.

Prior to the 1970s, USDA/Agricultural Research Service (ARS) locations in Beltsville, Maryland, and Grand Forks,

North Dakota, were the only USDA locations conducting intramural (in-house) human nutrition research. Thus, much of the early USDA nutrition research with human volunteers was done through contracts and cooperative agreements with universities or State Experiment Stations.[3] As a follow-up to the 1969 White House Conference on Nutrition, which highlighted the need for expanded human nutrition research efforts, Congress funded the establishment of 3 new regional USDA human nutrition research centers in the United States. These new centers, located in Houston, Texas (south); Boston, Massachusetts (east); and San Francisco, California (west), were operational or under development by the late 1970s. Congress appropriated funds for a sixth USDA/ARS Center, in Little Rock, Arkansas, in 1994.[3] All centers included a human MRU used for highly controlled residential studies and/or free-living studies, depending on the degree of research control required.

WHY USE A METABOLIC FACILITY FOR HUMAN NUTRITION RESEARCH?

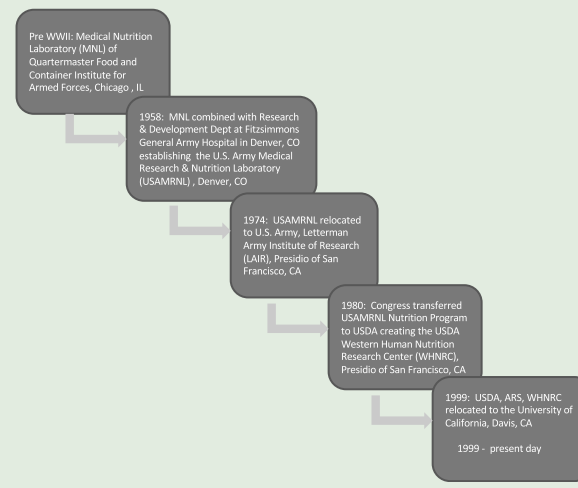
Metabolic units are equipped with the requisite facilities, equipment, and staff (medical, nursing, and dietetic) to control research environmental conditions and to precisely measure human intake (foods, beverages, dietary supplements, and water), body weight and composition changes, and human nutrient and metabolite levels in blood, urine, feces, sweat, skin, flatus gas, and so on. For studies requiring a high degree of research control, human volunteers reside in the facility with dietary intake, physical activity, and living conditions carefully controlled. These conditions allow for calculations of human energy and nutrient intake/output balances and minimize the influence of outside environmental factors on study outcomes. Today, stable isotope methodology has largely replaced the use of balance calculations in nutrition research, but metabolic units are still used for both in-house and free-living studies with volunteers receiving controlled diets and biological sample collections/measurements at the facility.

ESTABLISHING THE USDA/ARS, WHNRC, SAN FRANCISCO, CA

During the 1960s and 1970s, the US Army had a highly regarded human nutrition research program. The Medical Nutrition Laboratory of the Quartermaster Food and Container Institute for the Armed Forces in Chicago, where Dr Calloway had worked earlier in her career,[1] relocated in 1958 and became part of the US Army Medical Research and Nutrition Laboratory at the Fitzsimmons General Hospital in Denver, Colorado. Controlled medical and human nutrition research studies were conducted using the clinical and metabolic ward facilities at that location. In 1974, the US Army Medical Research and Nutrition Laboratory relocated to the newly built Letterman Army Institute of Research (LAIR) at the Presidio of San Francisco. Facilities for nutrition research included a metabolic unit with kitchen and analytical laboratory, research laboratories, and capabilities for research with experimental animals. Highly respected human nutrition researchers, Robert Herman, MD, Howerde Sauberlich, PhD, and C. Frank Consolazio, transferred from the Colorado location and assumed leadership positions at LAIR. Nutrition research was 1 of the 4 research divisions.[3]

