



American University of Armenia
Center for Health Services Research and Development



Nork Marash Medical Center

**THE EVALUATION OF MEDICAL RECORDS
DOCUMENTATION AND SURGICAL SUMMARY
DATABASE AT NORK MARASH MEDICAL
CENTER**

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EXECUTIVE SUMMARY

Purpose. Nork 2-Record Review Project (N2-RR) was conducted to validate patient specific information collected at NMMC. Two aspects of data collection at NMMC were selected for evaluation: medical records documentation in the Adult Cardiology Clinic (ACC) and surgical summary database at Nork Marash Medical Center (NMMC). The aim of the project was to establish the adequacy of patient records and databases, so that the quality of care provided at NMMC can be evaluated through retrospective review of these sources.

Introduction. Medical records and clinical databases are an important source of patient information used for quality assurance (QA), medical audit, reimbursement purposes, research, and educational activities. Patient records can serve as a defense against medical malpractice as well. However, before relying on medical records and clinical databases, the reliability and validity of their content should be evaluated. Several studies were conducted to assess the adequacy of medical records in various hospital and outpatient settings. Some indicated incomplete and inaccurate recording of elicited patient information. The necessity to create high quality databases for monitoring cardiac surgery outcomes and measuring case mix and severity of illness has been long ago recognized in developed countries.

An initial survey on Data Collection and Analysis at NMMC identified that a variety of medical forms and databases are completed at each step of patient management that can be used to assure quality of care and to monitor health care outcomes over time. However, the process of reviewing clinical records and databases is not established at NMMC. Moreover, the validity of patient records and databases has never been evaluated.

Methods. The study design was cross-sectional with implementation of both observations and record reviews as the means to collect data. The accuracy and completeness of the first-visit structured encounter forms (SEF) were assessed through comparing of recorded information with observations of actual patient-cardiologist encounters, considering the latter as a “gold standard.” Survey participants were females and males aged 18 and older, admitted to the ACC for the first time. The instrument was developed based on the content of the first-visit SEF. SEFs were reviewed approximately 30 days after the completion of observations, the results were compared and full, partial, and no credit was assigned to each item included in the instrument.

The accuracy and completeness of the surgical summary database were evaluated comparing the data entered into database with the relevant information documented in medical records, considering the latter as a “gold standard.”

Sample. The sample size needed to assess the adequacy of the first aspect of N2-RR was 66. The hypothesized percent agreement between observations and records was 85% and the least difference desirable to detect was 10%. There were five adult cardiologists at NMMC, four of whom participated in the study. The number of patients managed by each cardiologist was represented in the sample proportionally to the volume of cardiologists’ practices. The sample size needed to evaluate the adequacy of surgical summary database was calculated as 61. The medical records were selected from sequential cases.

Ethical considerations. The research proposal was reviewed and approved by the Institutional Review Board (IRB) committee within the College of Health Sciences at the American University of Armenia (AUA).

Results: Evaluation of medical records. The mean observation time was 29 min and the average auditing time was 4 min. The overall mean agreement between observations of the actual encounters and SEFs was 69.8%. Data analysis was performed to identify the percent agreement for each domain and variable. Excellent agreement was observed for tests performed and ordered for patient, good agreement for patient complaints and physical examination results, and poor agreement for medical history and patient habits. The recording pattern was examined to indicate inaccurate, under- or over-recording for each item in the instrument. Generally, there was significant under-recording of both positive and negative findings for patient complaints, medical history, patient smoking status, and physical examination findings. Analysis of validity of the recorded data indicated that SEFs were a valid source of patient information in terms of tests performed and ordered for patients.

Evaluation of surgical summary database. Overall, 88.74% agreement between patient records and surgical summary database was observed. Data analysis indicated 81-100% agreement for all variables except the following: diagnosis, heart failure class, ICU stay, and blood usage. The percent agreement for these items varied from 47.54% to 77.05%. It was revealed that, overall, the surgical summary database was sensitive (86.26%) and specific (100%) enough to be used as a valid source of patient data. Validity analysis indicated that this database reflected true positive findings by 77-100% and true negative findings by 79-100% for almost all items, except gender, diagnosis, heart failure class, and blood used for transfusion.

Conclusions. Excellent overall agreement between medical records and surgical summary database, as well as good overall agreement between observation of the actual cardiologist-patient encounters and SEFs indicated that they could be used as a source of patient data after appropriate improvements are designed and implemented. The study results emphasized the necessity of:

- developing guidelines on patient health assessment at the ACC;
- conducting trainings on completion of the first-visit SEFs;
- establishing standards for coding of diagnosis and surgical procedures;
- redesigning the surgical summary database in accordance with existing standards;
- establishing internal evaluation processes at NMMC.

1. INTRODUCTION

1.1 RATIONALE

Medical records are an important source of patient information used for quality assurance (QA), medical audit, research, and educational activities. Based on the standards of Joint Commission on Accreditation of Healthcare Organizations (JCAHO), clinical records should contain sufficient information to identify the patient; to support the diagnosis; to justify the treatment, its course, and results; and to promote the continuity of care [1]. Good medical records ensure continuity of care and serve as reliable means of communication among various health care providers. Comprehensive medical records prove compliance with health care standards and justify deviation from those standards when necessary to assure quality of health care [2].

Patient records can be used for medicolegal purposes and serve as a defence against medical malpractice. The necessity for carefully prepared and thoughtful medical records have been heightened since the introduction of Quality Management and Improvement (QMI) programs to monitor and assess clinical outcomes [2]. In developed countries, the documentation in medical records assures reimbursement for the health care delivered to patients. Adequate medical records are an irreplaceable source of patient information most frequently used for research purposes [3].

Recently, technological developments have prompted the creation of high quality databases (HQCD) to collect accurate systematic information used in clinical practice and health care management. HQCD is a source of patient specific information that enables generalizability of study results and analysis within subgroups. Such databases can be used also by administrative leaders in planning and managing health care services [4].

Before relying on medical records, the reliability and validity of their content should be evaluated. Donabedian pointed out, "...an important weakness in data: the medical record does not show all that has been done for the patient, and certainly does not show all that should have been done" [5]. According to him, "The medical record kept by health care practitioners for each patient under their care is the most frequently used source of information about the process of care and about such outcomes as appear during care or soon afterward. Good records are essential for good care and for credible assessments of quality as well" [6].

Clinicians may argue that a record review is an evaluation of record keeping rather than an evaluation of quality of care. Despite the possible logic and truth of this argument, it has to be admitted that it is difficult to provide health care of high quality without adequate documentation to support decision-making and management of a patient [7]. Moreover, Lyons and Payne showed that "On the group level, on the individual physician level, and on the individual care level...1) good recording is related to good practice, and 2) the relationship is not perfect, but it is statistically significant" [8].

Several studies were conducted to assess the adequacy of medical records through comparison of verbatim transcripts of patient-provider encounters or computerized medical records with the information in patient records [8-11]. Research conducted by the Johns Hopkins Health Services

Research and Development Center sought to determine the extent by which the evidence of coordination of care was reflected in the medical record. This study revealed that observations and medical record agreed 70-85% of the time depending on the type of information. Higher concordance between observations and records was found for salient patient information: 82% agreement for symptoms, signs, and diagnosis, 81% agreement for prescribed therapies, while for the specific tests ordered the concordance was 70%. The investigators concluded that medical records contain adequate patient information and supported the use of medical records to ensure continuity of care [10].

Zuckerman A.E., *et. Al*, validated the content of pediatric outpatient medical records through comparison of tape-recordings of patient-provider encounters and the information documented in medical records. The study findings indicated good concordance between tape-recordings and medical records for patient chief complaints, 96%, diagnosis, 70%, non-drug therapies, 96%, and for follow-up appointments, 100%. However, agreement was poor for other types of patient information, such as drug name (34%) and drug dosage (58%). The authors speculated that medical records can serve as a source of patient information for various purposes after assessing their adequacy and making appropriate revisions [12].

Research aimed to validate the medical records of general medicine clinics of the North Carolina Memorial Hospital indicated that the actual concordance between medical records and interview transcripts ranged from 26 to 100%, where the chief complaints had the greatest agreement (92%), diagnosis or its impression, diagnostic tests, and therapy agreed by approximately 70%, while the agreement of medical history was 29% [13]. The study showed that medical records are imperfect and documentation of patient information and patient education should be improved, particularly the discussion of diagnosis, tests, and proposed therapies [13].

Provider performance and recording may vary by the format of medical records. It was shown that the use of a structured encounter form increased provider performance and recording compared with the use of a free text format [9, 15-16]. A study conducted in the Harriet Lane Primary Care Program (HLPCP) of the Johns Hopkins Hospital indicated that there was over-recording for the physical examination findings in the SEF and under-recording for the history of disease in the free text format records [9]. The investigators concluded that the record format may improve health care provider performance and documentation of patient information and delivered health care [9, 16].

There is no available data on similar studies conducted in Armenia. Thus, determining the suitability of patient records' use for quality assurance and research purposes in an Armenian health care organization is a topic worthy to investigate.

1.2 BACKGROUND INFORMATION

A collaborative project between the Center for Health Services Research and Development (CHSR) at the American University of Armenia (AUA) and the Nork Marash Medical Center (NMMC) was jointly proposed in March 2000. The AUA/NMMC joint project (ANP) was designed to improve managerial systems and quality of care in the hospital. In the scope of this

project, NMMC was the first health care institution in Armenia that has undergone internal evaluation to assess the extent of its compliance with Joint Commission International Accreditation (JCIA) standards [17]. The evaluation revealed that NMMC has the ability to generate all the clinical, financial, and utilization data needed to meet its managerial and other needs. A patient record was initiated for each surgical patient and various structured encounter forms (SEFs) were developed by most administrative and clinical departments to collect adequate information about each patient and to ensure continuity of care. The medical records and existing databases serve as the primary source of patient specific information used for decision-making, monitoring key clinical indicators, and improving the quality of care. However, the process of reviewing patient clinical records has not been established at NMMC. Medical records are reviewed mainly in cases of referral to another health care organization and in cases of follow-up visits to ensure continuity of care [17].

The next step undertaken by the joint project was to explore the flow of patient-specific data and to reveal strengths and weaknesses of data collection and analysis at NMMC. This study revealed that NMMC has rich databases of patient specific information and a variety of medical records that can be used to ensure continuity of patient care, to monitor health care outcomes over time, and to compare those outcomes across similar organizations [18]. However, the reliability and validity of patient records and hospital databases have never been evaluated.

Invasive cardiology and cardiac surgery health care organizations are those fields of clinical medicine expected to adopt and implement quality management and improvement activities at relatively early stages considering its invasive nature, the associated risks, and the rapid growth of these interventions [19-21]. Although the philosophy of Continuous Quality Improvement (CQI) is not formally established at NMMC, it is recognized that the accuracy and completeness of routinely gathered information significantly influence the decision-making process and eventually, the outcomes of care. Hence, before relying on medical records and clinical databases for retrospective data collection, it is important to assess the quality of these sources of patient information.

Patients aged 18 and older are admitted to the Adult Cardiology Clinic (ACC), an outpatient clinic, where patient health status is assessed and, when necessary, appropriate treatment is proposed. At the outpatient clinic, a first-visit patient record is initiated for each patient. The record is developed in a structured form and only the history of disease is recorded in a free text format (Appendix 1).

The surgical summary database is completed for each surgical patient at discharge. While the first-visit SEF captures the initial pre-operative information about patients, the surgical summary database includes pre-operative risk factors and information on post-operative patient health status that can be used to properly adjust for patient case mix, enabling a fair comparison of indicators over time and across institutions of similar type.

Considering the importance of valid and reliable data in medical records and clinical databases, the Nork 2-Record Review project (N2-RR) was proposed to evaluate the first-visit SEFs in the Adult Cardiology Department and surgical summary database at NMMC. The research questions were as follows:

1. Is the first-visit structured encounter form (SEF) in the Adult Cardiology Clinic an adequate data source for quality assurance activities and research purposes at NMMC?
2. Is the surgical summary database an adequate data source of patient specific information that can be used for quality assurance and research activities at NMMC?

