Minutes from the meeting in "SBPC Expert Forum" January 24th, 2020

Asbjørn welcomed the Forum and made an outline of the concept with this meeting being the 7th. As usual the group has changed over time, and people are coming in and out but we are > 30 experts in the group and 24 participating today including surgeons from Northern Germany. A short presentation round was made (name, country, main interests).

Stephan: explained about the progress in the Forum and the growth, The idea was raised whether we shall include recurrent acute pancreatitis and pancreatic cancer and whether or not we shall include more centres. He stressed that we now have access to a huge number of patients and also that the data quality has to be optimal.

Camilla shortly presented the homepage. There is need for an update of papers and it shall be linked to EPC, and the SBPC meetings (forthcoming in Stockholm).

Asbjørn presented status of the database. There were no new changes for statutes but these were briefly discussed and the revised database SC was presented with Miroslav presenting Stockholm and Tobias Northern Germany. Mylan representatives (also from the global team sponsoring the meeting) participated in the meeting and we are grateful for their support.
The papers proposed in 2017-2020 were presented (slides in the end of the minutes, with blue fond for those submitted/published). There are several new studies proposed but our main challenge is the prospective registrations.

Jakob showed the enrolment of patients at the different centres and the quality of the prospective data (see slides at the end of minutes). It shall be added to the statutes that only patients that are followed regularly can be considered valid as prospective records (see later). Completeness of follow up data were shown (se slides). There could have been a data validation option, but that will be for future databases.
There was a lot of discussions on how to recruit patients (involvement of nurses, students etc.) and the data quality, including referral bias and timepoints for follow-up. Patients that have not been followed up can be excluded, but that may worsen the bias – on the other hand this is real life and also happens in other databases. We can learn from HIV databases where many sites pay for data managers prize goes down – this will be discussed in the future. EPC could also host the database, but then it will not be anchored at SBPC any more – to be considered. On option is to reset the database, but that will mean that we lose a lot of data and gives no guarantee for better data. Jakob volunteer to make a video showing the data quality of each centres own data.

After lunch we continued with the database discussion:

Johanna presented her involvement in a lot of prospective databases and the quality of these. She stressed that dedicated doctors/nurses/secretaries are mandatory if it shall fly. The drop-out is in general low if it is decided that patients shall be followed up e.g. at year 1,2 and 5. There is ethical approval by signed permission in Finland, and GDPR problems were solved.

Matthias suggested that the database is affiliated with EPC and officially be part of this society. Also that a data manager is needed, and that the cost does not need to be more than 1000 Euro/year per site if there is e.g. 10 sites. It could be a secretary under the supervision of Jacob.

Asbjørn wrapped up with a round table discussion: it will be nice with a database manager but some sites have very little money for research, a visit every 2nd year is realistic, a working group changing the statutes is needed, but could likely be an initiative from Aalborg to be circulated to the group.

According to the agenda the different centres then presented their research:

Matthias presented the local database in Stockholm and patients reported outcome measures together with the projects within hereditary pancreatitis (>100 patients); gender differences/portal thrombosis studies to start after IRB approval of RedCap that has stalled everything currently because of GDPR. The AIP database was presented with about 620 patients (PRESCRAIP database with offspring in SBPC database and Jakob as data manager). Finally the program for the 2nd SBPC meeting was presented with a master class in pancreatology on Wednesday before the official meeting. There will be posters, break-out sessions, prizes and a formal structure for the SBPC with statutes etc. Funding was also discussed, there may be some money from EPC as we can document a huge database with 5-6 publications and therefore we can also approach UEG. It was also discussed whether we could move into cancer as the funding possibilities are better there.

Johanna presented Tampere University Hospital with its satellites and a big volume with 65 beds in the GI ward and > 60,000 outpatient visits yearly, with a steady increase due to centralization of surgery etc. The teamwork was stressed. The different registers and databases were also highlighted including complications to surgery. The different research groups were shortly presented, and about 80% of doctors have a PhD and most are involved in research. Tampere Pancreas Group include 11 senior and 7 PhD students together with 2 nurses and 1 lab technician. Research has changed the clinical guidelines and the centralisation for surgery.
Round the table about 80% of consultants in Finland, 80% in Sweden, 75% in Norway, 50% in Baltics and 50% in Denmark (with large variability from 90 to 2%) have a PhD. Germany has another tradition, but most consultants have co-authored > 5 papers.
The surgical projects in the SBPC database was also discussed. 1327 patients from 8 centres were included with data from the database + an extra sheet for complications. Seven percent had surgery with a two-year median follow-up. Most patients having surgery are from Oslo and Kaunas/Tampere, but most patients that have ERCP are from Hvidovre. Most surgical patients were operated due to pain (55%) and preliminary data were presented. GDBP was also mentioned and the problems accordingly.

