# Table of Content

Preface ............................................................................................................................................................... 4

1. Purpose ...................................................................................................................................................... 5

2. Introduction ............................................................................................................................................... 5

3. Database Content ...................................................................................................................................... 6

   3.1. Variables ............................................................................................................................................ 6

   3.2. NPU terminology and the DNK codes .............................................................................................. 6

   3.3. National short names (NKN) .............................................................................................................. 8

   3.4. Analysis codes .................................................................................................................................... 8

4. Project guide .............................................................................................................................................. 9

   4.1. Contact group and collaboration ....................................................................................................... 9

   4.2. Documentation .................................................................................................................................. 9

   4.3. Initiation .......................................................................................................................................... 10

   4.4. Identifying biomarkers in the LABKA database ............................................................................... 15

   4.5. Data management ........................................................................................................................... 17

      4.5.1. Errors ....................................................................................................................................... 17

      4.5.2. Completeness .......................................................................................................................... 18

      4.5.3. Traceability .............................................................................................................................. 18

      4.5.4. Comparability .......................................................................................................................... 19

   4.6. Data analysis .................................................................................................................................... 20

   4.7. Interpretation .................................................................................................................................. 22

5. References and links ................................................................................................................................ 23

   5.1. NPU terminology and NKN .............................................................................................................. 23

   5.2. Links for lists of analyses ................................................................................................................. 23

   5.3. Guides for data management and analysis ..................................................................................... 24

   5.4. References ....................................................................................................................................... 24

   5.5. Previous KEA studies with LABKA .................................................................................................... 24

Appendices ...................................................................................................................................................... 26

Appendix A. Codes for municipalities and regions ...................................................................................... 26

Appendix B. List of contact persons ............................................................................................................ 33

Appendix C. Checklist for data management ............................................................................................. 34
Preface

The LABKA database is one of many Danish health databases available for research. When combining it to the other existing health databases in Denmark, endless opportunities for high-quality and high-impact research are available. Nevertheless, the actual work with the LABKA database can be cumbersome and difficult. This was a general conception among researchers and statisticians at the Dept. of Clinical Epidemiology.

Therefore, a process was undertaken to identify the actual problems with LABKA data and how they were dealt with. From these experiences came a request for a manual on how to approach projects using LABKA data. This is the first version of this manual.

The Sundhedsdatastyrelsen is expected to open a nationwide database for routine biomarkers. At current, it is not known what the actual content of the database will be, e.g. which variables it contains, completeness etc.. Therefore, it is uncertain whether this manual will satisfy the needs of researchers and statisticians using nationwide data, and the manual will most likely need to be updated when more experience with the nationwide database has been gathered.

All contributors to this manual are greatly acknowledged. For readers, please report back with any suggestions for improvements and comments to the authors. Thank you.

Fall 2016, Aarhus, Denmark.

Johan Frederik Håkonsen Arendt

1. Purpose

The purpose of this manual is to introduce researchers at KEA and their collaborators to the LABKA database, its content and how to approach a project using LABKA data. This manual is not a fulfilling A-Z manual that can eliminate all problems or challenges encountered when working with LABKA data. It should be considered a systematic guide, from which the steps in a project using LABKA data are addressed, including which things to consider in each step of a project, how to identify problems and also suggestions for solving the problems at these steps.

For non-Danish speakers, please note that a lot of the information on LABKA, e.g. codes and biomarkers and most of the references and links provided here are in Danish and are adjusted to Danish standards. For you, it’s advisable to consult Danish speaking collaborators.

If you are in doubt about how to approach LABKA data or the collaboration with clinical biochemist (see 4.1.), then contact Johan Frederik Håkonsen Arendt, jfba@clin.au.dk.

2. Introduction

The LABKA database is short for the “Clinical Laboratory Information System Research Database”. The name “LABKA” comes from the IT software providing integration of information from various parts of the software used in hospital laboratories. The database holds information on hospital laboratory analyses performed at departments of clinical biochemistry on blood samples, urine, cerebrospinal fluid and other bodily fluids. The geographical area covered corresponds to the current Regions of Northern and Central Denmark (The Danish Regions were formed in 2007), the same area as the former Counties of Aarhus, Viborg, Ringkøbing and North Jutland (Denmark was divided in Counties until 2007) plus the area corresponding to the municipality of Horsens and Brædstrup (formerly located in Vejle County, now in the region of Central Denmark). For former and current municipalities with corresponding codes, please see appendix A.
The analyses were requested from physicians at both public and private hospitals and general and special practitioner’s offices. The requests were done as a part of routine clinical practice in the process of diagnosis and monitoring disease progress and treatment effects. This in turn means that all persons in the database are to be considered patients. The LABKA database is also described in detail by Grann et al (see 5.4. References).