The main objectives of the study were the following:

1. Assess the agreement between observations of patient-provider encounters (“gold standard”) and medical records;
2. Assess the agreement between patient records (gold standard) and surgical summary database; and
3. Assess the validity of the first-visit SEFs and surgical summary database (sensitivity, specificity, and positive predictive value).

The specific aims of the study were:

1. Investigate the completeness of the first-visit SEFs and surgical summary database for future quality assurance and research activities at NMMC;
2. Investigate the accuracy of the first-visit patient SEFs and surgical summary database; and
3. Provide recommendations to improve patient specific data collection at NMMC.

The N2-RR project was an internal evaluation endeavor proposed and undertaken by CHSR and NMMC. The aim of this project was to investigate the accuracy and completeness of medical records and surgical summary database. After the adequacy of patient records and database at NMMC is established, the quality of care can be evaluated through retrospective review. The availability of high quality clinical database may promote fair comparison of health care outcomes over time and within similar organizations, as well as may provide researchers with and adequate patient-specific information. Based on the study results, recommendations for improvement of data collection can be made building foundation for further improvement of health care quality and patient health outcomes at NMMC. The study is addressed to NMMC clinical and administrative leaders for consideration in decision-making and implementation of quality assurance and research activities.

2. EVALUATION OF MEDICAL RECORDS DOCUMENTATION AT THE ADULT CARDIOLOGY DEPARTMENT OF NORK MARASH MEDICAL CENTER

2.1. METHODS

2.1.1. STUDY DESIGN

The study was descriptive cross-sectional utilizing direct observations and record/database reviews. The accuracy and completeness of the first-visit SEF were assessed comparing the recorded information with the observation of the actual encounter, which was considered as a “gold standard”. Similarly, the accuracy and completeness of the surgical summary database were evaluated comparing data entered into the database with information documented in patient records, i.e., “gold standard”.

Generally, the completeness of a data source has two facets: the extent to which the items recorded in the assessed source match with those in the original source and the number of items that should have been recorded in the source according to the clinical guidelines set by the organization. The first aspect reflects the administrative quality, while the second one reflects the quality of care. Due to time limitations, the second definition of completeness was considered beyond the scope of this project and was not addressed. For the SEFs, the accuracy was defined as the extent to which the recorded item matched the observed item, while for the surgical summary database, accuracy was defined as the extent to which the item entered into the database matched the recorded item.

2.1.2. STUDY PROTOCOL

Generally, patients are admitted to the ACC on a pre-assigned date based on the urgency of their needs. Exceptions are made for patients from remote regions, from outside of Armenia, and for emergency cases admitted on the day of the visit. At the ambulatory clinic, there are three cardiology residents and five adult cardiologists. Each of cardiologists is responsible for primary patient admission one day a week. The residents perform patient health assessment and management independently, though under the supervision of cardiologists. ECG and blood pressure measurement are performed and patient demographic data and lifestyle habits are documented in the SEF by nurses. Physicians perform the physical examination, EChO, and other procedures and record clinical information (history of disease, patient complaints, diagnostic test results, etc).

One visit was observed at any given time. If there was more than one patient visit scheduled for the same time, the investigator selected the one that had begun first until the number of observations for a particular cardiologist was fulfilled.

SEFs were reviewed approximately 30 days after the completion of observations. This delay was considered necessary to minimize the likelihood that cardiologists and residents would modify the records. The SEF and observation were considered concordant if both contained comparable information regarding a particular item. For each item a score from 0 to 1 was assigned, meaning

full (1), partial (between 0 and 1), or no (0) agreement. Coding was generous giving credit to partial entries that reflected the patient-provider encounter. For example, if during the encounter a patient reported no chest pain, no shortness of breath, and no orthopnea, but complained about irregular heartbeat and frequent loss of consciousness, and the SEF stated subsequently that the patient did not have any complaint, except arrhythmia and frequent syncope episodes, full credit was given to all five items. If a patient reported 3 comorbid conditions and only two of them were recorded, a partial credit (i.e., 0.67) was given to this item. The same rule of scoring was applied if the number of stated and recorded comorbidities was the same, but one of the reported comorbid conditions was different from what was recorded in the SEF.

Both positive and negative findings observed during a patient visit should appear in the SEF. This decision was based on literature that stresses the importance of concordance of negative findings also [13].

2.1.3. STUDY INSTRUMENT

The instrument was developed based on the content of the first-visit SEF and was limited to a 22-item questionnaire to verify the accuracy and completeness of recording of each item. Items commonly audited were included in the instrument, such as diagnosis, medications (current treatment), ordered diagnostic tests, and allergies. Some items not typically included in the medical audit like patient complaints and previous surgical operations were also included. The investigator prepared the questionnaire in consultation with the cardiologist, a counterpart of N2-RR project. Selected items were relevant and essential to quality assurance and research purposes and the same weight was assigned to each item.

Considering the nature of the study, the instrument was designed in a way that would facilitate data collection rather than data entry. Thus, it included both close-ended and open-ended questions (Appendix 2). Open-ended questions were intended for family history, comorbid conditions, previous surgical operations, current treatment, and blood tests prescribed. The possible responses for each question were also different depending on the nature of the question. Items regarding the actual procedures performed by health care providers, such as physical examination, ECG, EChO, prescription of X-ray, blood test, treadmill, and cardiac catheterization, had Yes/No responses. Other items, such as exertional chest pain, exertional shortness of breath, arrhythmia, orthopnea, family history, allergy, comorbidities, current treatment, previous surgical operations, and smoking status had 1/2/3 responses. For example, when a question on presence of a compliant was raised during the first visit and the patient reported having that complaint, response 1 was assigned to the item. When the question was raised and the patient reported absence of that compliant, response 2 was assigned to the item. Finally, response 3 was given to the item when the question was not discussed during the first-visit. The same assignment of responses was applied to SEFs review, which allowed capturing both positive and negative patient responses. The investigator developed instructions on assigning responses for both observation and audit (appendix 3 and appendix 4 respectively), so that a person without medical background could collect data after a short-term training.

Usually, the diagnosis, proposed treatment, and health education are communicated to patients and family members after the results of ancillary tests are available to cardiologists. Completion of these tests requires 30-45 minutes. Due to the time constraints, it was considered infeasible to observe this second part of patient-provider encounters, and so, only the initial part of the first visit was observed.

The instrument was pre-tested on 9 patients who were admitted to the outpatient clinic for the first time. Several problems were noticed in “the current treatment” and “blood pressure measurement” items. At the time of admission to the ACC some patients were already receiving antihypertensive and/or anti-anginal treatment. Some physicians recorded in the SEF the medications that a patient was receiving under the assigned treatment in instances when the cardiologist would prescribe the same medications. This did not allow differentiating the drugs that were newly prescribed by the cardiologist from those that the patient was receiving before the referral. Thus, if a question about the current treatment was raised during the observation and the response was positive, but this treatment was not recorded specifically as a current treatment, the item was considered discordant.

The pre-test revealed that nurses may measure either sitting or lying blood pressure (BP). It is known that BP level may differ depending on the patient position, and so, this should be considered by physicians when interpreting the results. Thus, the instrument was redesigned to capture the information not only whether this procedure was actually performed and the results were recorded, but also whether the patient position while measuring BP was noted in the SEF.

The pre-test also pointed out that comorbid conditions imply both the diseases that a patient has currently and the diseases that s/he endured previously. Although the latter refers more to the medical history, it was decided to include both groups of diseases in the item of comorbid conditions.

The pre-test results indicated that some patients are prescribed a treadmill test and cardiac catheterization for diagnostic purposes. The treadmill test is performed outside of NMMC and patients are referred to those health institutions where this test is available. Cardiac catheterization and treadmill examination are costly procedures and some patients are unable to pay for them, so that the test results are not always available. However, the prescription of these procedures is recorded in the SEF and the investigator evaluated the concordance of the verbal prescription of cardiac catheterization and treadmill test to the recorded one.

Generally, smoking status is asked and recorded by nurses at admission. The SEF format is designed in a way that it captures only positive and rarely negative findings (for example, when patient does not smoke but quit it just recently). Response 3 (nothing recorded) was assigned when the item was left blank, as it was impossible to separate negative findings from missing values.

2.1.4. STUDY POPULATION

The eligibility criteria for participation in the first-visit SEF evaluation project at the ACC were the following:

- primary patients admitted to the ACC
- 18 and more years old

The exclusion criteria were as follows:

- patients admitted to NMMC for the first time on an emergency basis
- patients admitted to NMMC for a follow-up visit.

The sample size of the study was determined using one-sample proportion formula in the STATA statistical software (version 7.0). The standard agreement was 0.95, the hypothesized agreement between observations and records was 0.85 (based on expert opinion), and the least difference desirable to detect was 0.10. With 80% power and alpha error of 0.05, the sample size was calculated as 53. This size was increased to 66, considering possible problems that might naturally rise during the study implementation.

A quota sampling procedure was used in the survey. The numbers of each provider's patients involved in the study was proportionate to the volume of the provider's practice. Out of five adult cardiologists at NMMC, four participated in the study. The volume of their practice was calculated using 3-month data on first-visit patients. The percentage of patients examined by each cardiologist was calculated and applied to the sample of 66 patients to find the number of study participants drawn per cardiologist. This required 17, 22, 12, and 15 patients of the four cardiologists involved in the study.

2.2. ETHICAL CONSIDERATIONS

The research proposal was reviewed and approved by the Institutional Review Board (IRB) committee within the College of Health Sciences at the AUA (Appendix 5). A consent form was not provided to patients and/or cardiologists. The study possessed minimal risk for patients, as the probability and extent of anticipated harm and discomfort were equal and not greater than that of routine physical and psychological examinations or tests performed in ordinary daily life. The first-visit SEF review is part of the official ANP and its assessment was considered an internal evaluation process. Moreover, the presence of staff members (e.g. residents or other employees) during an examination is not uncommon at NMMC. In those cases when the patient was confused or discontent by the presence of the investigator, the willingness of patient was respected. The study involved only those cardiologists who were willing to participate and who were supportive to ANP. The cardiologists' agreements to participate in the study was obtained prior to its initiation.

The study involved the use of patient names, as the SEFs of study participants were later reviewed. The medical records were reviewed in the hospital to ensure confidentiality. In addition, patient names were coded and entered into the computer in a separate file, which was destroyed after the data was analyzed. Only the consultants of ANP, and the primary investigator had access to the data.

2.3. STUDY LIMITATIONS

The study involved direct observations of patient visits that could influence provider performance and recording. However, the reactive effect of the direct observation and consent statement on provider recording was assessed in the Harriet Lane Primary Care Program of the Johns Hopkins Hospital and was found to be not statistically significant for study participants [9]. Taking into account this and the self-assessment nature of the project, an additional review of SEFs completed by participating cardiologists during unobserved visits was considered unnecessary.

The study has limited generalizability because the findings were restricted to the structured encounter forms of the Adult Cardiology Clinic. In addition, the small sample size might not allow detecting difference in percent agreement across patient diagnoses, gender, and within cardiologist and cardiologists-resident pairs. Nevertheless, the study revealed preliminary results regarding the adequacy of the first-visit SEFs, building evidence for making relevant conclusions and recommendations.

The analysis of percent agreement was carried out including those cases when the question was not raised during the first visit or the procedure was not performed, which artificially lead to increased overall and per variable percent agreement. This can be considered as a limitation of the analysis.

2.4. DATA ANALYSIS

The data was entered into SPSS 10.0 statistical software and the analysis was performed in SPSS 10.0, STATA 7.0, and MS Excel statistical software. As noted earlier, the instrument was designed in a way to facilitate data collection rather than data entry, so that the physical structure of the instrument and data entry format for some items, particularly for blood pressure, peripheral hemodynamics, and open-ended questions were modified. To eliminate the possibility of additional errors double entry with error checking was performed.

