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Epidemiology of chronic and acute pancreatitis in India (EPICAP-India): protocol for a multicentre study

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ABSTRACT

Introduction Acute and chronic pancreatitis (CP) are inflammatory conditions of the pancreas that cause local and systemic complications. The epidemiology of these conditions are not well-known in India.

Methods and analysis We describe the protocol and procedures of a multicentre study for delineating the epidemiology of pancreatitis in India. We plan to cover 110 000 people across 10 geographically distributed sites in 10 states of India to estimate the burden and risk factors of CP. Trained investigators will make house visits and screen for abdominal pain requiring hospitalisation or pre-diagnosed CP. The screened positive participants will be reviewed by a gastroenterologist to confirm the diagnosis of CP based on radiological imaging. For each case, four controls will be selected and data on risk factors for CP (tobacco, alcohol, family history, metabolic causes) and blood for genetic markers will be collected. Information on the cost of treatment and quality of life will be collected from patients with CP. For estimating incidence of acute pancreatitis (AP), hospital-based sentinel surveillance will be conducted in 10 districts across these 10 states. All hospitals in the district will be contacted to provide a line list of admissions due to acute abdomen including AP for 2 years. The spread of acute abdomen cases will be used to define the catchment area and estimate the denominator population. The line-listed cases with AP living in the catchment area will form the numerator to calculate the incidence. The study will provide critical information for planning pancreatitis-related services in the country.

Ethics and dissemination The institutional ethics committee (IECs) at all the participating sites have given their approval for the study. All the participants whose data will be collected will be included after written informed consent. The results may be presented at national or international conferences and will be reported in peer-reviewed publications.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ There is a lack of evidence on the burden and aetiological factors contributing to chronic pancreatitis in India. Its impact on the quality of life of patients, healthcare expenditure, and the economic burden is also not well known. There is thus a need to study prospectively the epidemiology of pancreatitis across India.

WHAT THIS STUDY ADDS

⇒ In this study, 10 academic institutions across India are collaborating to quantify the burden of acute and chronic pancreatitis in India.

⇒ For CP, the proposed study adopts a cross-sectional design covering more than 110 000 people above 18 years to assess the prevalence of CP. A hospital-based study will be conducted to assess the incidence of acute pancreatitis.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study will estimate the prevalence of CP, its risk factors and the annual incidence of AP in India using hospital-based surveillance for acute AP in 10 geographically defined areas across India. The data will be helpful in ascertaining the disease burden and aid appropriate resource allocation.

INTRODUCTION

Acute pancreatitis (AP) is an acute inflammatory disease of the pancreas that causes acute abdominal pain and various local and systemic complications.[1 2] In a recent review, the estimated incidence of pancreatitis was shown to vary from 30 to 80 per 100 000 people in different countries. Many studies from the same region have

reported an increase in the incidence of AP over the past two decades.[3–7]

Chronic pancreatitis (CP) is a progressive inflammatory disorder characterised by recurrent abdominal pain, diabetes, and malnutrition.[8 9] The predominant cause of CP is alcohol abuse in the Western countries while it is idiopathic in India.[10] The estimated prevalence of CP in Western-industrialised countries is approximately 10–15 per 100 000 people.[11] In Japan, the reported prevalence of CP was 44.5 per 100 000 people in 2000[12] and the prevalence of early CP was estimated to be 3.5 per 100 000 in 2019.[13]

The burden of any disease can be quantified in epidemiological (prevalence/incidence), utility (quality of life (QoL)), and economic (treatment or total economic costs) terms. Almost all patients with AP require hospitalisation or injectable analgesics due to potentially severe pain or complications. The mortality rate due to AP may go up to 40% in severe disease.[14] In the United States of America, AP accounted for 274 119 admissions annually with a more than $2.5 billion cost of treatment in 2009.[15]

The burden and epidemiology of AP and CP in India are not known. The only community-based study from Kerala, a southern state of India, estimated the prevalence of CP to be 125/100,000 in the late 1980s[16] in a population which was known to have high insulin-dependent diabetes mellitus (IDDM), a known complication of pancreatitis.[17] However, there has been no published community-based epidemiological study for AP or CP in India since then.

