EXECUTIVE SUMMARY

EpiCap: Strengthening capacity in analytic epidemiology for causal inference- teaching for learning

This initiative intends to strengthen the capacity in analytic epidemiology at the University of Bergen (UiB), the Norwegian Institute of Public Health, and Innlandet Hospital Trust in Norway and in collaborating institutions in India and Sub-Saharan Africa. Further, EpiCap will strengthen the pedagogic skills of young epidemiologists in collaborating institutions and support them to become better communicators of research findings. They will be engaged as co-facilitators in courses held by scholars such as Profs. Krista F. Huybrechts, Matthew Fox, Håkon K. Gjessing, Kåre Mølbak, Tor A. Strand, and John Bradley. In this endeavor, we will draw on research by and experience of two of UiB leading pedagogues, Prof. Arild Raaheim and Associate Professor Monika Kvernenes. The co-facilitators and course participants are expected to pass on their acquired competence on to others within and outside our consortium.

The EpiCap initiative emerges from CISMAC, the Bergen Centre for Ethics and Priority Setting in Health (BCEPS), and the Centre for International Health (CIH) at the Department of Global Public Health and Primary Care (IGS) of UiB's Faculty of Medicine and the Department of Education at its Faculty of Psychology. The Society of Applied Studies with its Centre for Health Research and Development and the Indian Council of Medical Research with India's premier epidemiologic research institute, ICMR - National Institute of Epidemiology are our partners in India. In Sub-Saharan Africa, our partner institution is Makerere University School of Public Health in Kampala, Uganda. Aligning with the Research Fairness Initiative and in accordance with the Research Council of Norway's strategy on New Priorities for Global Health Research, CISMAC will endeavor to work in close partnerships also with other low- and middle-income country (LMIC) research institutions to further develop this initiative.

EpiCap's next upcoming course, "***Advanced epidemiology***" will be held by Prof. Matthew Fox and EpiCap co-facilitators in collaboration with ICMR-National Institute of Epidemiology in Chennai, India in January, 2024.

Strengthening capacity in analytic epidemiology for causal inference - teaching for learning (EpiCap)

This document outlines a strategy for training a cadre of researchers in epidemiologic concepts and methodology, both to foster their ability to undertake cutting-edge research and to teach analytic epidemiology geared towards causal inference. By supporting such an activity, the Centre for Intervention Science for Maternal and Child Health expects that the involved researchers will pass on their acquired competence to others within and outside our consortium. This is meant to be a "living document", i.e. is to be molded by the involved researcher-teachers.

Objectives:

1. Through participatory teaching and learning, strengthen our team members' skills in applying and teaching advanced analytic epidemiological methods for causal inference.
2. After a series of courses, the team members are expected to lead courses like those listed in this document.

Target group:

Postdoctoral fellows, faculty members and other researchers with solid expertise and a genuine interest in deepening their understanding of and their skills to teach analytic epidemiology.

Background and rationale

Our teams of researchers have experience in conceptualizing, developing, implementing, and analyzing *observational and experimental* epidemiologic studies. While the latter (randomized controlled trials or RCTs) are considered the gold standard for inferring causation, they are often neither ethically or politically possible nor required to generate effects with a confidence sufficient to guide public health or clinical action. Strengthening the capacity in advanced analytic epidemiology will enable our teams to design better studies and apply biostatistical methods that minimize confounding and other biases.

Improving didactic/pedagogic skills in analytic epidemiology. The best way to learn epidemiology is to combine a deeper understanding of its conceptual foundations with applying its methods and teach others about them. To hold high quality courses in epidemiology also requires skills in modern *pedagogic* principles, including student-active teaching and learning. Our courses will be held by leading scholars, such as Profs. John Bradley, Matthew Fox, Kåre Mølbak, and Tor A. Strand, and we will engage researches from our collaborating institutions as their co-facilitators. In the process of learning how to better teach epidemiology, they will also strengthen their own subject-matter understanding, as student-active teaching demands deeper reflection and comprehension. Good teaching skills will also strengthen the ability of the co-facilitators to convincingly communicate research findings.

PEDAGOGICAL TRAINING

Following an introductory workshop on modern pedagogic principles in teaching epidemiology, co-facilitators (i.e. the potential epi-cadres[1]) will develop data analysis exercises and co-facilitate subsequent courses in analytic epidemiology. Co-facilitator teams of 3-5 may be supported by other co-facilitators who will act as peer-reviewers and in other ways be their sounding boards when developing and running the exercise workshops. Prof. Arild Raaheim will lead the first workshop together with Assoc. Prof. Monika Kvernenes and they will give inputs on videotaped snippets of the computer exercise sessions organized by co-facilitators in later courses (they can at this stage not commit to attend these other courses in person).