Sixty-six patients participated in the study. The proportion of study participants among four cardiologists was the following: 17 (25.8%), 22 (33.3%), 12 (18.2%), and 15 (22.7%). The first-visit SEFs of all patients were available. Cardiologists alone performed 57.6% of patient assessments, while the rest was conducted by cardiac resident-cardiologist pairs. Male patients constituted 56.1% of the study participants and females composed 43.9% of the sample. The mean observation time was 29 minutes ranging from 10 minutes to 1 hour 40 minutes (sd=12 minutes). The mean auditing time was 4 minutes with range from 2 to 10 minutes (sd=1 minute).

2.4.1. PERCENT AGREEMENT

The overall mean score was 16.7 (sd=1.83, min=13, max=20) (Table 1), which corresponds to 69.8% agreement considering 24 (the number of items in the instrument) as a perfect score.

Table 1. Mean score and percent agreement per case

Minimum	Maximum	Mean	Std. Deviation	% Agreement
13	20	16.74	1.83	69.8

The hypothesis that the percent agreement between observations and SEFs is 85% was tested using one-sample t-test. The study hypothesis that the true average agreement between the observation and the first-visit SEF is 85% was rejected ($p < 0.000$) (Table 2). The actual mean agreement between observations and SEFs was 15.23% lower (95% CI: 13.36%, 17.11%) than the hypothesized value of the average agreement.

Table 2. The actual and hypothesized percent agreement and their mean difference with the 95% CI*

# of patients	Actual mean (X)	Hypothesized mean (Y)	Mean difference (X-Y)	Std. deviation	Sig. level (2-tailed)	95% confidence interval	
						Lower bound	Upper bound
66	69.78%	85%	-15.23%	7.62	.000	-17.11%	-13.36%

* CI- confidence interval

The items were collapsed to reveal the percent agreement for patient complaints, medical history, physical examination, tests performed, tests assigned, and patient smoking status (Appendix 6). It was found that patient complaints had 70.83% agreement, medical history had 52.73% agreement, physical examination had 60.61% agreement, tests performed and tests ordered had 100% and 97.35% agreement respectively. Patient habits had the lowest percent agreement, 45.45% (Table 3).

Table 3. Sum of the scores and percent agreement for domain

Variable name	Percent agreement (%)	Strength of agreement
Patient complaints	70.83	good
Medical history	52.73	poor
Physical examination	60.61	good
Tests performed*	100	excellent
Tests ordered†	97.35	excellent
Patient smoking status	45.45	poor

*Tests performed are electrocardiography and echocardiography examinations

†Tests ordered are X-ray examination, blood tests, treadmill test, and cardiac catheterization

The percent agreement per variable was also calculated considering 66 (the number of observations) as a perfect score. The results are presented in Appendix 7. Agreement was rather low for exertional shortness of breath, comorbidities, previous surgical operations, carotid artery auscultation, patient smoking status, family history, current treatment, patient position while measuring blood pressure, and position while assessing peripheral pulses. Low percent agreement for these variables was mainly due to under-recording of findings.

2.4.2 RECORDING PATTERN

Recording pattern was analyzed to reveal under- and over-recording of positive and negative findings and improper recording of patient complaints, medical history, and patient habits. The recording pattern was analyzed also for physical examination and tests performed and assigned for patients.

Under-recoding of both positive and negative findings for patient complaints, medical history, and patient habits was calculated as the percentage of responses not recorded in the SEF among all reported responses. Under-recording of positive findings was defined as the percentage of positive responses recorded in the SEF among all reported positive responses. Similarly, under-recording of negative findings was considered as the percentage of negative responses recorded in the SEF among all reported negative responses. Over-recording for these domains was calculated as the percentage of responses not obtained during the first visit among all recorded.

For physical examination, tests performed, and tests ordered under-recording was calculated as the percentage of results not recorded in the SEF among all performed procedures. Similarly, over-recording was computed as the percentage of procedures not performed among all results recorded in the SEF.

Generally, there were no cases of inaccurate recording of patient compliance or medical history, but these domains were under-recorded in 42.16% and 77.56% of cases respectively. Patient smoking status was improperly recorded in 7.32% and under-recorded in 68.29% of cases (Table 4).

Table 4. Recording pattern (%) for patient complaints, medical history, and patient smoking status

Domain	Under-recording of negative and positive findings	Under-recording of positive findings	Under-recording of negative findings	Inaccurate recording	Over-recording
Patient complaints	42.16	18.75	60	0	0
Medical history	77.56	72.22	92.31	0	8.33
Patient habits	68.29	26.67	92.31	7.32	27.78

Detailed examination of each variable collapsed into these domains revealed that the major problems of under-recording of positive findings were connected with recording of arrhythmia, orthopnea, allergy, and, especially, family history and current treatment. Under-recording of negative findings was found for exertional chest pain, arrhythmia, orthopnea, current treatment, comorbid conditions, previous surgical operations, and patient smoking status (Appendix 8).

X^2 test of independence was carried out to reveal the association between raising the question about smoking status and gender. This revealed that discussion of smoking status with patients is related to gender and the odds of raising this issue for men is 3.8 times higher than for women (Table 5).

Table 5. Raising the question on patient smoking status by gender

	Raised	Not Raised	# of patients	Percentage
Males	28	9	37	75.68
Females	13	16	29	44.83
Total	41	25		
Odds ratio = 3.82906			95% confidence interval	
Pr>chi2 = 0.0103			Lower bound	Upper bound
			1.194321	12.55209

Analysis of the recording pattern of physical examination and tests performed and ordered for patients indicated some under-recording for tests ordered (9.72%) and both under-recording (29.32%) and over-recording (28.13%) for physical examination (Table 6). Tests carried out and assigned to patients were never under- or over-recorded.

Table 6. Recording pattern (%) for physical examination, tests performed, and tests assigned to patients

Domain	Under-recording	Over-recording
Physical examination	29.32	28.13
Tests performed	0	0
Tests ordered	9.72	0

Analysis of each variable separately indicated that the results of blood pressure measurement and the assignment of blood tests and cardiac catheterization were perfectly recorded (0% of under- and over-recording). Significant under-recording was revealed for patient position (either lying or sitting) while measuring blood pressure, for assessment of peripheral pulses, carotid artery auscultation, and the prescription of chest X-ray examination. Over-recording problems were indicated for lungs auscultation, abdominal palpation, assessment of peripheral pulses, position of peripheral pulses assessed, and carotid artery auscultation (Appendix 9).

2.4.3. DIFFERENCE OF THE MEAN CONCORDANCE SCORE ACROSS PATIENT PRIMARY DIAGNOSES, CARDIOLOGISTS, AND CARDIOLOGY RESIDENTS

A set of independent variables was examined to reveal possible differences in the mean concordance scores. The hypothesis that the mean concordance scores are identical within patient diagnoses and among cardiologists was tested by one-way analysis of variance (ANOVA). F-test was performed to test whether the mean concordance scores were identical among cardiologists. According to the classification used at the ACC, patient diagnoses were divided into six categories, one of which (acquired heart disease/non-rheumatic) happened to be in the sample only once. To be able to detect possible difference in the mean concordance scores within diagnosis, this case was excluded from data analysis.

The ANOVA revealed that there was insignificant statistical difference between the mean concordance scores across patient diagnosis ($p=0.373$) and across cardiologists ($p=0.156$). One-way analysis of variance was performed to test the hypothesis whether the mean concordance scores were identical among cardiologists performing alone and residents performing under the supervision of cardiologists (resident-cardiologist pairs). One of the resident-cardiologist pairs

assessed only one patient included in the sample. Thus, the ANOVA was carried out after excluding this case from the data. Data analysis showed that the mean concordance scores were significantly different between one of the pairs (cardiologist 2 and resident 2) and the third cardiologist performing alone, as well as between the same pair and the fourth cardiologist performing alone (Table 7).

Table # 7. The difference in the mean concordance score between cardiologist and resident performing under the supervision of cardiologist

Cardiologist + resident id (X)	Cardiologist + resident id (Y)	Mean difference (X-Y)	Std. Error	Sig. Level	95% Confidence Interval	
					Upper bound	Lower bound
30	22	3.2813	.8821	.032	.1280	6.4345
40	22	3.9786	.9890	.012	.4431	7.5141

One-way analysis of variance was applied also to test the differences in the mean concordance scores for each variable across cardiologists. When a statistically significant difference was found, a post-hoc test with Bonferroni correction was applied to indicate the mean difference between the mean concordance scores for each discordant pair of cardiologists. The Bonferroni correction was used to set the overall probability of Type I error at 0.05 level, as the combined probability of Type I error for multiple tests is much greater than 0.05.

The ANOVA and the post hoc test revealed that the mean concordance scores were significantly different among cardiologists for arrhythmia, lungs auscultation, abdominal palpation, and assessment of peripheral pulses (Table 8).

Table 8. Differences in the mean concordance scores for arrhythmia, lungs auscultation, abdominal palpation, and peripheral pulses assessment across cardiologists

Item	Cardiologist id (X)	Cardiologist id (Y)	Mean difference (X-Y)	Std. Error	Sig. Level	95% Confidence Interval	
						Upper bound	Lower bound
Arrhythmia	3	4	.5379	.1512	.004	.1259	.9499
Lungs auscultation	2	5	.5412	.1374	.001	.1668	.9156
	3	5	.3727	.1298	.034	.0189	.7266
	4	5	.5167	.1502	.006	.1074	.9260
Abdominal palpation	3	2	.4198	.1512	.044	.0763	.8319
Assessment of peripheral pulses	3	5	.4902	.1348	.003	.1226	.8577
	4	5	.5583	.1560	.004	.1333	.9834

2.4.4 VALIDITY ANALYSIS

To measure the adequacy of SEF as a source of retrospective data collection, validity analysis was carried out. Sensitivity and specificity for each recorded domain were calculated. Positive predictive value (PPV) was also computed for each domain to indicate the percentage of true positives among all recorded positives.

Sensitivity, specificity, and PPV equal to or higher than 70% were found for tests performed and tests ordered to patients. Patient complaints, medical history, and patient habits had less than 70% sensitivity, but $\geq 70\%$ specificity and PPV, except for patient smoking status that had $<70\%$ PPV. On the contrary, physical examination had $\geq 70\%$ sensitivity and PPV, but $< 70\%$ specificity (Table 9). Validity of SEFs was examined for each separate variable as well, and the details are presented in Appendix 10.

Table 9. Sensitivity, specificity, and positive predictive value for each domain

Variable name	Sensitivity	Specificity	PPV*
Patient complaints	58.15	100	100
Medical history	22.45	97.01	91.67
Physical examination	70.68	38.04	71.87
Tests performed†	100	100	100
Tests ordered‡	89.39	100	100
Patient smoking status	24.39	80	66.67

*PPV is the positive predictive value

†tests performed are electrocardiography and echocardiography examinations

‡tests ordered are X-ray examination, blood tests, treadmill test, and cardiac catheterization

2.5. DISCUSSION

2.5.1. PERCENT AGREEMENT

Prior to implementing this study it was hypothesized that the mean percent agreement between observations and the first-visit SEFs was 85%, while the actual agreement was found to be 69.8%. On average, the actual agreement was 15.23% lower (95% CI: 13.36, 17.11) than the hypothesized agreement. Further, analysis of the percent agreement for each domain revealed that tests performed and tests assigned to the patients had perfect agreement, while patient complaints and physical examination had good agreement. The weakest area of data collection at ACC was the recording of findings on medical history and patient habits.

The findings of this study were similar to that of a similar study aimed to validate medical records, which revealed poor agreement for patient habits, allergies, current medications, family history, and social history (29%) [13]. On the other hand, the survey conducted at the ACC revealed excellent agreement for ordered tests and lower agreement for chief complaints, while other studies indicated the opposite results [10, 12]. This can be explained by a tendency of cardiologists at NMMC to under-record positive and negative findings on patient complaints.