Considering the impact of pancreatitis on the social, economic, and QoL of patients, families, and society, it is important to conduct a population-based study to estimate the burden of these conditions in India. Given that these estimates are likely to vary across India as some of the known risk factors or consequences, like alcohol use or DM prevalence, vary between different parts of India, it is necessary to conduct a multi-site study that represents the diverse geographical regions of the country. This multicentre study is being conducted to estimate the burden (epidemiological, economic, and disability) due to CP and to identify environmental and genetic risk factors for CP in India using a case-control approach. In a parallel study, we will also estimate the annual incidence of AP in India through a hospital-based approach. Here, we outline the protocol and procedures adopted for this study to delineate the epidemiology of acute and chronic pancreatitis in India.

Methodological approaches for estimation of the burden of pancreatitis

Before designing the study, we reviewed methodological approaches adopted to estimate the burden of pancreatitis, drawing lessons for our study. Some of the key studies used for this review are available in online supplemental table 1. Some of the key aspects are outlined below.

1. The incidence and prevalence rates are low, below one per thousand. This has implications for sample size and resource use.
2. Incidence estimation typically requires a cohort approach which is very difficult and all studies on AP have linked hospital-based data systems with population registries or with a known denominator population. These studies have been facilitated using databases, often linked to insurance-based payments and the use of ICD codes (ICD-9:577A; ICD-10:K85).
3. For estimating CP, Japan has used hospital-based surveys with adjustment for non-response, linking to the national population.
4. Such studies may be possible in developed countries with organised databases and population counts, these will need to be modified in the Indian context.
5. Systems will have to be in place to remove double counting of patients, as they may either get admitted repeatedly or in different hospitals.
6. Most diagnostic criteria used in these studies included clinical characteristics followed by raised pancreatic enzyme levels with confirmation by radiological or histological diagnosis.
7. Some assumptions or adjustments would be needed to ensure that all incident cases within a given geographical area are included and the at-risk population is included in the denominator for hospital-based studies.
8. The burden of pancreatitis is quite low below 10–15 years of age.
9. Some studies have considered the first episode of pancreatitis rather than including multiple episodes in a person. A study from Poland used an admission after 60 days to define a new episode in the same patient.

Validation of screening criteria to be used for chronic pancreatitis

A question-based clinical criterion for suspecting pancreatitis has been planned for the study in consultation with expert gastroenterologists. The following questions will be used to screen for CP. All eligible household members will be asked whether they have:

1. Been admitted to a hospital due to acute abdominal pain in the last 12 months? Or
2. More than one attack of severe acute abdominal pain in the last 12 months? Or
3. Ever been diagnosed with pancreatitis?

Those screened positive will be investigated to confirm CP using the standard definition.

The validity of these questions (sensitivity and specificity) has been evaluated in a sub-study. For this purpose, confirmed CP cases were recruited from the department of gastroenterology of the participating sites and three times more non-CP cases from out-patients or healthy controls from other departments or caregivers attending the facility were interviewed. The staff were blinded to the respondent's status and the objective of the exercise. Across, nine sites, (at one site the study started later), we enrolled a total of 993 participants – 135 CP cases,

445 non-CP cases and 413 healthy people. The analysis showed an overall sensitivity of 98.5% (95% confidence intervals (CIs) 94.8, 99.6) and a specificity of 77% (95% CIs 74.2, 79.8) for identifying patients with CP. This has been considered acceptable for the study. Among CP, 86 patients had been admitted to a hospital for abdominal pain in the last 12 months, 93 had more than one attack of abdominal pain in last 12 months and 128 were aware of a confirmed diagnosis of CP (this was not surprising as this was done in medical college hospitals). Major causes of false positives among controls were AP (2.4%), dyspepsia (2.3%), cholelithiasis (1.4%), chronic liver disease (0.9%), and cirrhosis of the liver (0.9%).

METHODS AND ANALYSIS

Study design

The study design for estimating the burden and risk factors for CP involves a cross-sectional community-survey, and a case-control component to identify risk factors. A detailed descriptive study of CP confirmed cases for its economic burden and impact on QoL is also planned. A hospital-based component will be adopted for estimating the incidence of AP in a defined population.

Study sites

We identified a total of 10 study sites across 10 states representing geographical diversity and capacity to undertake large population-based studies (figure 1).