Anne presented "Rigshospitalet" in Oslo with the HPB surgical unit and a referral area of nearly 3 MIO persons. Ulleval is another centre with about 20,000 outpatients where Truls is working. The organization is discussed with many hospitals (i.e. acute pancreatitis in Ulleval) and there is no pancreatic centre. There are less resources for surgery in chronic pancreatitis as most is used for malignancies. Different efforts have been done to make MDT meetings for chronic pancreatitis and discussions especially for those suggested for interventions. TPIAT indications were also discussed and is now established in Oslo as well as other preliminary data among them in chronic pancreatitis.

Uli presented the new hospital in Lübeck with 2,500 beds and a high degree of centralization. All pancreatic cases are recorded in a German database and there is a huge biobank. Many studies in pancreatic surgery have been performed and many are ongoing. The focus is as elsewhere cancer, but still there is room for

chronic pancreatitis. Patients reported outcome measures are reported routinely and there is collaboration with other groups in countries such as Holland. A lot of lab work is ongoing and examples presented.

Giedrius presented Kaunas and the department of HPB surgery where about 50 pancreatic resections are done yearly, about 50% are patients with chronic pancreatitis where Beger/Bern/Frey and Whipple procedures are done with Beger the most common. The Lithuanian University of Health Sciences also host facilities for basic research. It was considered to use the database to look into artificial intelligence and big data analysis, especially with the possibility to look into the radiology features to rule out cancer.

Riga was for different reasons not prepared for a presentations as there was a mismatch in the invitation list and who actually came.

Trond focused on the ongoing studies with the database. Smoking was the factor that mainly predicted the complications with a dose relating increase of risk. The imaging module studies were also presented with 7 centres included in these studies. The many data were shortly listed and relationships with clinical data shown. Manuscripts are circulating and will be presented for the whole group shortly. The discrepancies between the different studies done were also discussed and it was argued that we need the same criteria for low elastase, high alcohol use etc. There is an impressing portfolio of projects, but time didn't allow the presentations.

Camilla and Srdan presented the new pancreas centre (PACE) at Hvidovre with the structure and the different national and international collaborations. The multidisciplinary approach was shown and how it is embedded at the primary department of gastroenterology. The clinics span from acute to acute recurrent and chronic pancreatitis. The research is focused on complications to acute and chronic pancreatitis, extrapancreatic complications, fibrosis (most studies) and the database. Follow-up studies are included together with different other sites. The pancreatic function tests were discussed and how to get secretin today, which seems to be very difficult if possible at all.

Nanna presented Bispebjerg Hospital that is one of the major referral units in Copenhagen with > 500 beds. Surgeons and gastroenterologists are together in the ward (56 surgeons and 28 gastroenterologists). All PhD students but one are studying surgical problems, but the plans are to subspecialize into HPB in gastroenterology as well, and big efforts are undertaken to find patients for the database with good follow-up data. Other projects are mainly done in collaboration with other hospitals in the Copenhagen region.

Jens and Søren presented the work going on in Aalborg. The imaging module was shown with the associated projects. The first manuscript (under review) describing the module with interobserver reliability was shown. Prospective data were presented showing that tissue changes are more important than the duct structure and diameter, showing how important prospective data are. There are about 40 projects ongoing at the centre, and **Søren** showed a subset with focus on some of the studies in pipeline. One is predicting outcome with quantitative sensory testing together with different sites including Hvidovre, and another study in progress is in acute and acute recurrent pancreatitis with an opioid antagonist working outside CNS only (PAMORA).

Alexei presented different studies in AIP and inflammatory bowel disease where they looked at the pancreatic complications. Also different clinical forms of pancreatitis was explored. Collaborative studies together with the surgeons were also shortly presented with prospective data on the microbiome highlighted.

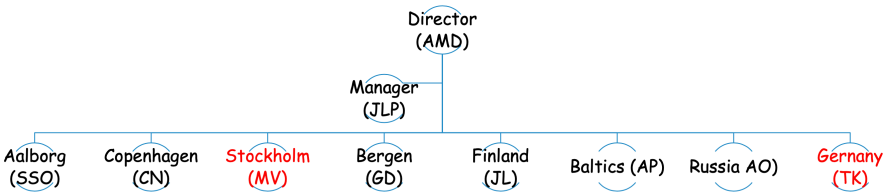
Enrolment for the database is running. Lastly the structure of Russian hospitals was discussed where most are now private and only persons that can afford it are offered optimal service.