3. Database Content

3.1. Variables

All records in all LABKA datasets hold information on CPR number, date and time of analysis, NPU code and/or analysis code and a result. Most records also hold a NPU name and/or NKN, (Nationale kortnavne, NKN; National short names), unit and reference range. The NPU/NKN name and the NPU codes and analysis codes are used to identify the biomarkers (see outline in 4.3. Identifying codes). Note that not all database outputs are equal and therefore do not contain all the same variables. Also note, that some of these variables can be erroneous and that results from the same biomarker are not always directly comparable. Also, you can find component names and codes that do not fit into the NPU terminology. These issues are addressed in the following sections.

3.2. NPU terminology and the DNK codes

The NPU terminology is an international classification system for medical laboratory analyses. The terminology is designed to give information on a current state of a relevant biological system at a specified time point. The terminology does not describe processes or specific phases of analytical procedures. The NPU codes are not assigned to specific analytical principles, methods or platforms, and therefore, results are not always directly comparable. The terminology assigns a unique five digit NPU number and corresponding name for each biomarker with the following syntax (please note the many Danish abbreviations used – these are the ones you will find in the LABKA database and other relevant sources):
NPU12345 System—Component; kind-of-property = ? (and sometimes) unit.

The system corresponds to the biological system in question, e.g. plasma P, cerebrospinal fluid Csv (“v” for “væske”, fluid in Danish), secretion Sekr. In parentheses after the System can sometimes be found specifications such as P(vB)— corresponding to plasma from venous blood or Sekr(Trachea) corresponding to secretion from trachea. Since serum is an artefact created in the laboratory, the abbreviation S is not found in the NPU terminology. Serum is used to approximate the state in the patient’s plasma and therefore P is used. The component is the biomarker in question – it is the part of the system in question. The component can be further specified using parentheses. After the semicolon is the kind-of-property. This corresponds to concentration, number, color, sequence variation etc. Very often, the kind-of-property is used to specify the use of arbitrary units, e.g. referring to international standard preparations, scales etc. also in parentheses. The kind-of-property differs a lot depending on the biomarker and type of analysis. The ? is the space for the actual result, and sometimes the NPU code comes with a unit.

The Danish version of the NPU terminology, called DNK, is translated using Kemisk Ordbog, Klinisk Ordbog and Dansk Retskrivningsorbdog. Not all words/terms are translated. The Danish version is updated monthly at www.labterm.dk, and all updates are approved by designated groups under the different scientific societies of laboratory medicine that use NPU codes. The administration and communication of the Danish NPU terminology is done by the National Health IT (NIS). The Danish version of the NPU terminology allows for extension into codes with only a Danish national relevance or that can’t fit into the NPU terminology. These codes are called DNK codes, and they have the same syntax as the NPU codes, but the prefix DNK instead of NPU before the five digit code. Also, other prefixes, such as AAA, AAB, etc. can be found. A list of their meaning is given in 5.1. References and links.
3.3. National short names (NKN)

The National short names (Nationale Kortnavne, NKN) have the purpose of giving the clinician a meaningful name for the biomarker in question, and are developed to display biomarker results at www.sundhed.dk. The results of biomarker analyses are transferred to the electronic medical files and other electronic platforms (e.g. general practitioners’ systems) with NKN as the biomarker identifier. They are the administered and published by National Health IT, and are assigned and approved by designated working groups within the relevant medical specialist areas in laboratory medicine. The NKN list is updated together with the update of the Danish version of the NPU terminology. Each NKN can cover several NPU codes/names, but NPU codes/names only refer to one NKN. The NKN have a different syntax than the NPU:

Component; System = ? and sometimes unit.