Component I: estimation of the burden of chronic pancreatitis

Sample size and sampling strategy

Based on an assumed prevalence of 0.125% (1.25/1000) from the Kerala study[15] with a relative precision of 15% and 5% level of confidence, a sample size of 107 060 would be required. Given that the incidence is quite low, clustering was not anticipated, and the design effect was also not considered. We plan to cover a total of 110 000 people (11 000 people at each site) in anticipation of potential non-response, equally between urban and rural areas (5500 each).

The strategy of multi-stage sampling will be implemented. Each participating site will select a block/district as the first step. Then, a list of Census Enumeration Blocks (CEBs) of the selected block/district will be collected from the district census office. Each CEB has 100–150 households. In the next stage, 17 CEBs, each from rural and urban areas, will be selected using a random number

Figure 1 Geographical distribution of Epidemiology of Chronic and Acute Pancreatitis (EPICAP) – India sites.

table. Assuming each household to have three members above 12 years of age, we anticipate roughly 300–450 participants from each CEB.

At each CEB, the study team consisting of field workers (FWs) and senior research fellows (SRF), will demarcate the boundaries of the selected cluster either using a pre-drawn map available from the census office or by doing the mapping themselves. They would number all structures within the demarcated area and identify residential structures. If the CEB has more than 150 households, it will be subdivided into segments of 50–75 households and two segments will be chosen randomly. If it has less than 90 households, it will be combined with a neighbouring CEB and use segmentation, if necessary.

A responsible adult available in the household will be approached for written informed consent to participate in the study. Subsequently, all individuals living in the household in the last 12 months will be listed. The screening questions will be posed to each person aged 12 years and older who has lived in the household for at least 6 months in the reference period. Assuming that CP is a serious medical condition, other adults in the household will be well-informed, hence information provided by proxy will be taken as adequate. Additionally, relevant socio-economic household-level data will be collected.

The SRF will visit all screen-positives later at a mutually agreed time to collect additional clinical data and review their medical and investigation reports. The records will be copied or photographed. These records will be evaluated by the site-specific gastroenterologist who will either rule out CP, confirm CP or, if necessary, suggest additional tests to confirm or rule out CP. The investigations will be done using study funds either close to the study participant's residence or at the participating medical centre whichever is convenient to the participants.

Diagnostic criteria for chronic pancreatitis

The diagnosis of CP will be made by a gastroenterologist based on suggestive clinical features (recurrent or chronic abdominal pain, steatorrhea, and/or diabetes mellitus) and pancreatic calcification and/or pancreatic ductal dilatation on any imaging test (x-ray, ultrasonography, computed tomography (CT) scan or, magnetic resonance imaging (MRI) of the abdomen) as reported earlier.**9**

All participating gastroenterologists will be sensitised to the case definition and this will be strictly followed. A senior gastroenterologist at the central coordinating site will review a sub-sample (10%) of confirmed and screened positives to ensure uniformity in the diagnosis or confirmation.

For all the confirmed CP cases, details of their treatment, direct and indirect costs borne in the last year, and QoL/disability estimation will be collected.

Case-control study

For each confirmed CP, we would identify gender and age (± 5 years) matched control in a 1:4 case-to-control ratio. Assuming a population exposure rate of 20% for a risk factor with 80% power and a 5% alpha error to detect an odds-ratio of 2.0, a sample size of 100 cases was computed. This matched with the prevalence rate assumed for the study and the sample size of the survey. The controls would be selected from a different CEB than the case (to avoid familial link), preferably from a CEB where no confirmed CP case is reported during the survey.

In both cases and controls, the SRF will administer a questionnaire on host, environmental and genetic risk factors. This includes tobacco and alcohol consumption, family history, gallstone disease, and metabolic workup (lipid and thyroid profile). For genetic risk factors, the 10 most prevalent single nucleotide polymorphisms (SNPs) in the genes SPINK1, CFTR, CTRC, and CLDN2/MORC4 found in Indian patients with CP will be tested.

Ten millilitres of blood will be drawn from each control and case for the genetic and biochemical assays. The serum samples will be stored at −80°C and will be shipped to the central laboratory located at AIIMS, New Delhi. To control pre-analytic variations resulting from the sample collection, storage and transportation; a training session detailing these issues will be organised for the participating laboratories before the start of this study component.