Because of cutbacks in military spending following the end of the Vietnam War (1975), US Army research funding priorities were evaluated, and nutrition research received a low priority score. This led to budget cuts that effectively eliminated the US Army's nutrition research program at LAIR. The imminent closure of the newly constructed LAIR (completed in 1974) attracted the attention of the scientific community as well as of Congress, and after considerable discussion, a transfer of the US Army's nutrition research program at LAIR to USDA was proposed. Negotiations ensued between the US Army and USDA, and in October 1979, Congress funded USDA to develop the WHNRC and directed the US Army to transfer the LAIR nutrition facilities and some of its assets to USDA. The WHNRC at the Presidio of San Francisco was officially created in April 1980 after LAIR facilities, equipment, supplies, and 19 permanent, full-time staff positions were transferred to USDA.[3]

Box 1. Historical Development of the US Department of Agriculture/Agricultural Research Services, Western Human Nutrition Research Center.



Dr Calloway's Leadership in Launching Human Nutrition Metabolic Research at the USDA, WHNRC

The USDA leadership recognized that specialized expertise in designing, implementing, and managing residential, controlled human nutrition studies was required for the new WHNRC metabolic unit. Legislative language establishing the

new human nutrition research centers encouraged affiliation with nearby universities. University of California at Berkeley's Department of Nutritional Sciences, located nearby across the San Francisco Bay with a number of highly recognized faculty conducting human nutrition research, was an obvious affiliation. Dr Calloway at UCB had highly regarded expertise in conducting human nutrition studies based on her earlier research at the Quartermaster Food and Container Institute, the Stanford Research Institute, and her many UCB metabolic unit studies.[1,2]

In June 1980, Dr Calloway, chair and professor in the UCB Department of Nutritional Sciences, was asked by USDA's Drs Mark Hegsted and James Iacono to advise on the conversion of the US Army's transferred metabolic facility into a "state-of-the-art" human nutrition metabolic unit to focus on USDA's research priorities. The LAIR MRU was originally designed for US Army "ward-type" medical and nutrition studies to benefit the soldier. Those studies used male military volunteers and included nutrition research but also research on shock and trauma, blood replacements, wound healing, and ocular and cutaneous hazards.[3] The metabolic unit was now being repurposed to address adult human nutrition requirements and nutritional status assessment methodology for the broader US population.

Dr Molly Kretsch, who completed postdoctoral training with Dr Calloway, had transferred from LAIR to the USDA, WHNRC, as a research scientist in 1980. Given her metabolic research training with Dr Calloway, she was appointed director of the WHNRC MRU in addition to her research responsibilities. As the MRU director, she worked in partnership with Dr Calloway, Dr Janet King (also a UCB faculty member and former student of Dr Calloway's), and their UCB staff to repurpose the existing LAIR metabolic unit for controlled human nutrition research studies with female and male volunteers. Except for physical renovation of the facility, which was delayed until 1981, everything, including hiring new staff, was accomplished in record time, with the first study commencing in September 1980. This quick turnaround could not have been accomplished without Dr Calloway and her senior staff from the UCB metabolic research facility. Three of the senior staff members had been part of the UCB metabolic research team from the beginning, that is, Delroy Brown, Fran Costa, and Doris Armstrong. That meant not only Dr Calloway's specialized expertise but a decade's worth of the staff's technical knowledge and practical experience in conducting controlled human metabolic studies was available to the new MRU at WHNRC.

The first human metabolic study conducted at the WHNRC addressed human dietary fiber requirements with Drs Calloway and Sharon Fleming, a new UCB faculty member, as the principal investigators.[4–6] Dr Kretsch and the UCB staff trained the newly hired WHNRC metabolic staff during this study, which ensured successful knowledge and methodology transfer as well as effective implementation of metabolic research protocols and procedures. The study also provided training opportunities for scientists and graduate students who had not previously conducted human metabolic research. Specific procedures and methods are described in detail in the following section.