The NKN often leaves out the kind-of-property and has a limit of 35 characters. If a kind-of-property is included it comes after the component (and component specifications) in the syntax. Danish translations are used when meaningful, e.g. “Sten” for “Calculus”. Otherwise, the terminology of the NPU is sustained. The NKN also allows for using clinical initialisms in square brackets, e.g. [APTT] and [CDT]. Note, that by October 6 2014, the NKN names are used in the laboratory list (“Analysefortegnelser”) from the departments of Clinical Biochemistry in the Region of Central Denmark (link found in 5.2.)

3.4. Analysis codes

The use of analysis codes was phased out in 2006/2007, and NPU/DNK codes were phased in. There is some overlap in the period, so you may find biomarkers with both analysis codes and NPU/DNK codes. These codes were allocated to specific biomarkers, just like the NPU codes. However, there are no available sources to identify which corresponds to which biomarkers. Only an incomprehensive list is available (see 5.1. References and links). These codes have a varying number of digits, but no letters. Unlike NPU codes, you may find a system called “S” for serum.
4. Project guide

4.1. Contact group and collaboration
In collaboration with the specialist council in clinical biochemistry in Region of Central Denmark, a contact
group has been established. It consists of three medical doctors specialized in clinical biochemistry, who all
show great interest in the research potentials of the LABKA database. Their contact information can be
found in Appendix B.

The agreement between KEA and the contact group was established to enhance the possibilities to
collaborate between epidemiologist and clinical biochemists, and to improve the research involving LABKA
data. In recognition that LABKA data have different properties than other types of registry data and that
each new biomarker give rise to new question, the contact group will work as consultants or collaborators
on specific projects, or facilitate contact with other clinical biochemists with the relevant expertise.
Therefore, project investigators using LABKA data are strongly encouraged to involve the contact group.
Depending on the type and amount of expertise needed, the number and type of biomarkers used and the
experience with those biomarkers, the level of collaboration or consultation will differ from one project to
the other. This manual will cover more general issues for consideration and problem solving.

4.2. Documentation
The use of LABKA data allows for the use of hundreds of biomarkers, and therefore, a great variety of
projects. Like all other types of research, the knowledge and experience with LABKA data accumulate from
different projects. To gain the most out of the LABKA data and the experiences gathered, researchers and
statisticians are strongly encouraged to document the knowledge and experience they gather during their
work with the specific biomarkers. This means, that for each individual project, the researchers should
write a summary of all the steps performed. To make this easier, a template for biomarker documentation
is available at O:\HE KEA-Klinisk\4 Grupper\LABKA\Biomarkers studied. Also, macros for SAS are available
for identifying and tabulating biomarker codes. Please read this template before starting your search for the biomarker of interest. This will make the documentation a lot easier.

Likewise, statisticians and researchers should consider including syntaxes, macros and other things of relevance from the statistical work done in the individual project.

By documenting the biomarkers that have been studied it will improve the possibilities for future projects and the quality of those projects. This does not mean that new projects should blindly follow the work of others, but documentation from previous projects should form a good platform for new projects, and new projects are encouraged to follow the outline in this manual. However, be aware that LABKA records hold sensitive data and should be treated accordingly.

Documentation should be done at O:\HE KEA-Klinisk\4 Grupper\LABKA\Biomarkers studied. An Excel sheet will provide an updated overview of the content of this folder. To give the best overview for others, please update the Excel sheet when you have used a new biomarker and added the documentation using the template provided.

4.3. Initiation

When initiating a project, the crucial element is always to construct a relevant hypothesis. To construct a hypothesis you need to have a reasonable amount of background knowledge on the topic of interest. For example, when you want to study the effect of a drug A on the risk or prognosis of a disease B, you need to know something about A, B, and when using registry-based data, how the data on A and B are collected into the registries. For the drug A you need to know something about the indications for treatment, the administration, the effects, side effects and interactions, the epidemiology and how data on A is collected in the database. However, drugs often come in different doses, preparations, and with the same overall group effect, but different specific effects. For the disease B, you need to something about risk factors, etiology, pathogenesis, diagnostic criteria, epidemiology and how data on B is collected in the registry. This is no different when initiating projects using LABKA data. Analogous to the example above, for biomarkers
you need to know the indication for requesting the test, how the test result can affect the patient’s probability of diagnosis and treatment, that is, you need some clinical background knowledge of the use of the biomarker. You also need to know about how, when and where the biomarker measurement was performed. And biomarkers of the same name and NPU code do not always have comparable results across calendar periods and hospital labs. Therefore, knowledge on the quality of the LABKA database content is needed. The output from the LABKA software corresponds well to the type of data that you would want to have in a database, so the output is more or less directly transferable from the laboratory to the database. However, we are now aware that this does not preclude errors, missing data and data of dubious quality to occur in the LABKA database. As in other studies, consider consulting a specialist – in this case, a laboratory physician specialized in clinical biochemistry. Just like consulting or including a cardiologist in your project when studying heart diseases, consider consulting a clinical biochemist in order to perform a project of high scientific quality and validity. Information on the contact group of clinical biochemist and the agreed procedure is found above and in Appendix B.