Separate analysis for each variable revealed an artificial excellent agreement for allergy, although there was considerable under-recording of allergies. This should be explained by the fact that the question regarding allergy was raised only during 5 observations (8.2%) out of 66 and all those cases when the question was not raised were considered concordant according to the study rules. Meanwhile, the attitude towards raising the question about presence of allergy could be a matter of concern at the ACC, because it is well known that obtaining careful history of previous allergies, including drug allergies, is an important prerequisite of reducing the probability of hypersensitive reactions to drugs [22].

The analysis of percent agreement was carried out including those cases when the question was not raised during the first visit or the procedure was not performed, which might artificially increase both the overall and the per variable percent agreement. Thus, it should be expected that the concordance between observations and SEFs would be lower if those cases are excluded from the analysis.

2.5.2. RECORDING PATTERN

One of the strengths of data recording at the ACC is the accurate and complete recording of tests performed and ordered for patients, except chest X-ray examination. Under-recording of chest X-ray prescription can be explained by cardiologist's reliance on the actual presence of X-ray films. However, these films are kept separately and are not attached to the ambulatory folder where the SEFs are kept. Thus, auditors or investigators would be unable to detect from the SEF whether chest X-ray test was prescribed if the prescription is not recorded there.

The study findings showed significant under-recording of both positive and negative findings regarding patient complaints, patient habits, and, especially, medical history. Family history of myocardial infarction, hypertension, sudden death, and stroke was generally raised during the first visit, but it was almost never recorded. Family history is one of the risk factors for heart disease, although unmodifiable, and should be carefully addressed by physicians [23-24, 27]. Another finding of the study, over-recording of medical history, can be explained by the fact that in some cases comorbidities and previous surgical operations were noted in the SEF as negatives, but these issues were not discussed during the first visit.

Recording of current treatment was another weak area of data collection at ACC. Medications prescribed to a patient by another health care provider were rarely recorded in the SEF, which might pose some difficulties for assessing continuity and quality of care [27].

It was mentioned previously that the detailed given to record comorbidities and previous surgical operations varied across cardiologists and residents-cardiologist pairs. Some of them recorded only those diseases that patients had at the time of referral and/or those conditions that were considered important for planning of patient management. This, however, could be a subjective judgement. Moreover, the absence of comorbid conditions and previous surgical operations should be also recorded in the SEF, but in most such cases the items were left blank, which did not allow differentiating negative responses from the missing ones. Meanwhile, it is known that some comorbid conditions and previous surgical operations are those preoperative variables that

should be considered for risk adjustment of health outcomes after cardiac surgery [25-26]. These are also indicators of disease severity and should be taken into account when planning alternative treatments for cardiac patients [25-26].

The same problem was found in recording pattern of patient habits: the positive findings were recorded, while the negatives ones were left aside. Moreover, there was improper recording of patient smoking status, though only in a small percent of cases. Analysis showed that the question about smoking status was raised 3.8 times more often in man than in women. This can be explained by the widespread perception that Armenian women normally do not smoke. It should be noted, however, that patient habits are important risk factors for cardiovascular diseases [23-24].

Under-recording and improper recording of these findings may impose difficulties in conducting effective patient education programs and may create obstacles for retrospective collection of data to be used for QA and research activities. Under-recording of both positive and negative findings may also lead to underestimation of cardiologist's performance, as without recording it is impossible to prove that the questions were raised [2,13]. It can be concluded that under-recording of positive and negative findings indicates the lack of established policy and procedures for recording patient's medical history and behavioural risk factors.

Data analysis also revealed that there were notable under-recording and over-recording of physical examination results. Examination of each item separately indicated that the major problems were found for patient position while measuring BP, position of pulses assessed, and carotid artery auscultation. Patient BP was measured in either sitting or lying position, but the position was never recorded in the SEF.

While collecting the data, it was revealed that the detail given to record peripheral hemodynamics and major arteries auscultation results varied among cardiologists and cardiac residents. The number of pulses assessed was identified from the item "peripheral hemodynamic/major arteries", while the pulse item of SEF showed which artery pulse had been assessed. The results of carotid artery auscultation were recorded under the item "major arteries" or as a separate item in remarks. The assessment of peripheral pulses (left and right radial and left and right pedal pulses) and carotid artery auscultation should be routinely performed in each patient admitted to the clinic. Data analysis indicated significant under-recording of these procedures, which in turn indicates the lack of standards on physical examination and documenting its results.

An over-recording pattern was indicated for lungs auscultation, abdominal palpation, assessment of peripheral pulses, and carotid artery auscultation. In a study aimed to evaluate the impact of structured encounter format patient records on provider performance and recording pattern, it was found that over-recording of physical findings was more common in structured, than in free text format patient records. The structured format for physical examination predisposed providers to check all physical examination results even if the examination was partially performed. Probably, this was the case at ACC. Meanwhile, partial performance of physical examination may lead to overlooking of patient health problems and to inappropriate patient management, possibly causing quality of care to suffer. It could be concluded that both the lack

of training on documentation of medical records and the absence of established guidelines on conducting patient physical examinations were responsible for the revealed shortcomings in recording pattern of this domain at ACC.

2.5.3. DIFFERENCE OF THE MEAN CONCORDANCE SCORE ACROSS PATIENT PRIMARY DIAGNOSES, CARDIOLOGISTS, AND CARDIOLOGY RESIDENTS

The study revealed that there was no statistically significant difference in the overall concordance score within patient primary diagnoses and among cardiologists, but there was a statistically significant difference between cardiologists performing alone and residents performing under the supervision of cardiologists. While analyzing the differences in the average scores for each variable across cardiologists, statistically significant differences were detected for arrhythmia, lungs auscultation, abdominal palpation, and peripheral pulses. Although larger sample size was needed to make appropriate conclusions and recommendations, the study presented pilot results to be used for planning further research.

2.5.4. VALIDITY MEASUREMENTS

Before relying on medical records as a source of patient data for research or other purposes, it is necessary to examine their validity. Data analysis was carried out to detect how sensitive, specific and predictive are the first-visit SEFs in terms of various types of patient information. When both sensitivity and specificity were equal or exceeded 70% the medical records were considered appropriate for use as a valid source of patient information for retrospective data collection.

Data analysis indicated that the first-visit SEFs were sensitive in terms of performance and/or prescription of ancillary tests and were specific enough to properly identify when these tests were actually not performed or assigned. Also, the medical records predicted with 100% accuracy the fact of performance/prescription of these tests. More detailed analysis indicated that the SEF reflected true positive findings on exertional chest and BP measurement by 76-100% and true negative findings by 100%. The remaining items had high sensitivity, but low specificity or low sensitivity, but high specificity (appendix 14) that should be considered when collecting patient information for research purposes.

2.6. CONCLUSIONS AND RECOMMENDATIONS

A comprehensive clinical record is a key source of specific patient information used for various purposes. Considering the importance of accurate and complete patient records, the study was conducted to evaluate the medical records documentation at the ACC at NMMC. The study indicated the following strengths and weaknesses of data collection at ACC:

- Good agreement between observations of the actual patient-provider encounter and medical records;

- Significant under-recording of positive findings regarding family history and current treatment;
- Significant under-recording of negative findings regarding patient complaints, medical history, and patient habits;
- Considerable under-recording of patient position while measuring BP and the results of particular peripheral artery assessments;
- Substantial over-recording of lungs auscultation, abdominal palpation, assessment of peripheral pulses, and carotid artery auscultation;
- Valid patient specific information with respect to BP measurement, tests performed and ordered to patients;
- Absence of established standards on history taking, physical examination, and documentation of medical records;
- Variability of the mean concordance score among providers.

Good agreement between direct observations of patient-cardiologist encounters and the first-visit SEFs supports the use of the first-visit SEFs as a source of patient information for further QA activities and research purposes only after some improvements are designed and implemented. The first-visit SEF was found to be valid source of patient data only with regard to BP measurement, ECG and EChO examinations, prescriptions of blood tests, treadmill test, and cardiac catheterization that had a high percent agreement, sensitivity, specificity, and PPV.

Under-recording of patient complaints, medical history, and patient smoking status resulted in decreased percent agreement and lowered the adequacy of patient records. It is necessary to emphasize the need for recording not only positive, but also negative findings, differentiating them from the missing ones. It is quite important to record patient family history and allergy and the SEF should be redesigned to include this information. Comorbid conditions and previous surgical operations had poor agreement that highlights the need to establish the standards on history taking regarding these items and to separate comorbidities from the previously endured diseases. Besides, to fairly compare indicators of health care quality at NMMC over time and within similar health care organizations, it is necessary to use standardized coding (e.g. ICD) of patient diagnosis and comorbid conditions.

Patient position while measuring BP was either sitting or lying. This indicates the necessity of implementing a standardized approach: either measuring BP in a single position or mentioning the position in the SEF. Further, under-recording of both the results of physical examination and the prescription of chest X-ray examination may lead to underestimation of provider performance and may diminish the adequacy of medical records for further research and quality assurance purposes. Thus, it is essential to improve recording patterns through conduction of trainings for medical staff.

Over-recording of lungs auscultation, abdominal palpation, assessment of peripheral pulses, position of peripheral pulses assessed, and carotid artery auscultation suggests an existence of a problem with documenting these items. In addition, incomplete assessment of patient health may lead to disregarding of disease symptoms and signs, which in its turn may result in under-

diagnosis, incomplete treatment and worsening of patient health outcomes. Thus, it is extremely important for NMMC:

- to develop clinical guidelines on history taking, physical examination, and data collection on patient health behavior;
- to train medical staff on accurate and complete documentation of patient information; and
- to establish internal evaluation processes at NMMC ensuring compliance of everyday practice with the existing standards.

Patient weight and height are excluded from the first-visit SEF, while overweight is one of the modifiable risk factors for heart disease [23-24]. The equipment to measure patient weight and height is available at NMMC and the measurements can be performed by nurses while patients are waiting for appointment with cardiologists. It is recommended also to note the type of patient visit, i.e. primary or follow-up, in the nurses' notebook when assigning a date and time for patient visit to facilitate purposeful data collection.

It should be noted that the intrusive nature of the study involving direct observations of patient-cardiologist encounters might lead to modified behavior and recording pattern. Although it is believed that the study results reflect the real situation at NMMC, it is desirable to assess the adequacy of medial records with implementation of less intrusive methods.

3. EVALUATION OF THE SURGICAL SUMMARY DATABASE AT NORK MARASH MEDICAL CENTER

3.1. METHODS

3.1.1. STUDY PROTOCOL

A medical record is initiated for each patient admitted to NMMC who should undergo cardiac surgery and/or cardiac catheterization. At discharge, specific data is collected for surgical patients and is documented in a handwritten SEF (“Heart Chart”) by cardiac surgery residents. Thereafter, patient information is entered into a surgical summary database by a cardiac surgery fellow. At the time the study was initiated, medical records and data entered into database were available for patients operated on in May-June. The adequacy of surgical summary database was evaluated comparing patient information documented in medical records and entered into the database.

Generally, some items are documented directly in patient records while others are first recorded in other SEFs used in different clinical departments of NMMC and are added to the clinical records when patients are discharged or transferred. Thus, medical records, charts of the intensive care unit (ICU), or transfusion cards were used as the primary source of recorded information.

Depending on the comparability of patient specific data in two sources (in the records and in the database) a response ranging from 1 to 5 was assigned to each item. Response 1 was assigned to an item, if the item was recorded in both sources of patient information and was the same in its content. Response 2 was assigned if the item was recorded in both sources, but was different in its content. Responses 3 and 4 were assigned if the item was recorded either only in medical records or only in the database respectively, while response 5 was assigned when the item was not recorded in either source. It should be noted that surgical summary database was designed in a way that captures only positive findings, thus, it was impossible to differentiate negative responses from missing ones. A blank field in the clinical database was considered as absence of that particular information and when the item was not recorded in medical record either, response 5 was assigned to the item.