In the years following the first study, WHNRC scientists with assistance from the metabolic unit staff conducted approximately 2 to 3 human studies per year until the USDA WHNRC relocated to the UC Davis campus in 1999. This early WHNRC metabolic research primarily focused on vitamin, mineral, and essential fatty acid requirements of humans for health and disease prevention, as well as research to undergird the development of dietary, biochemical, and anthropometric methods for field nutritional assessment studies. The initial studies included some of the first vitamin requirements research with female volunteers under controlled, metabolic conditions.[7–10] Results from many of the WHNRC human metabolic studies contributed to the establishment of national and international food and nutrition standards and public health nutrition policies.[3]

DR CALLOWAY'S CONTRIBUTIONS TO HUMAN NUTRITION METABOLIC RESEARCH METHODOLOGY AT THE WHNRC

Dr Calloway played an important role in pioneering the development of human nutrition metabolic research. This section details many of the methods used in the WHNRC metabolic research facility that originated from Dr Calloway's and Dr Margen's UCB residential metabolic unit studies (the "Penthouse") and from Dr Calloway's earlier research.[1] Methods covering formulation and use of defined, controlled formula diets; nursing procedures; breath and intestinal gas collection procedures; and others are described below.

Box 2. Importance of Dietetic, Nursing, and Medical Skill Sets for Human Nutrition Metabolic Research.

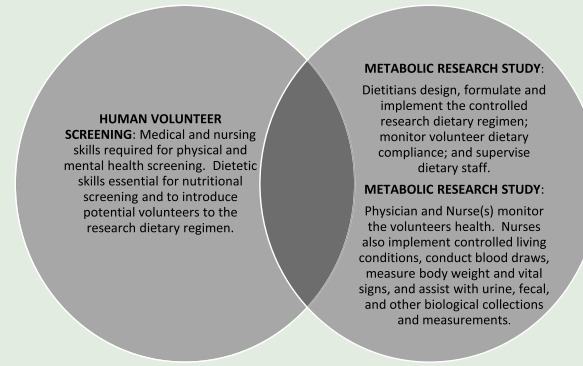


PHOTO 1. Preparation of defined formula diets in Western Human Nutrition Research Center's metabolic kitchen.

Dietary Procedures

Metabolic research unit dietitians calculated formula and/or real food diets to deliver precise nutrient regimen(s) based on the objectives of each study. Dietary composites, made from weighed food and beverage amounts for a set body weight, were analyzed by bomb calorimetry (for dietary energy) and chemically analyzed (for nutrients) to ensure that dietary energy and nutrient amounts met research design levels. Dietitians tracked the body weight of each volunteer throughout the study because unintended body weight gain or loss could alter study results. They made individualized energy adjustments, as needed, to maintain body weight throughout the study. Dietary staff were also present during mealtimes to help ensure each volunteer's complete food and beverage consumption. Any plate food waste or feeding container residues (if any) were measured and subtracted from daily food intake amounts. When liquid formula diets were fed, a quantified deionized water rinse procedure was performed to capture any nutrients remaining on container surfaces. These procedures provided study scientists with precise daily energy and nutrient intakes of each volunteer.

- *Defined, controlled formula diets*: Dr Calloway developed defined, controlled formula diets for use earlier in space flight research[11,12] based on NASA's elemental diet,[13] and she continued to use them for human nutrition studies at UCB. The dietary regimen consisted of a basic semipurified formula, to which was added a specified amount of extra-energy and/or extra-protein formula (to provide energy and/or protein adjustments for each volunteer), vitamin and mineral supplements, a purified dietary fiber component to ensure regular fecal flow, weighed amounts of decaffeinated coffee or instant tea, and ad libitum deionized water. In some dietary regimens, additional daily food items were incorporated to provide some resemblance to normal meals for the research volunteers. Because in many studies the formula diet was the sole source of nutrition for prolonged periods (ie, 2-3 months), nutrient adequacy especially for essential vitamins and minerals had to be ensured. This dietary approach allowed exact energy and nutrient intake control while providing flexibility to adjust the nutrients being investigated (Photo 1).