A good start is to go to “Analysefortegnelsen” from the Dept. of Clinical Biochemistry, Aarhus University Hospital. The list of analyses is alphabetically sorted (and so are the lists from other labs) and has a search function.
1. Graviditetsundersøgelse inkl. type
2. Graviditetsundersøgelse inkl. type
1. Graviditetsundersøgelse inkl. type
2. Graviditetsundersøgelse inkl. type
25-Hydroxy-Vitamin D(D3+D2)
2-Ethyliden-1,5-dimethyl-3,3-diphenylpyrrolidin (EDDP; specifik analyse)
3-Hydroxybutyrat
52 kDa Ro protein-Ab(IgG)
5-Aminolevulinat/Kreatinin
9 ml tørglas til SKkla
AB0i nyretrx, forundersøgelse, pt
AB0i nyretrx, Isohæmagglutinintiter
ABCD1-gen
Ability
Acanthocytter
Acarus siro (d70)-IgE
ACD-blod
ACD-blod 10 glas (10*9 ml)
ACD-blod 3 glas (3*9 ml)
ACE-gen; sekv. var
Acetaminophen
Here, many biomarkers in the LABKA database can be found with NPU/DNK code and name, and often with a short description on indication, interpretation, reference ranges and measurement ranges, type of
analysis and its imprecision (see marked with red). All of this information can be relevant for finding codes and names, and for later use in data management and analysis. Other departments of clinical biochemistry have similar lists available online (see 5.2.), and it is recommended to search those as well as previous papers and even Google to try to get an impression of the type of biomarkers available. Often you will have a clue of this when initiating your project. From this, you can also get an impression of the complexity in gathering the correct codes for your project (see 4.4.). Note, that some biomarkers in the "Analysefortegnelsen" (and similar lists) are not performed at the laboratory hosting the online list. In that case, there will often be a link and/or name for the performing laboratory.

Since finding the correct codes can be difficult, the statistician, epidemiologist and often also the clinical biochemist should work very closely together to identify the relevant search terms and codes. Otherwise, you risk doing the same work twice and also of missing measurement in the LABKA database.

Not all of this information is readily available from e.g. online sources, published articles or textbooks. Therefore, in order to gain knowledge about the biomarker in question, you often need to consult project collaborators or consultants in clinical biochemistry (see above and Appendix B).

In line with 4.2., document your considerations, your discussions and who was involved in these parts of the projects. Then others can benefit and learn from it.

Next is the need for the actual data and the expertise to handle, analyze and interpret the data. So when using LABKA data, you need to know which kind of data you need (which biomarker(s)), how they can be handled prior to data analysis, how these data should be included (single measures, repeated measures), how they should be analyzed (exposure, outcome, covariate) and how to interpret the results from the analytical phase. In order to plan all these steps you need to write a project protocol, and involve the collaborators relevant to execute the protocol. The following sections will help you to create the parts of a protocol that involves LABKA data.
4.4. Identifying biomarkers in the LABKA database

Once you have identified the biomarker(s) relevant for your project, you need to identify them in the LABKA database. This is done by basically searching for the relevant names and codes for the biomarker in question in all available resources (see 5.2.), and then cross check codes and names with the content in the LABKA database. If this has already been done for the biomarker of interest, you can find the codes and names at: V:4 Grupper\LABKA\Biomarkers studied. If you use codes and names already identified and documented, please still double check and see if you have identified the relevant codes yourself. You can’t expect the work from previous projects to be fully comprehensive for your new project. So try and go through the documentation of the previous project that you can be inspired from.

Start off with using “Analysefortegnelsen” from Aarhus University Hospital. From that, you can get the name(s) and code(s) used for the biomarker(s) of interest at present. Do the same with the other lists of analyses from the other hospitals, and make a spreadsheet/document of the relevant biomarkers you find.