Statistical analysis plan

The prevalence will be presented as a point estimate with 95% CI after combining populations from all sites on standardising to Indian population age and sex structure. The mean (SD) and median (IQR) cost of treatment will be presented and the proportion of cost contributed by different components will be presented. Adjusted odds-ratio with 95% CI for risk factors will be calculated from the case-control study.

Study duration and current status

The study was initially supposed to start collecting data from 2022 onwards but there was a delay due to the 2019 coronavirus pandemic (COVID -19) pandemic in recruitment of staff and inability to conduct house-to-house surveys. Currently, the field data collection at all sites is expected to end by December 2024 and the completion of the study and data analysis is anticipated in June 2025.

Component II: Hospital-based acute pancreatitis component

In component II each study site will identify a district as its study area. We adapted the procedure described in the WHO document "A manual for estimating disease burden associated with seasonal influenza".[18] This entails identifying all AP cases from a defined set of hospitals in the study area and demarcating their catchment area and their population to estimate the incidence of AP.

Based on the information available from the district authorities, a provisional list of hospitals (both public and private) will be prepared. From this list, hospitals with fewer than 25 beds, and specialty hospitals

(gynaecologic/orthopaedic) will be excluded. The remaining hospitals will be visited and consent for participation will be obtained. Each participating hospital will be requested to provide a line list of patients admitted with acute abdomen (DB10, DC12, DC11, DC31, DB30, DB32, ME24, DC70, DA61, DA62, DA94, DA25, DA60, DA63, DA91, and GB70) during 2022–2023. Depending on the start date at the site, some of this data collection would occur retrospectively and some would occur prospectively. For each patient we will ask for data on hospital ID, age, sex, colony of residence or, pincode, diagnosis, and date of admission. If data is already available in electronic form, it will be collected. If available only in registers, these will be transcribed manually into the Open Data Kit (ODK) platform (Version 2023.3.1)[19] or an Excel sheet. Based on the given colony or pincode, their geographic coordinates will be identified.

Case definition of AP

The diagnosis of AP will be made if any two of the following criteria are fulfilled: (i) Suggestive clinical features (pain in the upper abdomen); (ii) At least a 3-fold rise in serum amylase/lipase; and (iii) Imaging evidence of AP on abdominal ultrasonography and/or CT or MRI scan of the abdomen. The classification of AP will be as per the Revised Atlanta classification.[20] Efforts will be made to ascertain the basis of diagnosis by reviewing records, especially from the bigger contributing hospitals.

Numerator ascertainment

This line list with AP cases will combine the information from all the participating hospitals to form one dataset. Based on the date of admission (± 60 days), pincode, age, and gender, repeat admissions/referrals will be deleted to account for double counting. The final list of unique AP cases will be prepared separately for 2022 and 2023.

Denominator ascertainment

This series of steps will define the catchment area and its population. The steps [figure 2] include:

1. Start with a map of the district and the projected population of that district for the year 2022.
2. Map the location of all the eligible health facilities (both participating and refused).
3. If there are too many hospitals or the district is big, identify a population of up to 1 million within the district for further study.
4. Prepare a spot map based on the geographic coordinates of all line-listed acute abdomen cases from participating hospitals including those outside the district.
5. Confirm telephonically the veracity of the address in at least 100 participants (50 acute abdomen and 50 AP cases) at each site to estimate the proportion of patients from outside the districts.

