

INTERNATIONAL ATOMIC ENERGY AGENCY

NUCLEAR MEDICINE AND DIAGNOSTIC IMAGING SECTION DIVISION OF HUMAN HEALTH DEPARTMENT OF NUCLEAR SCIENCES AND APPLICATIONS

IAEA NON-INVASIVE CARDIOLOGY PROTOCOLS STUDY - INCAPS 4

## THE IAEA

The International Atomic Energy Agency (IAEA), based in Vienna, Austria, is an intergovernmental, science and technology-based organization in the United Nations family that serves as the global focal point for nuclear cooperation. Its mandate includes not just the weapons inspections for which it is best known, but rather all peaceful uses of ionizing radiation, including those in medicine. IAEA has 176 member states, and a particular focus on low- and middle-income countries. For its multifaceted accomplishments, the IAEA received the Nobel Peace Prize in 2005. Within the IAEA's Division of Human Health, the Nuclear Medicine and Diagnostic Imaging (NMDI) Section focuses on fostering the use of and improving the quality of medical imaging procedures in all of IAEA's member states.

# **INCAPS 1**

INCAPS 1, initiated by the IAEA in 2012, is an observational, cross-sectional study of worldwide nuclear cardiology practice, focused on protocols, technology, best practices, and doses used in nuclear myocardial perfusion imaging (MPI). INCAPS 1 invited laboratories performing MPI to retrospectively contribute data on each MPI study performed during one week of their practice, chosen by the respondent, between the weeks beginning 18 March and 22 April 2013, inclusive. These included both SPECT and/or PET studies performed. 308 laboratories in 65 countries contributed data, including a total of 7911 patients. Worldwide findings were published in *European Heart Journal* (available open access at <u>bit.ly/incaps1world</u>) and demonstrated considerable worldwide variability in MPI practice. This paper was followed by 6 regional papers, focusing on nuclear cardiology practice in (alphabetically, with links to papers) <u>Africa, Asia, Europe, Latin America, Oceania, and the US</u>. In addition, five thematic papers have been published, focusing on <u>gender differences</u>, the impact of <u>age, stress-only MPI</u>, <u>diagnostic reference levels</u>, and <u>technology and protocols</u>. Regional coordinators played leading roles in these manuscripts.

# **INCAPS COVID STUDIES**

While plans were being made for a follow-up INCAPS study 7 years after the first study, with expansion to include cardiac CT as well as nuclear cardiology, the COVID pandemic struck. Considering the marked changes in the practice of medicine in general and cardiac imaging in particular, the INCAPS executive committee deemed it a non-representative time to conduct a cross-sectional study of best practice use and delayed conducting a follow-up observational study to INCAPS 1. Rather, they shifted gears and conducted two worldwide surveys of the impact of the COVID pandemic on cardiac imaging, broadening the focus to all modalities. Each included

hundreds of participants from over 100 countries. INCAPS COVID 1 (the second study in the INCAPS family of studies, after INCAPS 1) compared 2020 imaging practice to that in 2019, finding dramatic reductions in use and changes in practice, while INCAPS COVID 2 (the third INCAPS study) focused on recovery of imaging after the height of the pandemic, noting marked disparities. Worldwide findings from each were published in JACC: INCAPS COVID 1 here and INCAPS COVID 2 here. In addition there have been several regional papers published from INCAPS COVID 1, including for Asia, Europe, Italy, Latin America, Oceania, and the US, with more in the works for INCAPS COVID 2.

# **INCAPS** 4

INCAPS 4, the fourth INCAPS study, is the follow-up to INCAPS 1, 10 years later. Like INCAPS 1, it will be a cross-sectional, observational registry. With the growth of cardiac CT worldwide, the focus has been expanded to include both cardiac CT and nuclear cardiology. Our goal is to study coronary heart disease imaging practice across the globe, better understand practice variation, including use of protocols, technology, best practices, and doses, and identify potential targets for improvement and future intervention. Participating sites will have the opportunity to contribute data on their lab's practices in coronary CTA and coronary artery calcium scoring, in MPI, or in both CT and MPI. Data from MPI and from CT need not be provided from the same week, but for each modality, laboratories will be expected to provide consecutive data from all patients imaged over a one week period, between the weeks beginning **15 October to 5 November 2023**, inclusive (data from one of the four one-week periods 15 to 21 October, 22 to 28 October, 29 October to 4 November, or 5 to 11 November). All data will be entered using IRIS, a secure, online system at the IAEA. We anticipate that data collection will take less than an hour to complete in total for most laboratories. The form can be completed by a physician, radiographer/technician, or physicist and can be completed in more than one sitting.

There are two types of data to be collected:

- Introductory data: A few short survey questions to define each institution's usual practice and procedure volumes.
- Primary data: De-identified (anonymous) patient level data from the week chosen by the lab.

### WHAT STUDIES WILL BE INCLUDED IN THE PRIMARY DATA FOR INCAPS 4?

Cardiac CT as studied here is limited to coronary imaging, i.e., coronary CT angiography and/or calcium scoring. Coronary CT angiography will include coronary artery bypass graft studies, coronary studies that are extended to image the thoracic aorta, and "triple rule out studies." Excluded are structural studies such as pre-TAVR evaluation, left atrial appendage, and pulmonary vein assessment. Congenital heart disease studies will generally be excluded, unless they are performed specifically for coronary evaluation, i.e., to assess for anomalous coronary arteries.