Then, search in the database www.labterm.dk. Below, is found a screenshot of the search tool that’s in Danish. Always check the box “Alle poster” to include outdated codes. In the example below, the word “albumin” is searched for. Consider using broader searches, e.g. “alb”, and remember to search for all synonyms, Danish, English and international. Searching for specific NPU codes can also be done, and can be helpful if to see of the NPU code(s) are/have been implemented in Denmark.
Then a list of hits is shown:

Download or copy this list into your spreadsheet/document, and in case of multiple searches, make a full list of candidate hits. Crosscheck the codes and names found in the different lists from departments of clinical biochemistry, previous projects and papers and/or Google.

Perform a similar search in the descriptive dataset of the LABKA database that was made at KEA, and use the exact same names and codes as found in the online sources for searching (usually the statisticians do this, since they have the access to the LABKA database). Go through all the codes found, and select the ones appropriate for your study. If in doubt, consult collaborators and/or consultants from clinical biochemistry.

In this phase, you can often get a first impression of the work load of data management. If the unit has changed, you can often find that in the list of hits from www.labterm.dk, and the use of different reference intervals or cut-offs should be obtained from the different “Analysefortegnelser” from the different hospital labs. So be aware of these issues during this phase, and you the next phase of data management is more likely to be successful.
4.5. Data management

Once you have found the relevant codes, the next phase is data management. During this phase, you should be able to uncover any errors in the records, the completeness, traceability and comparability of your biomarker(s), and consider the need for corrections, stratified analyses or exclusion. It can sometimes be advisable to exclude codes/names where relatively few patients are recorded, especially when sampling large cohorts. A check list of issues can be found in appendix C.

4.5.1. Errors

It is important to be aware of errors in the LABKA records. They can occur at three levels:

1. The laboratory level: Most biomarkers will have relatively few results showing a text string like the following: “Uegnet til analyse”, “Hæmolyse”, “Ikke nok prøvemateriale”, “Prøven bortkommet” and others. If you find such results, consider if they should be included or if the better option is to search for another record for the individual patient(s) close to the same date as the erroneous record. The biomarker will often be tested shortly after, if the clinician finds that the indication is upheld.

2. The database level: The most straightforward approach to identify errors at database level is to tabulate each of the variables relevant to your project, and look for clusters and outliers. The errors that have been found most often are on the time variables (hours, minutes, and seconds) and for biomarkers that are answered with a text string. For some of the erroneous time records, the error is obvious and can be corrected, if necessary. For example, a typical error is the misplacing of hours into minutes and minutes into seconds, leaving hours to 00 or 12. In principle, other variables from a LABKA record can also be erroneous.

3. Text strings: some biomarkers are answered using a text string. Usually these are functional test or genetic analyses. They are not always included in the LABKA database, but you will find text strings as the ones stated above. Be aware that some records will be with a “<” or “>”, meaning that the measured biomarker was below or above a certain cut-off or measurement range. They can be coded as text strings,
but consider including them as “normal” or “abnormal” (for cut-offs) or according to their numerical value (for outside a measurement range).

4.5.2. Completeness

The completeness of the LABKA database should both be assessed geographically and chronologically, if relevant to your project. This can be hard to assess because there is no identifier for the specific hospital labs. Instead, different approaches can be taken. First, if a visit to the general practitioners within a reasonably short time span of the blood sample is recorded within Sygesikringsregistret (5.4. References: Andersen et al), it is reasonable to identify the requester as the general practitioner. In particular, a specific code for blood sampling (2601, 2101) will imply that the general practitioner is the requester. The same goes for a hospital admission or outpatient clinic visit recorded in the Danish National Registry of Patients. Then if you compare the list from Sygesikringsregistret and DNRP to the list of general practitioners and hospitals in the geographical area, you can get an idea of the completeness of your data. Third, to assess chronological completeness, consider tabulating results identified to specific labs or areas by year. Then you can see if results are missing from specific areas or labs in different years. Be aware though, that hospital departments can request a blood sample that will then be taken by the general practitioner.