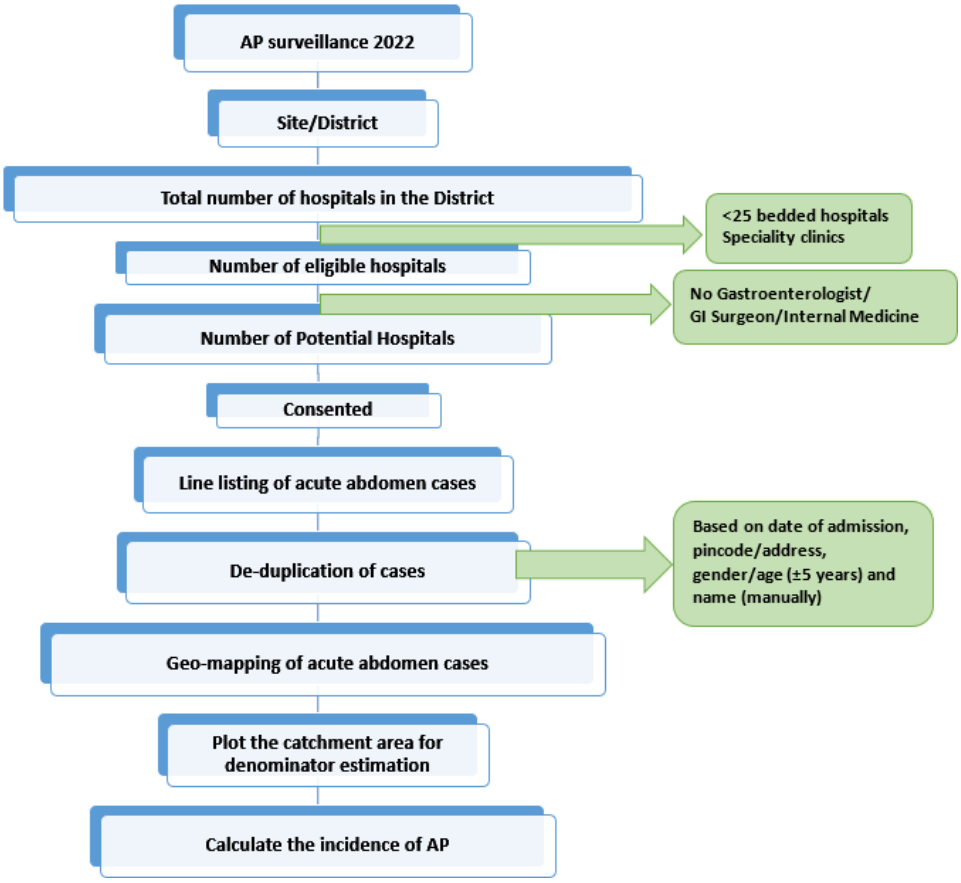

Figure 2 Schematic representation of the methodology for estimating the incidence of acute pancreatitis.

6. Look at the distribution of the cases in the district and check whether there are any areas in the district which are not contributing the patients or any areas of the adjacent district from where many patients are coming.
7. In the spot map shade the areas that deliver most of the cases to the participating hospitals (this should cover at least 80% of the cases).
8. This will be the final catchment area of the sentinel sites. This will be either a partial area of the current district or it could include a part of the neighbouring district or both. The default approach will be to take the full district.
9. Identify the villages/colonies inside this defined area and obtain population data for this area from census or municipal records. These will be extrapolated to the population estimate for 2022.
10. If the adjacent district is to be enclosed, we will consider additional eligible health facilities that could be included to add pancreatitis cases.

Estimation of incidence

The total number of AP cases identified by hospital surveillance will be divided by the estimated population of the defined catchment area to derive the annual incidence of AP per 100 000. The incidence estimate will be presented with 95% CI. The estimate will be adjusted for non-response of health facilities and the proportion of patients from outside the districts. The incidence will be presented by sex and broad age groups.

Training

The central study coordinating team (All India Institute of Medical Sciences, New Delhi -AIIMS) and the data management team (Translational Health Science and Technology Institute, Faridabad -THSTI) will organise a 2 day training course the will be phased in for the sites in three clusters. The training will cover the study protocol, questionnaire completion, data capture in an electronic platform, blood sample collection, processing and storage, study operations and, good clinical practices (GCP). The training will also include mapping and listing households. On day 2, the team will have field training for hands-on practice in mapping, listing and data capture on the electronic platform. The discussion followed by this activity will help the researchers to take corrective measures and achieve more clarity and confidence. After the training and before starting the main survey at each site, a pilot will be executed in one CEB (not selected for the main study).

Study tools

There are seven pre-designed forms in the electronic platform for data collection (online supplemental table 2). These include: the household screening form for all eligible participants, pancreatitis clinical assessment for screened positives, form for risk factors for cases and controls, burden of pancreatitis form for confirmed CP, and hospital resource utilisation form for assessing the burden of CP on healthcare, and hospital abstraction sheet for all acute abdomen cases and to screen potential AP cases.