Nursing Procedures

The MRU studies at the WHNRC entailed sequestering 12 volunteers in the metabolic unit on controlled daily schedules, dietary intakes, and physical activity regimens for up to 3 months. Volunteers resided throughout the study with other volunteers whom they had not previously known and with limited access to visitors and outdoor activities. Because MRU study designs usually precluded volunteer replacements after the first few weeks of the study, conflict resolution between volunteers was an important nursing function. Nurses with specialized training in psychology and with counseling experience were sought as they often functioned as counselors for the volunteers.

Nursing staff also worked with the study physician monitoring the health status of volunteers to ensure that their physical and mental health was maintained throughout the study. They supervised the volunteers' controlled daily schedules; measured daily vital signs, body weight, and water consumption; drew blood samples; managed 24-hour urine and fecal collections; oversaw volunteer exercise regimens, as prescribed by the exercise physiologist; and assisted research staff in specialized biological collections, such as flatus (gas) and sweat collections (see Photo 2) as well as fasting daily body weight measurements and blood draws that were carried out by the WHNRC metabolic nurse.

MRU Body Composition Procedures

Body fat and lean tissue of volunteers were measured by hydrostatic weight, also known as underwater weighing, and whole-body K-40 counting. Photo 3 shows hydrostatic weighing of a volunteer.

MRU Biological Sample Collection Procedures

Some examples of methods adopted from Dr Calloway's UCB metabolic research are described as follows:

PHOTO 2. Breath gas collection method developed by Dr Calloway being conducted by Doris Armstrong, University of California at Berkeley metabolic unit nurse.

PHOTO 3. Hydrostatic underwater weighing conducted with metabolic unit volunteer.

- *Urine and fecal collection procedures*: Methods to measure and collect urine and feces of human military research volunteers used at LAIR[14] were modified to UCB methods to ensure complete 24-hour collections essential for intake/output in nutrient balance studies. They were also modified for collections from women as the previously conducted military studies had been restricted to male volunteers. In fact, some of the first nutrition studies with female volunteers under controlled metabolic conditions were done at UCB and the WHRNC.
- *Breath and flatus gas production*: Dr Calloway was instrumental in developing methodology in her early research with space diets and nutrition[1] to determine intestinal microbe gas production under varying dietary conditions, a concern in the limited space craft environment. Development of methods to measure gas production in real time was still needed. Dr Calloway's early work and collaboration with scientists at the USDA/ARS Western Regional Research Center in Albany, California, yielded methods by which both breath and flatus gas production could be reliably measured.

These breath collection[15,16] and flatus gas measurement[17,18] methods developed by Dr Calloway were transferred to the WHNRC and used in the first MRU study.[4] Samples of expired air were collected at hourly intervals, beginning 2½ hours after breakfast, and analyzed for hydrogen and methane content. For flatus gas collections, rectal adhesive patches with tubing connected to gas-impermeable collection bags were affixed to the volunteers before a meal and gas samples collected for the next 6 hours. Gases obtained were dehydrated and samples measured for methane, hydrogen, and oxygen chromatographically.

- *Sweat and skin loss collections*: Another example of a specialized biological collection procedure developed at the UCB metabolic facility and transferred was sweat collection for nitrogen[19] and trace element loss.[20] This unique method to determine estimates of total sweat losses built on earlier studies[12,21–23] in which patches or sweat samples were collected at various times. Skin loss methodology involved using body coveralls and carefully collecting hair, nail, and other skin losses through bathing and towel collection and sampling (Photos 4 and 5).
- *Collection methods for other body losses*: New methods to obtain estimates of other losses, not previously accounted for, were developed by Dr Calloway and subsequently transferred to WHNRC.[19] These unavoidable losses had usually been ignored in determining the adequacy of nutrient intakes. Nitrogen research in young men indicated that approximately 115 mg of nitrogen (equal to 0.7 g protein) was not accounted for by

PHOTO 4. Dr Calloway demonstrating skin loss collection at University of California at Berkeley metabolic unit.