4.5.3. Traceability

Traceability refers to two things. 1. Tracing the requesting physician or department. 2. Tracing the hospital lab performing the test you identified as a LABKA record. As stated above, no identifier for specific labs or requesting physician/department is found in the LABKA database. This makes it difficult to trace both the requester and the performing lab at a specific hospital. Again, the following approaches can be considered. First, some biomarkers are hardly ever used by general practitioners or only used in highly specific diagnostic procedures. To get an idea about this, go to “Analysefortegnelsen” from Aarhus University Hospital. It has separate lists for general practitioners and hospitals. Second, if a visit to the general practitioners within a reasonably short time span of the analysis is recorded within Sygesikringsregistret, it can be considered as requested from a general practitioner. For some, the Sygesikringsregistret will also
have recorded that a blood sample was taken at the general practitioner. Likewise, if a hospital admission or outpatient visit is recorded in the National Patient Register within a reasonable time span from the analysis, it can be considered as requested from a hospital department. Note that some general practitioners sent their patients to the hospital lab for blood sample collection. And, for some types of analyses, the sample can’t be taken at by the general practitioners because of laboratory standards precluding this. Go to “Analysefortegnelsen” from Aarhus University Hospital. In the list for general practitioners you can collect the information given to the general practitioners on which samples should be taken exclusively at the hospital labs. Further, hospital departments can request a blood sample that will then be taken by the general practitioner. When the requesting physician/department has been identified you can approximate at which hospital lab the sample was analyzed. This can be very helpful if you have problems with comparability and want to consult specific labs that you have identified to have analyzed the biomarker and produced the results. Also, if you are interested in specific subgroups, e.g. patients treated by the general practitioners, the traceability is an important issue.

4.5.4. Comparability

Comparability should always be assessed. The same biomarker with the same NPU code and name will not necessarily give comparable results if the sample is analyzed at different laboratories on different analytical platforms. So when generating large cohorts, as often done in registry-based research, results for one specific biomarker can have different levels, units and reference ranges or cut-offs. Therefore, obtaining comparability is crucial when using LABKA data and should always be assessed. Before assessing the comparability of results you should already have selected your codes so that you do not pool data of biomarkers that are difficult or impossible to compare, e.g. B-Glucose and P-Glucose. If you have pooled such data, you need to go back to 4.4. Identification in the LABKA database and reconsider the identified codes. If in doubt on which biomarker codes/names that can be considered comparable, consult your collaborator/consultant in clinical biochemistry.
This part can perhaps be considered the trickiest part of data management. Since the NPU terminology and the corresponding Danish modification don’t allocate codes and names to specific laboratory analyses, the comparability across labs and codes can be difficult. Especially, in the early periods of the database where accreditation standards and national/international quality control programs were not fully implemented. Further, the suboptimal traceability to specific labs can complicate any attempt to correct results from different labs and across different years with the purpose of increasing comparability.

At present, the best option is to tabulate individually all codes used and then stratify by calendar year. If differences in patient’s median, mean, minimum, and maximum values are seen it could indicate differences between codes or across years (see example below). Also from 4.4. Identifying biomarkers in the LABKA database, you can get a clue of the potential for obtaining comparable results by looking for changes in biomarker units and reference ranges. If incomparable results are suspected, it is recommended to try to track the hospital lab using the specific code(s) and ask them to track the analytical changes for the biomarker and ask for advice on comparability. Not always, can results be converted with standard conversion factors and exclusion or stratification of results is the best option. Exclusion and/or stratification can have an impact on sample size, statistical power and generalizability of your results.

4.6. Data analysis

There are many ways of applying LABKA results to your analyses. Many biomarkers are continuous results and often have reference ranges or cut-offs. And depending on whether the biomarker is the exposure or outcome of interest or a covariate, the options for using LABKA data in projects are numerous. This section is not an outline of different study designs or different statistical models. It is some advice on how to take earlier steps in this manual into consideration in the analytical phase of a project.

In the data management phase, you should have gained insight into the completeness, traceability and comparability of LABKA records. So if “your” LABKA data are not geographically complete you should consider restricting your analyses to an area that is complete on all data. Further, if you have not managed
to obtain comparability for your LABKA results, consider either excluding the results considered incomparable or dividing your analyses using strata of comparable results. Multiple imputation is also a potential tool for handling missing data.

For some biomarkers, results outside the reference range can represent very sick patients. That is, they die or experience outcomes that make analyses of the outcome of interest infeasible. To solve this, consider a time period or a range of results for further exclusion to obtain a more homogenous study population. Or consider identifying a population of more “healthy” patients, e.g. patients with blood samples taken at their general practitioner’s request.