Nuclear cardiology as studied here includes all SPECT and PET MPI studies performed during the week selected by the laboratory. This includes viability studies, which typically involve perfusion assessment. Excluded are studies such as PET for sarcoid/inflammation/infection, MUGA/ERNA, and Tc-99m pyrophosphate, HMDP, or DPD used for amyloidosis assessment.

### **ETHICS CLEARANCE**

The Columbia University Institutional Review Board has determined that INCAPS 4 is "exempt" and that informed consent is not required (under US law in 45 CFR 46). For UK sites, following the national Health Research Authority standardised assessment process, INCAPS is deemed to not be research, and not in need of formal HRA or REC review. For Swiss sites, the Bern Kantonale Ethikkommission für die Forschung has determined INCAPS 4 to be "Nicht zuständig, d.h. das Vorhaben ist nicht bewilligungspflichtig." Documentation of any of these is available upon request. For many institutions, this means that additional ethics approval is not warranted. If you have questions about your institution or are uncertain, please reach out to your ethics committee and check if additional approval is warranted. Please <u>email us</u> if you have further questions or concerns.

## WHAT IS THE PLANNED TIMELINE FOR INCAPS 4?

INCAPS 4 is scheduled to take place in October-November 2023. Participating sites can contribute data regarding their laboratory practices in nuclear cardiology, cardiac CT or both, over a one-week period. Participants can select the week for which they want to provide information and select the week starting on 15 October, 22 October, 29 October, or 5 November.

#### WHO IS THE STUDY LEADERSHIP?

The section head of NMDI which is leading INCAPS is Dr Diana Paez (d.paez@iaea.org), who originates from Colombia, trained in Colombia and the US, and is now based at IAEA headquarters in Vienna. The principal investigator of INCAPS 4 is Dr Andrew Einstein (andrew.einstein@columbia.edu), an American cardiologist who practices multimodality cardiovascular imaging and clinical cardiology at Columbia University Irving Medical Center and New York-Presbyterian Hospital in New York City. Also leading efforts from IAEA are the former section head of NMDI, Dr Maurizio Dondi (mauriziodondi@yahoo.it), who now divides his time as a consultant to IAEA and practicing cardiology and nuclear medicine in Italy. The executive committee includes Drs Nathan Better (Australia), Rodrigo Cerci (Brazil), Andrew Choi (US), Ganesan Karthikeyan (India), Thomas Pascual (Philippines), Leslee Shaw (United States), Joao Vitola (Brazil), Jonathan Weir-McCall (United Kingdom) and Michelle Williams (United Kingdom). They are joined by leadership from numerous professional societies focusing on imaging across the globe, and by an organizing committee, regional coordinators, and national coordinators, a list of which is still in formation.

#### SAMPLING ISSUES

INCAPS strives for comprehensive sampling of laboratories, not convenience sampling. We aim to include as many laboratories as possible, not skewed towards leading centres or academic centres. Coordinators should unselectively aim to facilitate participation from all sectors of cardiac imaging practice in their region/country. This includes reaching out to practitioners at public hospitals, private hospitals, academic medical centres, private practices, freestanding clinics and imaging centres, government, and military facilities, etc. This will include facilities with lower and higher uses of best practices, lower and higher doses, and lower and higher volumes.

#### WHY SHOULD SITES PARTICIPATE?

Sites should participate to provide the best possible representation from their country in INCAPS 4 and advance scientific knowledge regarding cardiac imaging practice in their country, which has the ability to help improve the healthcare of patients. We learned a tremendous amount about worldwide and regional nuclear MPI practice in 2013 from INCAPS 1 and hope to similarly learn a great deal about current MPI and cardiac CT practice from INCAPS 4. By providing data, sites contribute towards providing a more comprehensive picture of cardiac imaging practice in your country. The information obtained, which will not be specifically identified with the participant's site, can potentially help all our practices in the future.

# BENEFITS TO PARTICIPANTS AS INDIVIDUALS INCLUDE:

- 1) Participants providing usable data will receive a Certificate of Participation from the IAEA, suitable for framing.
- 2) As in INCAPS 1, participants providing data for INCAPS 4 will be included among the INCAPS 4 Investigators Group for co-authorship on papers, insofar as allowed by journal policy. The INCAPS 1 Investigators Group have been co-authors of 12 papers, which they include on their curricula vitae. The INCAPS COVID 1 Investigators Group members have been co-authors on an additional 7 papers, and the INCAPS COVID 2 Investigators Group members on the JACC paper, with more papers recently submitted. Each of these 20 papers includes the related INCAPS Investigators Group in the authorship

list, and typically in an appendix, as well as in PubMed as below where allowed by the journal, lists each member of the INCAPS Investigators Group by name. There will be separate investigators groups for MPI and CT.

3) We anticipate that the first 500 individuals who provide complete CT data, and the first 500 who provide complete MPI data, will receive an honorarium of 100 Euros.



Collaborators, Affiliations - collapse

#### Collaborators

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## WHAT DO SITES NEED TO DO TO PARTICIPATE?

It will be helpful if sites indicate in advance that they intend to participate, by emailing us at <u>INCAPS@iaea.org</u>. Nevertheless, even without advanced notice, sites can participate simply by collecting and providing data during the requested time windows (Time windows: Data collection from one week beginning 15 October through 5 November inclusive, complete data receipt by IAEA by 30 November). Entering all data will typically take under an hour and can be delegated to other trained staff members.

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