INTERNATIONAL ATOMIC ENERGY AGENCY

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

INCAPS INITIATIVES – GENERAL INFORMATION
AND
IAEA NON-INVASIVE CARDIOLOGY PROTOCOLS STUDY – INCAPS 4
DETAILED INFORMATION FOR NATIONAL COORDINATORS

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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 178 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 bit.ly/incaps1world) 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) Africa, Asia, Europe, Latin America, Oceania, and the US. In addition, five thematic papers have been published, focusing on gender differences, the impact of age, stress-only MPI, diagnostic reference levels, and technology and protocols. 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 10 December 2023, inclusive.

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 Approval

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 implies that additional ethics approval is not necessary. It is important to highlight that all sites should adhere to local laws and regulations. If any participating centre has questions or concerns, please contact the IAEA – INCAPS 4 team here.

What Is the Planned Timeline for INCAPS 4?

Centres can contribute data from one of these nine-week periods:

- 15 to 21 October
- 22 to 28 October
- 29 October to 4 November
- 5 to 11 November
- 12 to 18 November
- 19 to 25 November
- 26 November to 2 December
- 3 to 9 December
- 10 to 16 December

All data will be entered using IRIS, a secure, online system at the IAEA. We anticipate that data collection will take approximately one hour to complete, for most laboratories. The form can be completed by a physician, radiographer/technologists, or physicist and can be completed in more than one sitting. We kindly request you complete only one survey per centre.

The last possible week of data collection is 10 to 16 December 2023. Complete data must be received by 16 December. Data cleaning, clarification, and analysis will commence upon completion of data entry by centres, and it is expected to be completed the first trimester of 2024, after which manuscript(s) writing will begin. In case of clarifications the IAEA -INCAPS 4 team will reach you.

Centres Interested in Participating Should:
1. Have an IAEA NUCLEUS account, that can be created by accessing this link the account should be activated via email. NUCLEUS is the IAEA’s Scientific, Technical, and Regulatory Information Resources.

2. From October 15, centres can start completing the form, for which they can choose one of the nine weeks available (weeks beginning October 15, 22, or 29, November 5, 12, 19, or 26, or December 3 or 10). IAEA - INCAPS 4 - IRIS Survey

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 (m.dondi@iaea.org), 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.

WHAT ARE THE ROLES AND EXPECTATIONS OF NATIONAL COORDINATORS?

National coordinators are the key figures in ensuring worldwide participation. National coordinators are individuals who are well connected with the cardiac CT or nuclear cardiology practitioners, community, and professional society in their region or country and the ability and drive to facilitate their participation in INCAPS 4. We anticipate holding a few Zoom meetings for regional and national coordinators during the deployment of INCAPS 4, to answer questions. National coordinators who have not already done so should attempt to obtain lists of potential participants from relevant professional societies ASAP and provide this to the IAEA to include these individuals on INCAPS 4 related emails. Coordinators should also attempt to arrange with the professional societies and certifying authorities for these organizations to send emails to potential participants.

Beginning 15 October, coordinators should work with IAEA to monitor online data collection and contact sites to encourage participation. Such encouragement should be across the board, not focusing on particular classes of sites. It should be tailored to what the coordinators believe will be most effective in obtaining participation in that country.

It is essential for maintaining the scientific integrity of the study that regional and national coordinators avoid taking any efforts, at any time before or during data collection, that could influence or skew the data collected, which should derive from routine clinical practices. INCAPS 4 is purely an observational study. You should not be encouraging sites to use particular practices (e.g., low kV CT scanning or stress-only MPI) or even mention or hint of such practices to study participants or members of their practice. You should not be providing education to participants, before or during the study, as to how to practice cardiac imaging. Rather, it should be communicated to potential participants that INCAPS 4 is not a test of their practice. We are simply trying to find out what each centre is doing in 2023, so that further information can be gathered that potentially could help all of our practices in the future. Coordinators will also work with IAEA to contact sites for which missing data or errors are identified with their online data, to clean the data collected. Regional and national coordinators will be listed as such at the front of the authorship group for papers published from INCAPS 4. Coordinators should contact the IAEA contact point (INCAPS@iaea.org) and Principal Investigator (andrew.einstein@columbia.edu) with any questions that arise.

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 when allowed by the journal; and lists each member of the INCAPS Investigators Group by name. There will be separate investigators groups for MPI and CT.

3) If more than one person, from the same site, contributes to data collection, as in INCAPS 1, they will be included in the INCAPS 4 Investigators Group for co-authorship on papers (maximum two co-authors per centre).

4) 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.

[List of INCAPS papers is included under INCAPS references - Here.]