In order to validate your results, consider making them stratified by covariates, such as sex, calendar year, follow-up strata, comorbidities etc. Then you can assess whether relevant covariates mark a difference in indication for requesting a biomarker among different subgroups of patients and across the study period. Another approach is to consider making sensitivity analyses, outlining relevant alternative scenarios and repeating the analyses.

Because a blood sample is requested in diagnosis and treatment of diseases, patients with LABKA records will have a both prior and subsequent higher risk of diseases than people in the background. Prior because they consult the health care system because of symptoms (“doctor-seaking behavior”), and the health professional finds indication for requesting a blood sample. And subsequent because depending on the biomarker result(s) their risk of disease is modified. This in turn means that using standardization or matching a comparison population to your patient population may be confounded by both the indication for requesting and the results of the biomarker. Therefore, consider making analyses comparing the risk of outcome(s) within your patient population with LABKA records, e.g. within and outside the reference range or in different levels of the biomarker in question. Assuming that the indication for requesting the measurement is the same (which is of cause debatable), the prior risk of disease is then comparable between patients, and you will then only assess the subsequent risk – the risk of disease given the result(s) of the biomarker.
4.7. Interpretation

The interpretation of results is naturally different for each specific project. Some general issues for consideration are outlined below. They are not essentially different from projects not using LABKA data.

As stated above, the indication of a biomarker request and the disease risk related to the biomarker result can confound the results. This warrants consideration when interpreting results. Further, if including many biomarkers in your study and restricting the analyses to patients with complete data on these biomarkers, the confounding by indication is likely to increase.

On the other hand, if results are robust within strata, e.g. strata of incomparable biomarker results or of other covariates, the association is strengthened. The same goes for robust results in sensitivity analyses.

Like for any other project, the better the project is planned and executed, the more valid the results can be considered.

Also in this phase of a study, a laboratory physician can be helpful when interpreting results from your study. They will often have a good overview of which diseases/outcomes are associated with the biomarker of interest, and that may be potentially relevant for some studies.
5. References and links

5.1. NPU terminology and NKN

NPU terminologien – Brugermanual. Principper, administration og brug. Sektor for National Sundheds-IT.
Statens Serum Institut. 2014
Can be found in O:\HE_KEA-Klinisk \Biostatistik & Data Management\Stat Journal Club\2015-02-16 LABKA - Introduction and example of use\articles
List of translation from NPU names to NKN names “Analysefortegnelser” in Region of Central Denmark. The NKN names replaced the NPU names in the “Analysefortegnelser” in 2014 October 6 . See: V:\4 Grupper\LABKA
List of analysis codes and odd prefixes: O:\HE_KEA-Klinisk\4 Grupper\LABKA\Biomarkers studied\analysis codes NB not complete; O:\HE_KEA-Klinisk\4 Grupper\LABKA\Biomarkers studied\prefix codes

5.2. Links for lists of analyses

Database on all NPU and other codes used in Denmark: www.labterm.dk
Analysefortegnelsen from the Dept. of Clinical Biochemistry, Aarhus University Hospital:
http://www.auh.dk/om+auh/afdelinger/klinisk+biokemisk+afdeling/for+sundhedsfaglige/analysefortegnelsenbg
Analysefortegnelsen from the Dept. of Clinical Biochemistry, Randers Hospital:
http://www.regionshospitalet-randers.dk/afdelinger/klinisk+biokemisk+afdeling/analysefortegnelse
Laboratorievejledning from the Region of Northern Denmark:
http://www.laboratorievejledning.dk/prog/view.aspx
Analysehåndbog from Dept. of Clinical Biochemistry, Hospital unit West:
http://e-dok.rm.dk/symfonidms/d_hove_labkba.nsf/AabnKapitel/B58EF601F6C4B218C1257044001E2F8F
5.3. Guides for documentation, data management and analysis

O:\HE_KEA-Klinisk\4 Grupper\LABKA\Biomarkers studied\Template Documentation of LABKA biomarkers

O:\HE_KEA-Klinisk \Biostatistik & Data Management\Stat Journal Club\2015-02-16 LABKA - Introduction and example of use