Instructions were developed for auditing surgical summary database to ensure its objectivity and to facilitate further data collection by persons without medical background (Appendix 10).

3.1.2. STUDY INSTRUMENT

The instrument was developed based on the content of the handwritten patient record (Appendix 11) and consisted of 23 closed-ended questions (Appendix 12). The instrument included items that were relevant to or essential for quality assurance activities and/or were the risk factors for cardiac surgery. The investigator prepared the questionnaire in consultation with the cardiac surgery fellow, a counterpart of N2-RR project.

The instrument was pre-tested on 10 patient records. The major problems were indicated for “patient diagnosis”, “surgical procedure”, and “other post-operation complications” items. It was revealed that patient diagnoses and surgical procedures were entered into database in words, sometimes using abbreviations. A list of patient diagnosis and surgical procedures was developed to ensure consistency while assessing the adequacy of database regarding these variables (Appendix 13).

Generally, the afore-mentioned variables are documented in patient records before surgery, while the surgical protocol is completed after the operation. In those instances, when inconsistency between patient records and the database was indicated regarding patient diagnosis, surgical procedure, and other post-surgical complications, the concordance was checked comparing the information entered into the database with that recorded in the surgical protocol. This strategy was applied to check the consistency of patient diagnosis across several sources of patient information and to reveal whether these sources are routinely reviewed before and after surgical operations.

Some technical problems were noted for “re-operation”, “post-surgical in-hospital death”, “mediasthenitis”, “wound infection”, “blood used for transfusion”, and “insulin administered to patients” items. In both sources, these items were only checked as positive or left blank, so that response 2 (recorded in both sources but different in content) was not applicable for them.

3.1.3. STUDY POPULATION

The eligibility criteria for inclusion into the evaluation of surgical summary database sub-project were the following:

- surgical patients of NMMC
- patients who underwent open-heart cardiac surgery no latter than June, 2001.

The exclusion criteria were as follows:

- patients who underwent surgical procedures other than open-heart cardiac surgery (i.e. cardiac catheterization, other close-heart invasive procedures).

The sample size of the study was determined using one-sample proportion formula in the STATA 7.0 statistical software. The standard agreement was 0.95, the hypothesized agreement between medical records and surgical summary database was 0.85 (based on expert opinion), and the least difference desirable to detect was 0.10. With 80% power and alpha error of 0.05 the sample size was calculated equal to 53 patients. Considering possible problems that might naturally rise during the study implementation the sample size was increased to 61 patients.

The latest 61 medical records starting from June 2000 were selected and the database information for these patients was reviewed.

3.2. ETHICAL CONSIDERATIONS

The study possessed no risk for patients, as it involved secondary data analysis. Thus, informed consent was provided neither to patients nor to medical staff members of NMMC. However, approval to access surgical protocols, surgical summary database and medical records from the archive was obtained prior to initiating the study. Patient records and surgical summary database were reviewed in the hospital to ensure patient confidentiality. In addition, the investigator undertook necessary actions to ensure confidentiality when there was a need to use patient names for retrieving patient records.

3.3. STUDY LIMITATIONS

Although patient records were selected non-randomly, it was believed that the study results reflected the true picture of data collection at NMMC, as a single person transferred patient data from handwritten patient records into the database. Therefore, the variation of data entry depending on operators was minimized. For such surveys, sequential record analysis is normally considered adequate.

3.4. DATA ANALYSIS

The data was entered into SPSS 10.0 and was analyzed through SPSS 10.0 and MS Excel statistical software. Double entry with error checking was performed to eliminate possible errors. A total of 61 patient records/surgical summary charts were reviewed. In both sources, scores (1 to 5) were assigned to each item to allow comparison between them. As the medical records were considered as a “gold standard”, both response 2 (recorded in both sources, but different in its content) and response 3 (recorded in the record and missing in the database) were treated similarly during the analysis of validity.

3.4.1. PERCENT AGREEMENT

The overall percent agreement between patient records and surgical summary database constituted 88.74%. This was not significantly different from the hypothesized percent agreement of 85% (Table 11).

Table 11. The actual and hypothesized percent agreement and their mean difference with the 95% CI*

# of medical records	Actual mean (X)	Hypothesized mean (Y)	Mean difference (X-Y)	Std. deviation	Sig. level (2-tailed)	95% confidence interval	
						Lower bound	Upper bound
61	.8874	.85	.0374	.0405	.4133	.8081	.9667

* CI- confidence interval

Percent agreement for each item was calculated considering 61 (# of medical records included in the sample) as a perfect agreement. The results showed that there was 81-100% agreement for all

variables except diagnosis documented in patient records, heart failure class, ICU stay, and blood used for transfusion (Appendix 14). Heart failure and ICU stay items had 77.05% agreement, while diagnosis and blood used for transfusion had 47.54% agreement. Further data analysis was performed to reveal the consistency of patient diagnoses and surgical procedures between the surgical protocol and database. The percent agreement for surgical procedures between these two sources of patient information was significantly higher than that between patient records and database. The percent agreement for diagnosis between surgical protocol and database was 59.38%, while it was only 47.05% between medical records and database (Table 12).

Table 12. The percentage of agreement for patient diagnosis and surgical procedures between database and patient records and between database and surgical protocols

Item	Percent agreement between surgical summary database and patient records*	Percent agreement between surgical summary database and surgical protocols†
Patient diagnosis	47.54%	59.38%
Surgical procedure	93.44%	100%

* Percentage of agreement was calculated among all 61 cases

† Percentage of agreement was calculated among cases that were discordant between database and patient records

3.4.2. VALIDITY ANALYSIS

Validity of surgical summary database was examined to identify its appropriateness as a valid source for retrospective data collection. When both sensitivity and specificity were equal to or exceeded 70%, the medical records were considered as a valid source of patient specific information.

Data analysis indicated that the overall sensitivity of the surgical summary database, i.e. its ability to reflect positive findings among true positives, was 86.26% and the overall specificity of it, i.e. its ability to reflect negative findings among true negatives, was 100%. Also, the database was able to correctly predict positive patient information 96.96% of the time (i.e. the findings stated as positive were really positive in 96.96% of cases). Validity analysis for each variable indicated that the database reflected true positive findings by 77-100% and true negative findings by 79-100% for almost all items, except gender, diagnosis, heart failure class, and blood used for transfusion. Gender had 100% sensitivity, but 0% specificity, which can be explained by a general tendency of not mentioning patient's gender in medical records relying on first names of patients that usually reflect his/her gender. Unlike this, patient diagnosis, heart failure class, and blood usage had low sensitivity (3-48%), but high specificity (85-100%). Other post-surgical complications were 100% sensitive and 85% specific, but the database was able to predict the existence of post-surgical complications in only 18% of the cases (Appendix 15).

3.5. DISCUSSION

3.5.1. PERCENT AGREEMENT

Data analysis indicated that all variables had perfect agreement, except patient diagnosis, heart failure, ICU stay, and blood usage. ICU stay and heart failure class had good agreement, while patient diagnosis and blood usage had poor agreement. Poor agreement for patient diagnosis can be due to entering data without use of standardized coding. Although a single person enters data, diagnosis description entered into database can be different from terminology used by another individual who documents patient diagnosis in medical records. In addition, patient diagnoses and surgical procedures are recorded using abbreviations that can be unfamiliar to researchers or auditors. In databases of other medical centers, diagnoses and procedures are recorded using the International Coding of Diseases (ICD) [4]. It should be noted that patient diagnosis is the most important data that should be accurately recorded to enable monitoring of health care quality indicators over time.

Poor agreement of blood usage can be explained by clinicians' reliance on availability of blood transfusion database with detailed information on blood and blood products usage at each department and for each patient. However, these databases are linked only by patients' names and by medical records' numbers, and so, it is impossible to switch directly from one database to another.

Lower percentage of agreement between medical records and surgical summary database for ICU stay can be explained by the fact that the duration of patient stay in ICU is calculated by hand and recorded in Heart Chart by cardiac surgery residents. There are no established rules for calculation of ICU stay and so, this can be done differently by different residents. For example, one person can calculate the ICU stay using hours typed at the top of the columns in the ICU chart, another resident may calculate it using number of those columns where the patient information is recorded. The latter way can be imprecise as a column can be filled not only for an hour, but also for half an hour. Although the detected difference is not big (1-3 hours), patient stay in the ICU is considered as a quality of care indicator. Therefore, it is necessary to ensure identical calculation and recording of ICU stay. Further, heart failure class is documented in medical records by cardiologists before the operation, while this data is entered into database by cardiac surgery fellows after the operation is performed and the final diagnosis is confirmed. A process of revising medical records after operation, however, is not established at NMMC, which can explain the inconsistency between these two sources of patient information.

The completeness of surgical summary database in comparison with databases used by other similar health care organization was considered beyond the scope of this study. However, the study revealed a lack of several important variables related to patient health care outcomes. The Cooperative Coronary Artery Bypass Graft (CABG) Project that was conducted in 1993-94 reached a consensus on risk factors for post-CABG mortality and identified three groups of these factors depending on their relation to post-operative mortality [25]. The scientific literature indicates that some core variables related to operative mortality, such as left ventricular ejection fraction, percent stenosis of left main coronary artery, number of major coronary arteries with stenosis > 70%, urgency (acuity) of operation, etc. should be routinely collected for each patient

[24-26, 28]. This study revealed that some of these variables were documented only in handwritten patient records. Considering the potential use of surgical summary database for epidemiological purposes and for fair comparison of health care outcomes over time and within similar institutions it is necessary to include these post-surgery outcomes related variables into the surgical summary database.

The study revealed that patient comorbid conditions and post-surgical complications were also entered into the database without using any standardized coding, which might result in variation of terminology by operators. Standardized coding will facilitate the adjustment for patient case mix and will contribute to the comparability of quality indicators over time and across other similar organizations.

Some errors in data may be eliminated if software used for data entry notifies the user that the data entered in a given field exceeds the acceptable (higher or lower) limits (e.g., for creatinine level).

3.5.2. VALIDITY ANALYSIS

Clinical databases have a great potential to facilitate research, audit, quality assurance, and other activities. Prior to their use, however, it is necessary to evaluate the validity and reliability of such databases. The N2-RR project revealed that the surgical summary database is sensitive, specific, and predictive enough to be considered as a valid source of patient information. However, the per-variable analysis of validity indicated that diagnosis, heart failure class, and blood usage had low sensitivity. Considering the relation of these variables to post-operative health care outcomes, it is important to accurately record this information to properly adjust for patient case mix and facilitate monitoring of health care outcomes.

It should be noted also that the absence of a specific patient condition is never noted in the surgical summary database, so that it is impossible to differentiate negative responses from missing ones. This can create obstacles for both the assessment of health care quality at NMMC and the research activities based on this database.

3.6. CONCLUSIONS AND RECOMMENDATIONS

A high quality clinical database is an important source of patient information used for QA, research, medical audit, reimbursement, and other purposes. The study indicated the following strengths and weaknesses of data collection at NMMC:

- Excellent overall agreement between patient medical records and surgical summary database
- Good agreement for heart failure class and patient stay in the intensive care unit
- Poor agreement for patient diagnosis and blood usage
- Entering data without usage of standardized coding of comorbid conditions, patient diagnoses, surgical procedures, and post-surgical complications

- Entering data without coding the names of patients and/or clinical staff members to ensure confidentiality
- Lack of strategies to mention negative findings (absence of a particular patient condition) in the database
- Lack of strategies to range check data that exceed acceptable limits
- Incomplete clinical database in comparison with those used by other health care institutions of similar type
- High overall sensitivity, specificity, and positive predictive value of the database
- Low sensitivity of data on patient diagnosis, heart failure class, and blood usage.