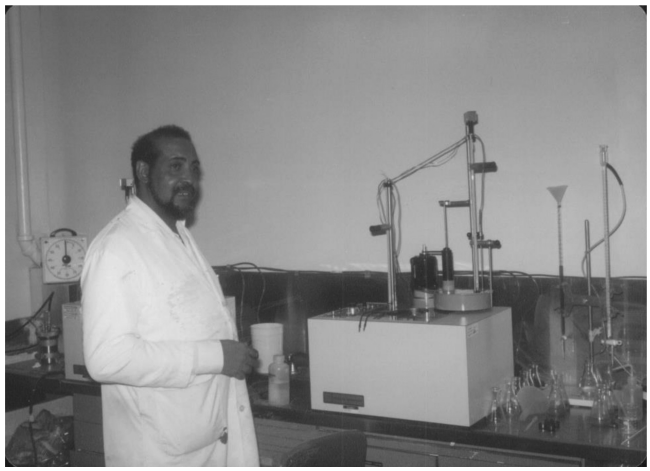


PHOTO 5. Dr Calloway's research assistant, Mr Delroy Brown, analyzing biological samples from the Western Human Nutrition Research Center metabolic unit.

measuring urine, fecal, and integumental losses and was determined to be lost via toothbrushing, on toilet tissue, via plate waste, and as exhaled ammonia. Procedures to estimate other body nitrogen losses, such as those due to blood sampling (32 mg N/100 mL), saliva (0.9 mg N/g), and semen (37 mg N per ejaculate), were also developed.[19] Other measurements made in UCB studies and subsequently transferred to WHNRC include menstrual[20] and vaginal losses.[24]

IMPACT OF DR CALLOWAY'S CONTRIBUTIONS TO USDA HUMAN METABOLIC RESEARCH

Dr Calloway's leadership in helping to establish the WHNRC metabolic unit had both short- and long-term impacts. It expedited the launch of a state-of-the-art MRU for USDA researchers and collaborating academic scientists, which enhanced the success of the USDA's WHNRC research program and similar programs in other facilities throughout the nation and world. Scientists trained in human nutrition and those trained in related biological fields, such as biochemistry, immunology, physiology, molecular biology, and exercise physiology, applied their knowledge to nutrition studies conducted in this new metabolic unit research facility. Those not trained in human nutrition could rely upon the highly trained human metabolic unit staff to use the established protocols and procedures to implement and carry out their research investigations. This expansion of scientific disciplines in human nutrition metabolic research helped advance the overall science of human nutrition and facilitated the growth and impact of the field in the latter part of the 20th century. Many of the human nutrition metabolic research approaches and techniques developed by Dr Calloway and her collaborators and students have also had an impact on human studies conducted at the other USDA Human Nutrition Research Centers and indeed on human metabolic studies conducted throughout the field of nutrition.

It should also be noted that a number of Dr Calloway's graduate and postdoctoral students became research scientists and leaders within the USDA/ARS, both at the USDA Human Nutrition Research Centers and within USDA Senior Leadership. They and their leadership positions are listed in alphabetical order as follows:

- **Dr Lindsay Allen**—USDA/ARS, center director, WHNRC at UC Davis, 2004-2019
- **Dr Nancy Butte**—professor/senior scientist, USDA/ARS, Children's Nutrition Research Center at the Baylor College of Medicine, 1980-2016
- **Dr Janet King**—USDA/ARS, center director, WHNRC, San Francisco, and UC Davis 1997-2003.
- **Dr Molly Kretsch**—USDA/ARS National Program Leader, Human Nutrition, Beltsville, Maryland, 2004-2008; USDA/ARS Deputy Administrator, Nutrition, Food Safety and Quality, Beltsville, Maryland, 2009-2013, and USDA Office of the Chief Scientist, Senior Advisor, Washington, DC, 2009-2013
- **Dr Allison Yates**—USDA/ARS, center director, Beltsville Human Nutrition Research Center Director 2006-2011; USDA/ARS Northeast Area, associate director, 2011-2014

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