[1]A co-facilitator will be called an "epi-cadre" once (s)he has contributed to courses #1, #2 and #3 and becomes part of a team that further develops and teaches the courses mentioned in this document or courses derived from them.

Only the prospective epi-cadres will be invited to the important "kick-off" course/workshop #1, while also additional participants (PhD students, postdoctoral fellows, scientists and faculty members) will be invited to the subsequent courses.

COURSES/WORKSHOPS IN ANALYTIC EPIDEMIOLOGY GEARED TOWARDS CAUSAL INFERENCE

1. ***Teaching and Learning epidemiology*:** Introductory course/workshop by Profs. Raaheim/Kvernenes and Sommerfelt ***16-23 February 2024*** (several co-facilitators also attended a SPEAKLAB workshop in effective presentation on Saturday 24 and Sunday 25 February)
    - Participants: Co-facilitators in subsequent courses.
    - Course text:
        - Pedagogics:
            - Raaheim: *A guide to better teaching at university*
            - Scientific articles provided by Profs. Raaheim/Kvernenes ahead of the course
        - Smith, Morrow and Ross (eds.): *Field Trials of Health Interventions*
    - Prerequisites for participation: Good understanding of analytic epidemiology, such as from studying "Epidemiology – an introduction", "Field Trials of Health Interventions" and having attended Profs. Rothman's and Ehrenstein's course in Bergen in April, 2022[2].
    - Content in brief: The course will be integrated with the last parts of the Centre for International Health (CIH) course Experimental epidemiology (5th to 23rd February) held for Masters/PhD students in Bergen:
        - Friday 16 February: Lectures for the co-facilitators by Raaheim: "Modern teaching and Learning in higher education" based on the Course text in Pedagogics (see above). The co-facilitators will also attend an introduction by Sommerfelt/Sandøy for the Masters/PhD students in preparation for the following week's RCT data analysis exercises.
        - Monday 19th – Wednesday 21st of February: During the Experimental epidemiology course, Profs. Sommerfelt and Sandøy will address *Key conceptual and analytic aspects of RCTs*. After a brief recapitulation of the counterfactual ideal underlying RCTs and some basic principles used in statistics applied to analytic epidemiology, the course initially demonstrates the analysis of data derived from a small vaccine trial, followed by hands-on exercises using data adapted from an RCT of zinc treatment of children with diarrhea. The co-facilitators will assess the teaching and learning activities, and are encouraged to support the students during the data analysis sessions.
        - After each course day, the co-facilitators worked in groups of three to develop suggestions for how they would enhance the course participants' learning.
        - Thursday 22 February and Friday 23 February, Profs. Raaheim/Kvernenes worked with the co-facilitators to develop plans and strategies for the parts of the upcoming EpiCap courses (#2 through #7) that the co-facilitators will lead.

2. ***Conceptual foundations of Epidemiologic Study Design and Analysis geared towards Causal inference***: This course, which was held in Bergen 21-27 May 2024 by Assoc. Professor Krista F. Huybrechts included a brief recapitulation of what was presented in the course held by Profs. Kenneth J. Rothman and Vera Ehrenstein in Bergen in 2022, and then proceeded with more advanced topics, including those most relevant for causal inference. It:
    - covered the last chapter (introducing advanced epidemiologic methods) of the *course text, Epidemiology - an introduction 3rd edition*,
    - illustrated key aspects using examples from Assoc. Professor Huybrechts pharmacoepidemiologic studies,

[2]For those who did not attend the Rothman/Ehrenstein course and want support when studying Prof. Rothman's book, please contact CISMAC attn. Iselin Henriksen Kvamme (Iselin.Kvamme@uib.no) who can give access to video recordings of its preparatory webinar series.

- presented the use of episheet, illustrating how it is not only an effective analytic tool but also contributes to better quantitative understanding, and ensures adequate specification of the analytic approaches used by other software, and
- encompassed computer analysis exercises developed and implemented by the co-facilitators. These exercises were done using both Stata® and R.