The excellent overall agreement between patient records and the surgical summary database and its high validity could support the use of this clinical database as a source of patient specific information for QA and research activities at NMMC. However, it is necessary to design and implement several improvements in data collection at NMMC to ensure development of high quality clinical database. Thus, it is recommended:

- To establish standards for coding of patient diagnoses and surgical procedures (e.g., ICD)
- To redesign surgical summary database to include negative findings
- To use software strategies notifying the user about missing data and monitoring for data that exceed acceptable limits
- Based on international standards, to redesign the surgical summary database to include variables important for adjustment of patient case mix
- Train staff members on completion of medical records and data entry.

The completeness of surgical summary database in comparison with the international clinical standards and timeliness of data entry were considered beyond this study. It is recommended to conduct further research to indicate timeliness of the surgical summary database completion and quantify completeness of this database according to international standards.

In conclusion, the study confirmed that the accuracy and completeness of medical records and clinical databases should be evaluated prior to their use as a source of patient data for QA and research activities. This study can serve as a basis for designing and implementing improvements in other aspects of patient data collection at NMMC. It is recommended to identify and solve problems using a group approach with involvement of employees who are in charge of enacting changes. This may result in improvement of health care quality and, consequently, of patient health outcomes. Moreover, in a broader view, the NMMC may serve as a model of successful introduction and implementation of QA activities in the Armenian health care system. NMMC experience in this sphere can be used by other hospitals in Armenia to accept the “philosophy” of QA as an indispensable function of any health care organization to provide high quality health care.

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APPENDICES

APPENDIX 1. The first-visit structured encounter form of the Adult Cardiology Clinic

Սրտաբան _____ 1-ին այցի ա/թ _____ / _____ / _____ թ.
 Ա.Ա.Յ. _____ Սեռը _____
 Ծննդյան ամսաթիվը _____ / _____ 19 _____ թ. Տարիքը _____ տ.
 Պետություն _____ Մարզ _____ Քաղաք _____
 Փողոց _____ Տուն _____ Բնակ. _____ Հեռ. _____
 Աշխ. վայր _____ Հեռ. _____
 Բարեկամ _____ Հեռ. _____
 Ուղարկող բժիշկ _____

Ախտորոշում _____											
Ուղեկցող հիվ. _____											
<u>SA-FC-</u>	I	II	III	IV	<u>UA</u>	<u>HF-FC-</u>	0I	II	III	IV	
Հիվ. տեսակը՝											
		<input type="checkbox"/> IHD		<input type="checkbox"/> AHD//Rheumatic		<input type="checkbox"/> AHD//NonRheumatic		<input type="checkbox"/> CHD			
		<input type="checkbox"/> Hypertension		<input type="checkbox"/> Arrhythmia		<input type="checkbox"/> Cardiomyopathy		<input type="checkbox"/> NS		<input type="checkbox"/> Other	
Գտնվում է՝											
		<input type="checkbox"/> Medication		<input type="checkbox"/> Follow-up		<input type="checkbox"/> X-ray		<input type="checkbox"/> Holter		<input type="checkbox"/> Treadmill	

ՆԵՐՍՐՏԱՅԻՆ ՀԵՏԱԶՈՏՈՒԹՅՈՒՆ
 _____ / _____ / _____
 _____ / _____ / _____
 _____ / _____ / _____
 _____ / _____ / _____

ՎԻՐԱՀԱՏԱԿԱՆ ՄԻՋԱՄՏՈՒԹՅՈՒՆ
 _____ / _____ / _____
 _____ / _____ / _____
 _____ / _____ / _____

<input type="checkbox"/> Ծխախոտ	<input type="checkbox"/> Ալկոհոլ	<input type="checkbox"/> Կլինաքս	<input type="checkbox"/> Հիպերխոլեսթերինեմիա	<input type="checkbox"/> Հիպերգլիկեմիա	<input type="checkbox"/> Այլ
---------------------------------	----------------------------------	----------------------------------	--	--	------------------------------

Մահվան ա/թ. _____ / _____ / _____
 Պատճառը _____

Արտի առևկուլտացիա՝ տոները՝ I _____ II _____ այլ _____, ռիթմիկ՝ այո , ոչ . ,
 սիստոլիկ աղմուկ , բնույթը _____ մաքսիմալ լսում է՝ _____
 դիաստոլիկ աղմուկ , բնույթը _____ մաքսիմալ լսում է՝ _____

Ռենտգեն

ԷՍԳ՝ ռիթմը՝ _____ զարկ 1 րոպեում, ՍԷԱ՝ _____
 հիպերտրոֆիա՝ _____, այլ _____

սպիական փոփոխություններ՝ _____

ԷԽՈ-ՍԳ: _____ ժապավեն # _____

LA _____; Ao _____; LV ed _____; LV s _____; PW d/s _____; IVS _____; RV _____; RVAW _____;
 EF _____ %; PAAT _____

Եշումներ _____

Այլ հետազոտություններ

- | |
|-----------|
| 1.tredmil |
| 2.holter |
| 3. CT |
| 4. MRI |

Կրկին քննություն _____ / _____ / 200 թ.

Դեղորայք՝

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____

APPENDIX 2. Instrument for the evaluation of medical records documentation at the Adult Cardiology Clinic

1 = raised/positive	1 = recorded/positive
2 = raised/negative	2 = recorded/negative
3 = none	3 = none

1-3 responses for A and D sections

Yes = test performed/ordered	Yes = results recorded/prescription recorded
No = test not performed/not ordered	No = results not recorded/prescription not recorded

Yes/No responses for B and C sections

Date: ____/____/2001 Observation Start time: ____: ____

Observation End time: ____: ____

Patient ID:

Resident ID:

Auditing Start time: ____: ____

Auditing End time: ____: ____

#	Item	Observation	1 st visit SEF	Score
		Response	Response	0-1
A.	Anamnesis Morbi:	1/2/3	1/2/3	
	Exertional chest pain			
	Exertional shortness of breath			
	Arrhythmia			
	Orthopnea			
	Family history (e.g. for myocardial infarction			
	hypertension			
	stroke			
	diabetes			
	renal failure			
	others)			
	Allergy			

	Current treatment				
	Comorbidities (e.g. myocardial infarction, <i>stroke</i> <i>diabetes</i> <i>gastric ulcer</i> <i>rheumatic fever</i> others)				
	Previous surgical operation(s) (e.g. cardiac surgery, <i>gastric ulcer resection</i> , <i>others</i>)				
B.	Physical examination	Yes	No	Yes	No
10a.	Blood pressure measurement				
10b.	Sitting/lying position while measuring BP				
	Heart auscultation				
	Lungs auscultation				
	Abdominal palpation				
14a.	Peripheral hemodynamics (left radial pulse, right radial pulse left pedal pulse right pedal pulse)				

14b.	Position of pulse assessed				
	Carotid artery auscultation				
C.	Other tests				
	<i>Electrocardiography (ECG)</i>				
	<i>Echocardiography (EchO)</i>				
	<i>Chest X-ray examination</i>				
	Blood tests				
	(prothrombin index,				
	electrolytes [Na, Ca, K],				
	creatinine,				
	glucose,				
	cholesterol,				
	triglycerides,				
	HDL,				
	LDL,				
	bun,				
	others)				
	Treadmill				
	Cardiac catheterization				
D.	Risk factor	1/2/3		1/2/3	
	Smoking status				

Patient name:

Patient primary diagnosis:

Patient secondary diagnosis:

APPENDIX 3. Instructions for observations of patient-provider encounters at the adult cardiology clinic

1= raised/positive*	The question was raised during the first visit and a patient answer was positive
2= raised/negative	The question was raised during the first visit and a patient answer was negative
3= none	The question was not raised during the first visit

* 1-3 responses for sections A and D
Yes/No responses for B and C sections

Section A / Anamnesis Morbi

1. Did a cardiologist ask a patient about exertional having chest pain? [1-3]

- 1 If a question about having exertional chest pain was raised and a patient had the exertional chest pain
- 2 If a question about having exertional chest pain was raised and a patient had not the exertional chest pain
- 3 If a question about having exertional chest pain was not raised

Note: Chest pain sensation can be described by a patient as an unpleasant feeling (e.g. pressing, squeezing, strangling, constricting, bursting, burning, etc). The exertional chest pain is defined as chest pain related to the physical activity.

2. Did a cardiologist ask a patient about having exertional shortness of breath? [1-3]

- 1 If a question about having exertional shortness of breath was raised and a patient had the exertional chest pain
- 2 If a question about having exertional shortness of breath was raised and a patient had not the exertional chest pain
- 3 If a question about exertional chest pain was not raised during the first visit

Note: A patient can describe the shortness of breath as a feeling of urgent need to take another breath. The exertional shortness of breath is defined as shortness of breath related to the physical activity.

3. Did a cardiologist ask a patient whether s/he has arrhythmia? [1-3]

- 1 If a question about having arrhythmia was raised and a patient had the arrhythmia
- 2 If a question about having arrhythmia was raised and a patient had not the arrhythmia
- 3 If a question about having arrhythmia was not raised during the first visit

Note: The arrhythmia can be defined by a patient or cardiologist as “pounding”, “stopping”, “jumping” or “racing”.

4. Did a cardiologist ask a patient about having orthopnea? [1-3]

- 1 If a question about having orthopnea was raised and a patient had the orthopnea
- 2 If a question about having orthopnea was raised and a patient had not the orthopnea
- 3 If a question about having orthopnea was not observed during the first visit

Note: Orthopnea is defined as having difficulties with breathing that occur in lying position and is relieved promptly by sitting or standing position.

5. Did a cardiologist ask a patient about having family history of any disease? [1-3]

- 1 If a question about having family history of any disease was raised and a patient mentioned one/some disease(s)
- 2 If a question about having family history of any disease was raised and a patient had not family history of any disease
- 3 If a question about having family history of any disease was not raised during the first visit

Note: If a patient had a family history of any disease, write down the diseases that the patient had reported.

6. Did a cardiologist ask a patient about having an allergy/ [1-3]

- 1 If a question about having an allergy was raised and a patient responded positively
- 2 If a question about having an allergy was raised and a patient responded negatively
- 3 If a question about having an allergy was not raised during the first visit

7. Did a cardiologist ask a patient whether s/he is receiving treatment for a heart disease? [1-3]

- 1 If a question about being currently treated for a heart disease was raised and a patient responded positively
- 2 If a question about being currently treated for a heart disease was raised and a patient responded negatively
- 3 If a question about being currently treated for a heart disease was not raised

Note: If answer is positive, write down the names of the drugs that the patient mentioned.

8. Did a cardiologist ask a patient about having comorbidities (illnesses other than heart disease)? [1-3]

- 1 If a question about having comorbidities was raised and a patient responded positively
- 2 If a question about having comorbidities was raised and a patient responded negatively
- 3 If a question about having comorbidities was not raised during the first visit

Note: If a patient answer was positive, write down those diseases that the patient had noted, both those that s/he currently has and that s/he had in the past.

9. Did a cardiologist ask a patient about having surgeries in the past? [1-3]

- 1 If a question about having surgical operations in the past was raised and a patient answered positively
- 2 If a question about having surgical operations in the past was raised and a patient responded negatively
- 3 If a question about having surgical operations in the past was not raised during the first visit

Note: If a patient response was positive write down those operations that the patient listed.