As we did discuss granting possibilities during the meeting, Camilla did present the possibilities for applications

Finally, **Asbjørn** shortly discussed the future of the Expert Forum and how this valuable initiative can continue. Mylan are still willing to support us and it was decided that the SC (merged with the database SC) will meet at EPC in Paris to make a program for 2021. Next year (28th to 31th January 2021) the German Pancreatic Club will meet in Lübeck and Tobias invited us to join. In case the Expert Forum could meet half a day for the yearly meeting and there could be a shard session entitled something like "How the SBPC has developed and expanded into the German area". The other possibility was to have the meeting as usual the 22nd January and then some from SBPC could join the German meeting still having the session. A round table discussion was pro and con as it is easy to reach Copenhagen for a one-day meeting, but on the other hand a new meeting structure could be refreshing. There will be a voting among participants in the Expert Forum send out with the minutes, and only those that answer within a week will be considered.
It was also highlighted that any new proposals for the database 2020 shall be submitted before March 31st according to the statutes.

Copenhagen, 24th January, 2020 Asbjørn Mohr Drewes

Database organisation by January 2020



Proposed studies 2017 (blue – submitted)

1. Description and status (Olesen et al. SJG 2017)
2. Regional study (Aalborg) - taken off the list
3. Clinical phenotype (Aalborg)
   a) Olesen et al. Factor analysis. AJG 2019
   b) Olesen et al. Pain study. J Gas Hepatol 2019
4. EPI (Bergen, Erchinger et al.). Problems with data completeness solved. First round send for commenting and awaiting new statistical analysis. Expect final draft 2020
5. Smoking and alcohol (Bergen, Tjora et al.) Submitted Pancreatol 2019
6. Genetics (Stockholm) – will be changed to a study with fewer centres and taken off the list

Proposed studies 2018

1. Calcifications (Aalborg, Olesen et al.– published Pancreatol 2019)
2. Diabetes in CP and risk factors (Aalborg, Olesen et al. UEG Journal 2020
3. RAP and hereditary (Stockholm) -is has same problems as the genetics study and will be taken off the list
4. AIP (Stockholm) – is changed to a European database study and taken off the list
5. Imaging manual description (Bergen) – taken off the list and presented together with the 2019 validation study proposed by Aalborg

Proposed studies 2019 to January 2020 (note that most are special modules)

1. Surgical intenvention (repeat from 2017) (Tampera, Johanna) – presented as two surgical and endoscopic studies, and a follow-up study
2. Validation of imaging database (Aalborg, Lisitskaya et al. resubmitted to Abd Radiol 2019
3. Progression of early CP from imaging database (Aalborg) – will be postponed due to few prospective registrations and overlaps with the next imaging studies (taken off the list)
4. Gender differences in CP (Stockholm, Stefan) – is to be continued in 2020
5. Risk factors associated with splenic/portal vein thrombosis (Stockholm, Stefan) – the database will be used to identify the probands and the rest shall be found in medical records
6. Prevalence of type 1,2 and 3 diabetes (Stockholm, Miroslav) – will be taken off the list as our data quality does not allow the analysis

Proposed studies 2019 to January 2020

7. Prevalence of type 1,2 and 3 diabetes (Stockholm, Miroslav) – will be taken off the list as our data quality does not allow the analysis
8. Quality of life (demographics and clinical characteristics) (Hvidovre) – status – will be discussed at a working group today
9. Imaging changes and etiological/demographics/complications (Bergen, Trond) – to be submitted 2020
10. SPBC imaging module used to to extract imaging scores from M-ANNHEIM and Cambridge including interobserver reproducibility (Bergen, Ingrid Nordås) – expected submission in 2020
11. New: **Prospective** imaging study relating to etiological and demographic factors (Bergen, Trond) – to be presented today and links to next slide

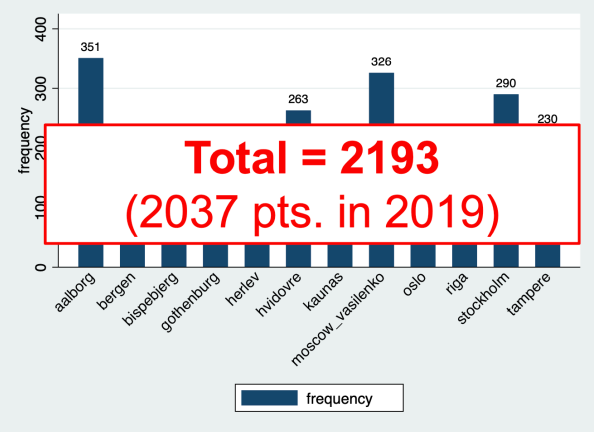
Potential follow-up studies

1) Pancreatic insufficiency (the natural disease course):
- EPI
- DM including Hb1AC