Data management

The Data Management Centre (DMC) at THSTI-Clinical Development Services Agency (CDSA) is in charge of managing data, creating paper and electronic-based data capture employing ODK, and assisting with formal analysis, data curation, and final reporting. A comprehensive data management plan has been developed to organise and manage the data ensuring data integrity and security throughout the study duration. This began with the designing of questionnaires in consultation with the study research team. The version-controlled questionnaires are securely maintained at the DMC, THSTI. The electronic version of the questionnaires will be designed on the ODK platform[19] on the approved final version. This application allows both online and offline data capture using mobile devices or tablets. The questionnaires will be translated into the local language and these will be incorporated into the electronic version.

In the preparatory stage, the edit checks and validation rules will be implemented in the application to minimise errors during the study database development. Database testing will be performed and approved by the clinical site users during the pilot run of the study. The tested database will then be migrated into the live environment for real-time data capture through mobile devices. The data management (DM) team will develop data checks to ensure the quality of collected data. A query management protocol will be developed wherein the queries generated manually by the DM team will be available online to the respective SRF for their response. The DM team will be responsible for reviewing and closing of the query responses. They will also track the status of all the queries generated and ensure that the queries are addressed in a timely way and satisfactorily until their resolution. The DM team will also send out the weekly status of each site to the respective research team.

Study management

The entire study has been conceptualised and designed by the research team from AIIMS, Delhi, which serves as the study coordination site. The principal investigators will oversee the project's management, administration, or execution at each study site. The site research team consists of researchers or investigators from each of the collaborating institutions (from the departments of gastroenterology/GI surgery, internal medicine, and community medicine) along with the research project team (three FWs and one SRF with a medical background).

ETHICS AND DISSEMINATION

The institutional ethics committee (IECs) at the participating sites have given their approval for the study (Institutional Ethics Committee approval numbers: AIIMS/IEC/2021/3875; IEC-163/06.03.2020, RP-23/2020; IHEC-LOP/2022/EL018; IEC/Pharmac/2023/649; HFW(MC-II) B (12); ETHICS/2020/20923;107 ECM IIA/P1; HEC NO:09/36/2021/MCT; IPGME&R/IEC/2022/063; MC/190/2007/p1-II/Feb 2022/1; IRB Min. No. 13753/27.010.2021; THS1.8.1/(126) (online supplemental table 3).

After written informed consent, data from all consenting participants whose data will be collected will be included.

The results may be presented at national or international conferences and will be published in a peer-reviewed journal.

DISCUSSION

The study's mixed approach, which measures the burden of both acute and chronic pancreatitis in India, makes it distinctive in its design. Considering the chronicity of the disease, we have designed the study through a nationwide household survey to estimate the prevalence of CP, whereas to estimate the burden of AP, the study design adopted is through hospital surveillance. The study will also assess the risk factors of CP through a case-control study.

The prevalence and incidence of CP has been studied in many countries through large-scale, nationwide epidemiological surveys. This includes Japan[7] (since 1970), Denmark,[21] Germany,[22] the Czech Republic[23] and France[24] at various timeframes. However, most of these studies were in developed countries with well-defined catchment areas and a likelihood of all cases being captured by a hospital-based design. In our context, we have adopted a screening test in the population to identify probable CP cases that would undergo a confirmatory test. It had a high sensitivity and modest specificity when tested in a hospital setting and is likely to not miss any CP cases. The second challenge is ensuring that all those screened positive undergo a confirmatory test. This will require study participants who are screened positive but who have not been fully investigated to travel to the study hospital or to have the necessary investigations done from a facility near their residence. We aim to achieve a low dropout rate at this level and will adjust for this in the estimation of prevalence. The denominators for the CP will be sourced from the survey itself and this is likely to be robust. Special efforts are being made to draw the boundaries of each block before initiating the survey followed by rigorous mapping and listing of residential structures.

Since our population screening is based on the question of abdominal pain requiring hospital visits or recurrent abdominal pain, it may lead to underestimation of the prevalence of chronic pancreatitis (CP) because many patients with CP might have either painless disease or milder pain or present with diabetes. We have earlier reported that around 10–15% of patients with CP present without pain or milder pain.[9] Thus, we recognise that we may underestimate the prevalence by at least 10%. However, the problem is that diagnosing such patients will require an extensive population-based screening study with advanced imaging including MRI and endoscopic ultrasonography (EUS). Few studies on the prevalence of CP are based on population screening using advanced imaging.