3. ***Advanced epidemiology***:
    - 3.a. November 11-14. Drs. Rizwan and Madhanraj will coordinate the course "Design and Analysis of Epidemiologic Studies for Causal Inference" at the ICMR - National Institute of Epidemiology (NIE) in Chennai for Indian scientists in preparation for:
    - 3.b. January 16-24, 2025, when Prof. Matthew Fox will hold his course arranged in collaboration with and hosted by the NIE at Hotel Halez in Mahabalipuram in Tamil Nadu, India. The course will be similar to that he held in Bergen in April 2022, expanded with half a day to 5 full days (January 16-21) to include a Q&A session and group work. The co-facilitators will thereafter jointly hold a 3-day workshop (January 22 to 24) with computer analysis exercises to illustrate the key aspects covered by Prof. Fox.
    - Co-facilitators' deadline for submitting the exercises to Drs. Rizwan/Loha: mid-November, 2024.

Courses #4. to #7. are yet to be decided upon but the scholars have in principle agreed to hold them.

4. **Outbreak investigation**: This 3-day course, by Prof. Kåre Mølbak, will include the following topics: Defining an outbreak, rationale for investigating outbreaks, outbreak detection[3], outbreak confirmation and description, hypothesis generation and analytical epidemiological approaches to investigate outbreaks, use of molecular microbiological methods, communicating outbreaks, controlling outbreaks by general and directed measures. The course will include group work and exercises prepared and taught by the co-facilitators in collaboration with Prof. Mølbak.

   The course will be followed directly by a 3-day course on "**Specific statistical approaches**" by Prof. Hugo Moreira (for more information, see below).

5. **Cluster randomized trials/stepped wedge studies**. Teacher: Associate Prof. John Bradley. For details, see https://www.lshtm.ac.uk/study/courses/short-courses/cluster-randomised-trials.

6. **Nutritional epidemiology**. Course teacher: Prof. Tor A. Strand. The course will address how RCTs can yield effect estimates quite different from the corresponding effects estimated in observational epidemiological studies, despite using appropriate strategies for confounder adjustment. It will also cover aspects of Effect Measure Modification (EMM), Generalized Additive Models (GAMs) and how GAMs can be effectively used to graphically present effects and EMM.

7. Together with Bergen Centre of Excellence for Ethics and Priority Setting (BCEPS), we plan to develop a course on **Equity impact studies**. Teacher(s): Tarun Shankar Choudhary and others. It will build on the existing UiB course "Equity and Fairness in Health - an Applied Approach to Ethics". This new course will cover the design, analysis and interpretation of both experimental (RCTs and stepped wedge studies) and observational studies.

For the epidemiology courses #2.-7., co-facilitators are encouraged to use their own data sets for the analysis exercises. The data sets can be truncated and modified to illustrate teaching/learning points such as confounding and EMM. Dr. Hans Steinsland has developed a computer program that generates epidemiological datasets (drawn from a large, constructed, population), where causal effects,

[3] https://www.cdc.gov/eis/field-epi-manual/chapters/Field-Investigation.html

confounding/selection bias and/or misclassifications can be specified. Co-facilitators are welcome to use the software to generate example datasets for their exercises.

In addition to the courses in epidemiology, we plan to organize two **courses in biostatistics** to strengthen the co-facilitators'/epi-cadres' biostatistical understanding of advanced epidemiology.

- Prof. Håkon K. Gjessing: **Advanced statistics.** Nepal (or India) Co-facilitators and participants are ahead of the course strongly encouraged to work through the course Prof. Gjessing held in Kampala 7-13 June 2023, "Fundamental concepts in medical statistics with applications to randomized controlled trials". Handouts and videos will be made available upon request from Iselin Henriksen Kvamme (Iselin.Kvamme@uib.no).
- Prof. Hugo Cogo Moreira will, immediately following the course on Outbreak investigation hold a 3-day course in "**Specific statistical approaches**" covering *Structural Equation Modelling* and/or ways to deal with missing data and suboptimal intervention compliance/fidelity in RCTs. Prof. Moreira will include exercises based on real datasets and invite epi-cadres and perhaps a few other course participants to provide their own datasets which they would like him to use in his course.

Courses under consideration:
Employing observational epidemiological methods to add information to estimates obtained from classical analysis of RCT data. We may invite Dr. Xabier García de Albéniz to hold such a course.

Course on bias analysis. We may approach Prof. Fox to hold a course on this important topic.

Process, credits and expectations:
The first epidemiology/pedagogics course (#1 "Teaching and Learning epidemiology") was held February 16-23 February 2024; with an optional additional two days' workshop with SpeakLab on presentation techniques.