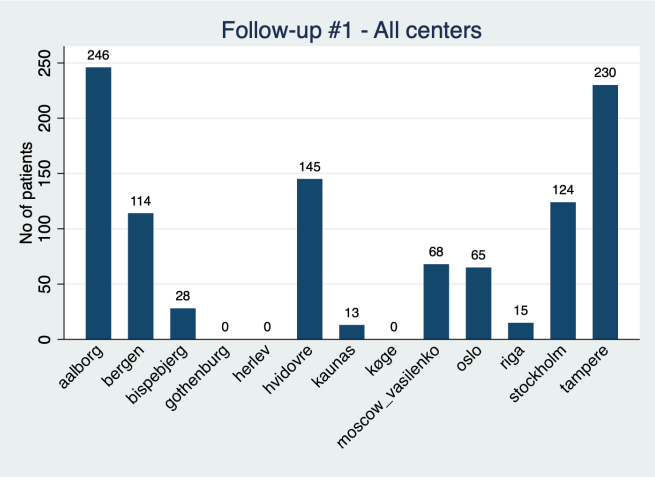
2) Complications to CP in a 5-year period (duodenal stenosis, common bile duct stenosis, GI bleeding, pseudoaneurisms, fistula, thrombosis, cancer)
3) Nutritional status of CP, progression over time (BMI and PERT, blood tests from medical records)
4) Pain progression in CP, a longitudinal study – type and intensity, analgesics (from medical records), mBPI
5) Risk factors (toxic) – will they change over time and relation to complications (stenosis of CBD etc.)?
6) Quality of life (QL30), stability and relation to other risk factors
7) Other "modules" in subgroups

Baseline as of 22nd January 2020

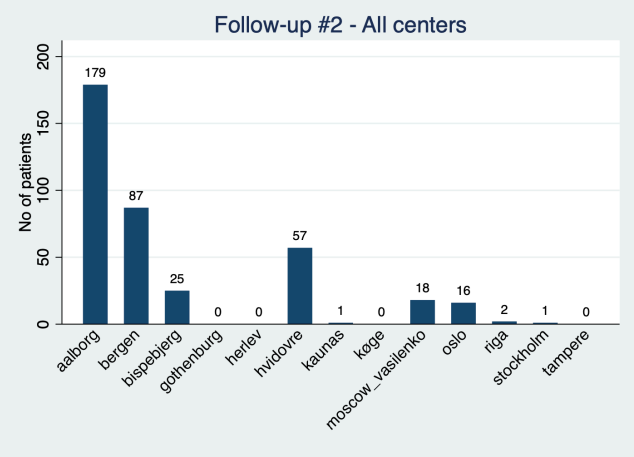
No of baseline visits/patients (with CP!)



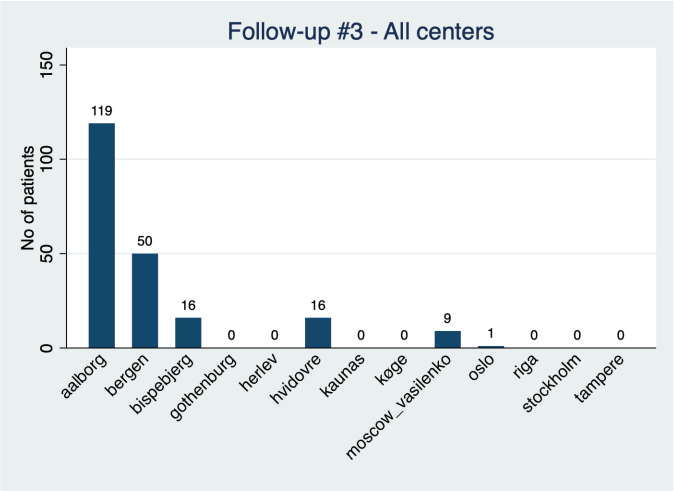
Follow-up visit #1, January 2020



Follow-up visit #2, January 2020



Follow-up visit #3, January 2020



Completeness (%) of follow-up data

MANDATORY (1878 visits)	
Weight	78
Reversible complications	
- Common bile duct stenosis	72
- Duodenal stenosis	72
Irreversible complications	
- Portal vein	72
- Splenic vein	71
Pain report	81
Pain control	79
Smoking: status	78
Smoking: pack years	32
Exocrine (categorical)	79
Diabetes yes/no	80
Hba1c	52
OPTIONAL MODULE	
Nutritional: F-elastase*	15
Albumin	50
D-Vitamin	41