There might be significant challenges in determining both the numerator and denominator in estimating AP incidence. For the denominator, two major issues are the delimitation of the catchment area and the estimation of its population. The level of difficulty is likely to vary by site and will be documented. As described in the method above, all due steps will be taken to ensure that the catchment population is defined properly and all AP cases within that area are identified. We also plan to ensure that double counting is not done within these facilities. We will ensure that the identified cases of AP comply with the study diagnostic criteria. An additional difficulty could be in getting the geocode of AP cases, as our preliminary observations show that at the time of admission often a complete address is not provided or patients from other districts often provide an address of a local contact at the time of hospitalisation. We will confirm the address in 10% of cases by direct questioning. The study also assumes that all AP cases seek care in a hospital. Therefore, there is a possibility that we might miss some patients with AP with mild pain who are either not hospitalised or are not tested for pancreatitis. In most published studies on the incidence of AP, the data have been derived from hospitalised patients and extrapolated to the community. This has remained a challenge in most studies even from developed countries. We have excluded small hospitals because AP is a disease which leads to early referral to larger hospitals where specialists are available. However, there is still a possibility of under-estimation of the incidence of AP.

While our study sample is not truly representative of India, we believe that 10 geographically spread sites across 10 states in the country should provide a fairly good assessment of the epidemiology of pancreatitis, at least in the states where the study is being conducted.

Despite these challenges, our strengths will be regular training, coordination and close monitoring by project coordination and the Indian Council of Medical Research (ICMR) Taskforce, the centralised DM team at THSTI, and the use of digital data collection tools and the rigorous procedures being followed.

As one of the by-products of the survey, we will be creating a cohort of AP cases for a longitudinal study to understand the aetiology and pathophysiological aspects including risk factors that contribute to the progression of the disease. The study will delineate

the prevalence of CP, its risk factors, the QoL of the affected and the financial impact on the family and health system level and ultimately assist in the planning and formulation of health programmes.

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Contributors PKG and AK - Conceptualisation, methodology, resources, writing - original draft, writing - review and editing, supervision, project administration, and funding acquisition. DP, and RA - Writing - original draft, supervision, validation and project administration. NW and VB – Data curation and writing - review and editing. AA, SSB, PB, BC, SDC, DD, PD, KD, GKD, AG, SJ, RK, SanK, SR, RS, BS, SS, CS – Resources, investigation, site supervision, writing - review and editing. VA, AS, DG, SauK, GKM, Sh, NM and SD - Writing - review and editing. AK and PKG are the guarantors.

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Competing interests None declared.

Patient consent for publication Consent obtained directly from patient(s)

Ethics approval This study involves human participants and was approved by Institutional Ethics Committee, All India Institute of Medical Sciences (AIIMS), New Delhi IEC-163/06.03.2020, RP-23/2020AII India Institute of Medical Sciences (AIIMS), Jodhpur, Institutional Ethics Committee AIIMS/IEC/2021/3875AII India Institute of Medical Sciences (AIIMS), Bhopal, Institutional Human Ethics Committee IHEC-LOP/2022/EL018AII India Institute of Medical Sciences (AIIMS), Nagpur, Institutional Ethics Committee IEC/Pharmac/2023/649Indira Gandhi Medical College & Hospital, Shimla HFW(MC-II) B (12) ETHICS/2020/20923King George Medical University, Institutional Ethics Committee, Lucknow 107 ECM IIA/P1Human Ethics Committee, Government Medical College, Thiruvananthapuram HEC NO:09/36/2021/MCTInstitute of Post Graduate Medical Education & Research, IPGME&R Research Oversight Committee, Kolkata IPGME&R/IEC/2022/063Office of the Principal-cum-Chief Superintendent, Guwahati Medical College & Hospital, Guwahati MC/190/2007/p1-II/Feb 2022/1Office of Research Institutional Review Board (IRB), Christian Medical College, Vellore IRB Min.No.13753[OBSERVE]27.01.2021Institutional Ethics Committee Biomedical and Health Research, Translational Health Science and Technology Institute, Faridabad THS1.8.1/(126) Participants gave informed consent to participate in the study before taking part.

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