Afte completing courses #1 (Pedagogics/condensed RCT analysis course), #2 (Conceptual aspects of epidemiology), and #3 (Advanced epidemiology), co-facilitators continue the track as so called "epi-cadres", a reflection of the competencies they have acquired. For the subsequent courses these epi-cadres choose which courses suit their interests and inclinations.

Process of supporting and shaping future teachers in epidemiology: As described above for courses #2, #3, #4, #5, #6 but also for further upcoming epidemiology courses, we encourage and support interested co-facilitators to enrich the courses with analysis sessions which illustrate and support relevant topics, using datasets provided by the main course teacher(s), their own datasets or datasets drawn from the constructed population created by Dr. Steinsland (see above).

Starting off with the learning on how to better teach epidemiology after course #1 in February 2024, the co-facilitators in the courses #2 to #7 (and subsequent courses) develop and implement data analysis exercises (for some of the courses together with the main course teacher). Those not engaged in a specific exercise can provide brief written feedback to those in charge.

Other participants in courses #2 to #7 and the statistics courses will include PhD candidates, postdoctoral fellows, and faculty members of collaborating institutions.

Credits: Participants can apply to their institution (e.g. UiB) to get credits for the courses based on the respective course descriptions, course schedules and defined course texts.

Expectations: As highlighted below, this endeavor represents a sizeable investment of teacher and co-facilitator time as well as of funds, primarily from CISMAC and, in the longer run, from other institutions contributing to this endeavor.

- This investment will in return strengthen the capacity in analytic epidemiology in the collaborating institutions, thereby increasing the prospects of developing high quality epidemiologic research. It

is our hope that, in the long run, this initiative will foster the formation of a cadre of LMIC and Norwegian epidemiologists striving for excellence in conceptualizing, designing, undertaking, analyzing and publishing important epidemiological research and that they will emerge as a pool of excellent teachers in analytic epidemiology.

- When developing the course exercises, the co-facilitators should be supported in their work by their peers (i.e. other co-facilitators) and by our collaborating institutions' faculty members or other senior scientists.
- The co-facilitators will submit their exercise sets to CISMAC attn. Sandøy/Sommerfelt/Loha within 6 weeks (excluding public holidays) before the course in question will be held. Sandøy/Sommerfelt/Loha will provide feedback, so that the exercises can be modified ahead of sending them to the course teacher no later than 2 weeks before the start of the course. This will ensure that the exercise material is of sufficient quality and adequately aligned with the main part of the course.
- As will emanate from the above, the co-facilitators/epi-cadres are expected to spend dedicated time preparing for and lead the data analyses sessions.
- We expect that the co-facilitators gradually develop their materials into epidemiology courses which can be organized by their own institutions. It is up to the main course teachers to decide if their materials can be used by these epi-cadres/their institutions, and if they do, whether they themselves wish to be involved in the courses.
- The material developed by the co-facilitators will be made freely available, e.g. based on a standard Creative Commons license at the CISMAC/Department of Global Public Health and Primary care (IGS) web pages and web pages of the institutions that hold the courses. A consideration will be made to the material is made available on an open-source platform.

Financing of and expected returns from the EpiCap initiative

CISMAC and suitable externally funded projects will support the development and implementation of the 7 listed epidemiology courses and the statistics courses that do not have funding from elsewhere. This contribution will be towards paying for venues and remunerating course teachers (and covering their travel, stay and board) as well as covering such expenses for co-facilitators from low- and middle-income country (LMIC) institutions that do not hold resources for such activities. Should the budget that CISMAC has approved fall short of the needs, the initiative will need to procure funding from elsewhere or cut back on the number or content of the courses.

The Department of Global Public Health and Primary Care at the University of Bergen (IGS) and possibly other Norwegian entities will also support the initiative through teacher/co-facilitator time and administrative support. High-income country (HIC) institutions and well-resourced institutions in LMICs are expected to cover travel, stay and board expenses for their own employees.

The co-facilitators will not receive payment or other remuneration (such as daily allowances) from CISMAC for their work towards the EpiCap initiative.

We will endeavor to avoid course fees for participants attending the EpiCap courses, but this initiative will not rule out the need to charge course fees for courses that the epi-cadres develop and hold in their respective institutions if such fees are necessary to sustain the courses. As the initiative matures and CISMAC funding is gradually phased out, the institutions involved in arranging the courses are encouraged to apply for other funding to sustain the initiative.

Bergen 14th of September, 2024

Halvor Sommerfelt (sign.)