O:\HE_KEA-Klinisk \1.4 Ansættelse, arbejdstilrettelæggelse og kompetenceudvikling\5 Uddannelse og kompetenceudvikling\Journal Club\02.12.13 Use of LABKA data

5.4. References

Grann AF, Erichsen R, Nielsen AG, Frøslev T, Thomsen RW. Existing data sources for clinical epidemiology: The clinical laboratory information system (LABKA) research database at Aarhus University, Denmark. Clin Epidemiol 2011:3;133-138


5.5. Previous KEA studies with LABKA

(list not comprehensive)


Holland-Bill L1, Christiansen CF, Ulrichsen SP, Ring T, Jørgensen JO, Sørensen HT. Validity of the International Classification of Diseases, 10th revision discharge diagnosis codes for hyponatraemia in the Danish National Registry of Patients. BMJ Open. 2014;4(4).


Gradel KO, Thomsen RW, Lundbye-Christensen S, Nielsen H, Schønheyder HC. Baseline C-reactive protein level as a predictor of mortality in bacteraemia patients: A population-based cohort study. *Clin Microbiol Infect.* 2011;17(4);627-32.


Appendices

Appendix A. Codes for municipalities and regions

Codes for the municipalities (kommune) in Denmark before and after the formation of the Danish Regions, January 1st 2007. Codes are only for municipalities in the Regions of Central and Northern Denmark

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Appendix B. List of contact persons

Department of Clinical Epidemiology

Johan Frederik Håkonsen Arendt, jfba@clin.au.dk, LABKA manual

Lars Pedersen, lap@clin.au.dk, LABKA database content

Hanne Kjeldahl Schlosser, hks@clin.au.dk, Access to LABKA database

Contact group from specialist council in clinical biochemistry in Region of Central Denmark:

Søren Andreas Ladefoged, soerlade@rm.dk

Anette Tarp Hansen, Anette.Tarp.Hansen@skejby.rm.dk

Jurgita Janukonytė, jurgjanu@rm.dk
Appendix C. Checklist for data management

Have you looked for?:

1. **Missing measurements**: if you fewer patients than expected with measurements of the biomarker in question, consider if you have find the right codes for that biomarker OR if the database is chronologically and/or geographically complete. Although difficult, you should from clinical knowledge be able to judge the expected number of patients with a biomarker measured.

2. **Data errors**: typically either laboratory errors so sample was not analyzed (expected to be very few) OR errors in the database. Database errors have most often been seen in relation to time variables for sample collection. Plot and tabulate the variables of relevance, and look for outliers, clusters and missing values. Remember to check for answers with “<” and “>”.

3. **Completeness**:
   3.1. **Chronological**: Tabulate proportions of missing biomarker records per year in your study population
   3.2. **Geographical**: Tabulate proportions of missing biomarker records for each hospital (or department) in your study population

4. **Traceability**: Note that the LABKA database does not have requester or lab identification codes. So in case you need to identify the requester look for either: A. a hospital contact within a reasonable timeframe before the biomarker record; B. a code for “consultation” or “blood sampling” in “Sygesikringsregistret”, corresponding to a fee given to the patient’s general practitioner.

5. **Comparability**: Although standardization has improved in recent years, biomarker results have an inherent challenge of comparability. Therefore, tabulate units, reference ranges, and values of minimum, maximum, mean, median and possible other distribution characteristics for each biomarker code (NPU, local Danish code, analysis code) and for each year of the study period.

You are strongly encouraged to work closely with the statistician and the contact group (see appendix B).
Reports/PhD theses from Department of Clinical Epidemiology


Særtryk: Klinisk Epidemiologisk Afdeling - De første 5 år. 2006.


34. Sygehuskontakter og lægemiddelforbrug for udvalgte kroniske sygdomme i Region Nordjylland. 2007.


71. Lars Jakobsen: Treatment and prognosis after the implementation of primary percutaneous coronary intervention as the standard treatment for ST-elevation myocardial infarction. PhD thesis. 2012.


75. Kristina Laugesen: In utero exposure to antidepressant drugs and risk of attention deficit hyperactivity disorder (ADHD). Research year report. 2013.


78. Risiko for kræft blandt patienter med kronisk obstruktiv lungesygdom (KOL) i Danmark. (Online publication only). 2013.


116. Regional Differences in Treatment of Patients with Inflammatory Bowel Disease in Denmark