Section B / Physical examination**10a. Did a cardiologist perform blood pressure measurement in patient? [Yes/No]**

- Yes If a cardiologist/nurse applied the cuff of the sphygmomanometer to a patient bare upper arm, placed the disk of the stethoscope face down under the cuff and immediately above a patient elbow, squeezed the had bulb rapidly, and delatated the cuff slowly

No If a cardiologist/nurse did not either apply the cuff of the sphygmomanometer to a patient bare upper arm, or did not place the disk of the stethoscope face down under the cuff and immediately above a patient elbow, or did not squeeze the had bulb

10b. What was a patient position while measuring blood pressure? [Yes/No]

Yes A patient blood pressure was measured either in sitting or lying position

No A patient position was not measured (see 10a No)

11. Did a cardiologist perform heart auscultation? [Yes/No]

Yes If a cardiologist applied the disk of the stethoscope on a patient chest in the area of the heart projection: second right interspace and the left third interspace adjacent to the sternum, second left interspace, fourth and fifth interspaces adjacent to the left sternal border, and cardiac apex

No If a cardiologist did not apply the disk of the stethoscope on a patient chest in the area of the heart projection

12. Did a cardiologist perform lung auscultation? [Yes/No]

Yes If a cardiologist applied the disk of the stethoscope face down on the anterior and posterior sides of a patient chest

No If a cardiologist did not apply the disk of the stethoscope on a patient anterior and posterior sides of chest

13. Did a cardiologist perform abdominal palpation? [Yes/No]

Yes If a cardiologist palpated a patient abdomen

No If a cardiologist did not palpated a patient abdomen

14a/b. Did a cardiologist assessed a patient peripheral pulses? [Yes/No]

Yes If a cardiologist took a patient radial and pedal pulses on both left and right hands and legs (e.g.: using tips of index and third fingers a cardiologist located the area between a patient wrist bone and tendon on the thumb side of either wrist

No If a cardiologist did not check radial and pedal pulses of a patient

Note: If a cardiologist assessed a patient peripheral pulses, write down for which arteries the pulse was taken.

15. Did a cardiologist perform the auscultation of carotid arteries? [Yes/No]

Yes If a cardiologist applied the disk of the stethoscope face down on the right and left lateral sides of a patient neck

No If a cardiologist did not apply the disk of the stethoscope face down on the right and left lateral sides of a patient neck

Section C / Other tests**16. Did a cardiologist/nurse perform electrocardiography? [Yes/No]**

- Yes If a patient was asked to lie on a bed or examining table and electrodes were attached to the skin of a patient legs, arms, and chest. After the recording process had begun, a graphic representation of a heart at work appeared on the paper
- No If electrodes were not attached to the skin of a patient legs, arms, and chest. After the recording process had begun, a graphic representation of a heart at work did not appear on the paper

17. Did a cardiologist perform echocardiography? [Yes/No]

- Yes If a patient was asked to lie on the table or the examination table, special jelly was applied to a patient chest, and as a cardiologist maneuvered the transducer on a patient chest, the reflection image of heart appeared on the screen
- No If a cardiologist did not maneuvered the transducer on a patient chest and the reflection image of heart did not appear on the screen

18. Was a patient prescribed the chest X-ray examination? [Yes/No]

- Yes If a patient was prescribed chest X-ray examination
- No If a patient was not prescribed chest x-ray examination

19. Was a patient prescribed blood tests? [Yes/No]

- Yes If a patient was prescribed blood tests
- No If a patient was not prescribed blood tests

Note: If a patient was prescribed blood tests mark those tests that a cardiologist reported.

20. Was a patient prescribed treadmill examination? [Yes/No]

- Yes If a patient was prescribed treadmill examination and was referred to the appropriate health care organization
- No If a patient was not prescribed treadmill examination

21. Was the cardiac catheterization proposed to a patient? [Yes/No]

- Yes If a patient was proposed the cardiac catheterization
- No If nothing was mentioned about the cardiac catheterization

Section D / Risk factor

22. Did a cardiologist ask a patient about smoking habit? [1-3]

- 1 If a question about being a smoker was raised and a patient responded positively
- 2 If a question about being smoker was raised and a patient responded negatively
- 3 If a question about being smoker was not raised during the first visit

APPENDIX 4. Instructions for auditing the medical records documentation in the adult cardiology clinic

1= recorded/positive	A patient respond was recorded and the findings were positive
2= recorded/negative	A patient respond was recorded and the findings were negative
3= none	The item on the SEF is left blank

Responses 1-3 for the sections A and D

Responses Yes/No for the sections B and C

Section A / Anamnesis Morbi

1. Was a patient complaint about having exertional chest pain recorded in the SEF? [1-3]

- 1 If a patient complaint about having or exertional chest pain was recorded in the SEF under the item “Anamnesis Morbi”
- 2 If a patient note about not having the exertional chest pain was recorded in the SEF
- 3 If nothing was recorded in the SEF regarding the exertional chest pain

Note: The exertional chest pain can be defined as the chest pain related to the physical and emotional activities.

2. Was a patient complaint about having exertional shortness of breath recorded in the SEF? [1-3]

- 1 If a patient complaint about having exertional shortness of breath was recorded in the SEF under the item “Anamnesis Morbi”
- 2 If a patient note about not having exertional shortness of breath was recorded in the SEF
- 3 If nothing was recorded in the SEF regarding the exertional shortness of breath

3. Was a patient complaint about having arrhythmia recorded in the SEF? [1-3]

- 1 If a patient complaint about having arrhythmia was recorded in the SEF under the item “Anamnesis Morbi”
- 2 If a patient note about not having arrhythmia was recorded in the SEF
- 3 If nothing was recorded in the SEF regarding arrhythmia

4. Was a patient complaint about having shortness of orthopnea recorded in the SEF? [Yes/No]

- 1 If a patient complaint about having orthopnea was recorded in the SEF under the item “Anamnesis Morbi”
- 2 If a patient note about not having orthopnea was recorded in the SEF
- 3 If nothing was recorded in the SEF regarding orthopnea

5. Was a family history of any disease recorded in the SEF? [1-3]

- 1 If a family history of any disease (i.e. mother or father or both parents had/have a particular disease) was recorded in the SEF
- 2 If a patient note about not having family history of any disease was recorded in the SEF
- 3 If nothing was recorded in the SEF regarding family predisposition

Note: If a response was positive, copy those diseases that were recorded in the SEF

6. Was a patient complaint about having allergy was recorded in the SEF? [1-3]

- 1 If a patient complaint about having an allergy was recorded in the SEF
- 2 If a patient note about note having an allergy was recorded in the SEF
- 3 If nothing was recorded in the SEF regarding an allergy

7. Did the SEF mention about patient receiving current treatment for a heart disease? [1-3]

- 1 If a note that a patient is receiving treatment for a heart disease was recorded in the SEF
- 2 If a note that a patient is not receiving treatment for a heart disease was recorded in the SEF
- 3 If SEF mentioned nothing about a patient receiving treatment for a heart disease

Note: If a patient answer was positive, copy the names of the drugs that were recorded in the SEF under the current treatment

8. Were patient comorbidities (illnesses other than heart diseases) recorded in the SEF? [1-3]

- 1 If the SEF mentioned about comorbidities that a patient has under the item “Other diseases”
- 2 If SEF mentioned that a patient does not have comorbidities
- 2 If the SEF mentioned nothing about comorbidities that a patient has

Note: If response is positive, copy those diseases that were recorded in the SEF.

9. Were previous surgical operations patient underwent in the past recorded in the SEF? [1-3]

- 1 If previous surgical operations were recorded in the SEF under the item “Other diseases”
- 2 If a patient statement about not having previous surgical operations was recorded in the SEF
- 3 If nothing was recorded in the SEF regarding previous surgical operations

Note: If a patient response was positive, copy those surgeries that were recorded in the SEF.

Section B / Physical examination**10a. Was a patient blood pressure recorded in the SEF? [Yes/No]**

- Yes If two numbers (for systolic and diastolic blood pressure) are recorded in the SEF under the item “Blood pressure”
- No If both numbers (for systolic and diastolic blood pressure) were not recorded in the SEF

10b. Was a patient position while measuring blood pressure recorded in the SEF? [Yes/No]

- Yes Either sitting or lying position of a patient while measuring blood pressure was recorded in the SEF
- No If a patient position while measuring blood pressure was not recorded in the SEF

Note: If a patient position while measuring blood pressure was noted in the SEF, write it down.

11. Were the results of heart auscultation recorded in the SEF? [Yes/No]

- Yes If marks (+ or N) were made or negative findings were recorded in the SEF under the item “Heart sounds and murmurs”

No If nothing was recorded in the SEF under the item “Heart sounds and murmurs”

12. Were the results of lung auscultation recorded in the SEF? [Yes/No]

Yes If vesicular respiration was marked or abnormal findings were recorded in the SEF under the item “Lungs”

No If the item “Lungs” is left blank

13. Were the results of abdominal palpation recorded in the SEF? [Yes/No]

Yes If a mark (+ or -) was made or negative findings were recorded in the SEF under the item “Abdomen”

No If nothing was recorded in the SEF under the item “Abdomen” on the SEF

14a. Were the results of peripheral pulses assessment recorded in the SEF? [Yes/No]

Yes If marks (+ or N) were made or negative findings were recorded in the SEF under the item “Peripheral hemodynamics” or “Major arteries”

No If the item “Peripheral hemodynamics” or “Major arteries” was left blank

14b. Was the position of pulses assessed recorded in the SEF? [Yes/No]

Yes If marks (+ or N) were made or negative findings were recorded in the SEF under the item “Pulse”

No If item “Pulse” is left blank

15. Were the results of carotid artery auscultation recorded in the SEF? [Yes/No]

Yes If a mark (+ or N) was made or negative findings were recorded in the SEF under the items “Great arteries” in the SEF

No If the item “Great arteries” in the SEF is left blank

Section C / Other tests

16. Were the results of electrocardiography (ECG) recorded in the SEF? [Yes/No]

Yes If ECG results were recorded in the SEF or the ECG list was attached to a patient ambulatory record

No If ECG results were not recorded in the SEF or the ECG list was not available in the ambulatory folder

17. Were the results of echocardiography recorded in the SEF? [Yes/No]

Yes If EChO results were recorded in the SEF under the item “Echocardiography”

No If the item “Echocardiography” is left blank

18. Were the results of chest X-ray examination recorded in the SEF? [Yes/No]

Yes If prescription of X-ray examination was recorded in the SEF or X-ray film was attached to the patient ambulatory record

No If nothing was recorded regarding the prescription of X-ray examination or X-ray film was not attached to the patient ambulatory record

19. Were the blood test results recorded in the SEF? [Yes/No]

Yes If the blood tests form with the recorded results was attached to the patient ambulatory record

No If blood tests form with the recorded results was not available in a patient ambulatory record

Note: If blood tests were prescribed to a patient write down the results of those tests that were recorded

20. Was treadmill test prescribed to a patient? [Yes/No]

Yes If treadmill test was circled in the SEF

No If treadmill test was not circled in the SEF

21. Was the cardiac catheterization proposed to a patient? [Yes/No]

Yes If a note that a patient was proposed the cardiac catheterization was recorded in the SEF under the item "Remarks"

No If nothing was recorded in the SEF regarding cardiac catheterization

Section D / Patient risk factor**22. Was a patient smoking habit recorded in the SEF? [1-3]**

1 If a note that a patient is a smoker was recorded in the SEF

2 If a note that a patient is not a smoker was recorded in the SEF

3 If the item "Smoking" on the ACD SEF is left blank

APPENDIX 5. Outline of items included in each main domain

Domain	Items
Patient complaints	Exertional chest pain, exertional shortness of breath, arrhythmia, orthopnea
Medical history	Family history, allergy, current treatment, comorbidities, previous surgical operations
Physical examination	BP* measurement, patient position while measuring BP, heart auscultation, lungs auscultation, abdominal palpation, assessment of peripheral pulses, position of peripheral pulses assessed, carotid artery auscultation
Tests performed	ECG† and EChO‡
Tests ordered	Chest X-ray examination, blood tests, treadmill test, cardiac catheterization
Patient habits	Patient smoking status

*BP – blood pressure

†ECG – electrocardiography

‡EChO - echocardiography

APPENDIX 6. Sum of the scores and percent agreement for each variable

Variable name	Sum of scores	Percent agreement (%)	Agreement value (%)	Strength of agreement
Exertional chest pain	51	77.27	61-80	good
Exertional shortness of breath	35	53.03	41-60	poor
Arrhythmia	47	71.21	61-80	good
Orthopnea	53	80.30	61-80	good
Family history	19	28.79	< 40	very poor
Allergy	63	95.45	81-100	excellent
Current treatment	28	42.42	41-60	poor
Comorbidities	32.1	48.64	41-60	poor
Previous surgical operations	34.5	52.27	41-60	poor
BP* measurement	66	100	81-100	excellent
Patient position while measuring BP	0	0	< 40	very poor
Heart auscultation	65	98.48	81-100	excellent
Lungs auscultation	50	75.76	61-80	good
Abdominal palpation	41	62.12	61-80	good
Assessment of peripheral pulses	42.5	64.39	61-80	good
Position of peripheral pulses assessed	27	40.91	< 40	very poor
Carotid artery auscultation	33	50	41-60	poor
ECG†	66	100	81-100	excellent
EChO‡	66	100	81-100	excellent
Chest X-ray examination	60	90.91	81-100	excellent
Blood tests	65	98.48	81-100	excellent
Treadmill test	65	98.48	81-100	excellent
Cardiac catheterization	66	100	81-100	excellent
Patient smoking status	30	45.45	41-60	poor

*BP – blood pressure

†ECG – electrocardiography

‡EChO - echocardiography

APPENDIX 7. Recording pattern for each variable of patient complaints, medical history, and patient habits*

Patient complain	Under-recording of negative and positive findings†	Under-recording of positive findings‡	Under-recording of negative findings§
Exertional chest pain	24.19	0	24.19
Exertional shortness of breath	49.21	5	69.77
Arrhythmia	43.18	37.14	66.67
Orthopnea	81.25	25	100
Allergy	60	60	0
Family history	97.92	92.97	0
Current treatment	95	96.67	90
Comorbidities	60.34	40	91.30
Previous surgical operations	64.44	42	94.74
Patient smoking status	68.29	33.33	92.31

*The recording pattern is presented in percentages

†The percentage of responses not recorded in the SEF among all cases when the question was raised

‡The percentage of positive responses not recorded in the SEF among all reported positive responses

§The percentage of negative responses not recorded in the SEF among all reported negative responses

APPENDIX 8. Recording pattern for each variable of physical examination, tests performed and assigned to patients^o

Item	Under-recording[§]	Over-recording[¶]
BP* measurement	0	0
Patient position while measuring BP	100	0
Heart auscultation	0	1.51
Lungs auscultation	0	75.76
Abdominal palpation	2.38	36.92
Assessment of peripheral pulses	3.33	48.21
Position of peripheral pulses assessed	92.5	40
Carotid artery auscultation	33.33	88.57
ECG†	0	0
EChO‡	0	0
Chest X-ray test	60	0
Prescription of blood tests	0	0
Assignment of treadmill	7.69	0
Assignment of cardiac catheterization	0	0

*BP – blood pressure

†ECG – electrocardiography

‡EChO - echocardiography

§ The percentage of responses not recorded in the SEF among all performed procedures

¶ The percentage of procedures not performed among all responses recorded in the SEF among

APPENDIX 9. Sensitivity, specificity, and positive predictive value for each variable

Variable name	Sensitivity	Specificity	PPV
Exertional chest pain	75.81	100	100
Exertional shortness of breath	51.61	100	100
Arrhythmia	56.82	100	100
Orthopnea	18.75	100	100
Family history	2.08	100	100
Allergy	40	100	100
Current treatment	5	100	100
Comorbidities	39.65	87.50	95.83
Previous surgical operations	35.56	85.71	84.21
BP* measurement	100	100	100
Patient position while measuring BP	0	0	0
Heart auscultation	100	0	98.48
Lungs auscultation	100	0	75.76
Abdominal palpation	97.62	0	63.08
Assessment of peripheral pulses	96.67	25	51.79
Position of peripheral pulses assessed	7.5	92.31	60
Carotid artery auscultation	66.67	48.33	11.43
ECG†	100	100	100
EChO‡	100		100
Chest X-ray examination	40	100	100
Blood tests	100	100	100
Treadmill test	92.31	100	100
Cardiac catheterization	100	100	100
Patient smoking status	24.39	80	66.67

*BP – blood pressure

†ECG – electrocardiography

‡EChO - echocardiography

APPENDIX 10. Instructions for auditing the surgical summary database

1 = present in both sources/the same	The item is recorded in both the patient record and entered into surgical summary database and it is the same
2 = present in both sources/different	The items is recorded in the patient record and entered into surgical summary database, but it is different
3 = present in the record/not present in the database	The item is recorded in the patient record, but it is not entered into surgical summary database
4 = not present in the record/present in the database	The item is not recorded in the patient record, but it is entered into surgical summary database
5 = none	The item is neither recorded in the patient record, nor it is entered into surgical summary database

* Response 2 for this item is not applicable (N/A)

1. Patient record number [1-5]

- 1 If a number of patient record in the general record and surgical summary database were exactly the same
- 2 If a number of patient record were mentioned in both the general record and surgical summary database, but were not exactly the same
- 3 If a number of patient record was mentioned in the general record, but was not entered into the surgical summary database
- 4 If a number of patient record was not mentioned in the general record, but was entered into the surgical summary database
- 5 If a number of a patient record was neither recorded in the general record nor entered into the surgical summary database

2. Patient name [1-5]

- 1 If a patient name was mentioned in both the general record and the surgical summary database and was phonetically the same
- 2 If a patient name mentioned in both sources of patient information, but is phonetically different
- 3 If a patient name was mentioned in the general record, but is not entered into the surgical summary database
- 4 If a number of patient record was not mentioned in the general record, but was entered into the surgical summary database
- 5 If a number of a patient record was neither recorded in the general record nor entered into the surgical summary database

3. Date of birth [1-5]

- 1 If a patient date of birth (day, month, and year) was mentioned in both the general record and the surgical summary database and was the same regardless of the cell format
- 2 If a patient date of birth (day, month, and year) was mentioned in both sources of patient information, but the year was different
- 3 If a patient date of birth was mentioned in the general record, but was not entered into the surgical summary database
- 4 If a patient date of birth was not mentioned in the general record, but was entered into the surgical summary database

5 If a patient date of birth was neither recorded in the general record nor entered into the surgical summary database

4. Gender [1-5]

1 If a patient gender was mentioned in both the general record and the surgical summary database and was the same

2 If a patient gender was mentioned in both sources of patient information, but was different

3 If a patient gender was mentioned in the general record, but was not entered into the surgical summary database

4 If a patient gender was not mentioned in the general record, but was entered into the surgical summary database

5 If a patient gender was neither recorded in the general record nor entered into the surgical summary database

5. Date of admission [1-5]

1 If a date of patient admission to the clinic (day, month, and year) was mentioned in both the general record and the surgical summary database and was the same regardless of the cell format

2 If a date of patient admission to the clinic was mentioned in both sources of patient information, but was different even for one of the numbers (day, month, and year)

3 If a date of patient admission to the clinic was mentioned in the general record, but even one of the numbers was not entered into the surgical summary database

4 If a date of a patient admission to the clinic, even one of the numbers, was not mentioned in the general record, but was entered into the surgical summary database

5 If a date of a patient admission to the clinic was neither recorded in the general record nor entered into the surgical summary database

6. Date of discharge [1-5]

1 If a date of discharge (day, month, and year) was mentioned in both the general record and the surgical summary database and was the same regardless of the cell format

2 If a date of discharge was mentioned in both sources of patient information, but was different even for one of the numbers (day, month, and year)

3 If a date of discharge was mentioned in the general record, but even one of the numbers was not entered into the surgical summary database

4 If a date of discharge, even one of the numbers, was not mentioned in the general record, but was entered into the surgical summary database

5 If a date of discharge was neither recorded in the general record nor entered into the surgical summary database

7. Date of surgery [1-5]

1 If a date of surgery (day, month, and year) was mentioned in both the general record and the surgical summary database and was the same regardless of the cell format

2 If a date of surgery was mentioned in both sources of patient information, but was different even for one of the numbers (day, month, and year)

3 If a date of surgery was mentioned in the general record, but even one of the numbers was not entered into the surgical summary database

4 If a date of surgery, even one of the numbers, was not mentioned in the general record, but was entered into the surgical summary database

- 5 If a date of surgery was neither recorded in the general record nor entered into the surgical summary database

8. Patient Diagnosis [1-5]

- 1 If a patient diagnosis was mentioned in both the patient record and the surgical summary database and was the same regardless the recording sequence of primary disease and comorbidities
- 2 If a patient diagnosis was mentioned in both sources of patient information, but was different by primary disease or even one of the comorbidities
- 3 If a patient diagnosis was mentioned in the general record, but was not entered into the surgical summary database
- 4 If a patient diagnosis was not mentioned in the general record, but was entered into the surgical summary database
- 5 If a patient diagnosis was neither recorded in the general record nor entered into the surgical summary database

Notes: a) Patient diagnosis is entered into the surgical summary database in the abbreviation format. The data collector will use the list abbreviations used at NMMC in English and respective diagnosis in English and Armenian.

b) If the score is 2, the consistency of diagnosis in the surgical summary database and surgical protocol should be checked.

9. Heart failure [1-5]

- 1 If heart failure class was mentioned in both the patient record and the surgical summary database and was the same
- 2 If heart failure class was mentioned in both sources of patient information, but was different in two sources of patient information
- 3 If heart failure class was mentioned in the general record, but was not entered into the surgical summary database
- 4 If heart failure class was not mentioned in the general record, but was entered into the surgical summary database
- 5 If heart failure was neither recorded in the general record nor entered into the surgical summary database

10. Surgical procedure [1-5]

- 1 If a surgical procedure was mentioned in both the general record and the surgical summary database and was the same regardless the recording sequence of procedures
- 2 If a surgical procedure was mentioned in both sources of patient information, but was different by even one of the procedures
- 3 If a surgical procedure was mentioned in the general record, but was not entered into the surgical summary database
- 4 If a surgical procedure was not mentioned in the general record, but was entered into the surgical summary database
- 5 If a surgical procedure was neither recorded in the general record nor entered into the surgical summary database

Note: Surgical procedure is entered into the surgical summary database in the abbreviation format. The data collector will use the list abbreviations used at NMMC in English and respective procedures in English and Armenian.

b) If the score is 2, the consistency of procedure in the surgical summary database and surgical protocol should be checked.

11. Cardiologist Name

- 1 If cardiologist name was mentioned in both the patient record and the surgical summary database and was phonetically the same
- 2 If cardiologist name was mentioned in both sources of patient information, but was phonetically different
- 3 If cardiologist name was mentioned in the patient record, but was not entered into the surgical summary database
- 4 If cardiologist name was not mentioned in the patient record, but was entered into the surgical summary database
- 5 If cardiologist name was neither recorded in the general record nor entered into the surgical summary database

12. Surgeon Name

- 1 If surgeon name was mentioned in both the patient record and the surgical summary database and was phonetically the same
- 2 If surgeon name was mentioned in both sources of patient information, but was phonetically different
- 3 If surgeon name was mentioned in the patient record, but was not entered into the surgical summary database
- 4 If surgeon name was not mentioned in the patient record, but was entered into the surgical summary database
- 5 If surgeon name was neither recorded in the general record nor entered into the surgical summary database

13. Patient weight [1-5]

- 1 If a patient weight was mentioned in kg or g in both the general record and the surgical summary database and was the same by kg
- 2 If a patient weight was mentioned in both sources of patient information, but was different by > 1kg
- 3 If a patient weight was mentioned in the general record, but was not entered into the surgical summary database
- 4 If a patient weight was not mentioned in the general record, but was entered into the surgical summary database
- 5 If a patient weight neither was recorded in the general record nor entered into the surgical summary database

14. Patient height [1-5]

- 1 If a patient height was mentioned in sm or m in both the general record and the surgical summary database and was the same by sm
- 2 If a patient height was mentioned in both sources of patient information, but was different by 1sm
- 3 If a patient height was mentioned in the general record, but was not entered into the surgical summary database
- 4 If a patient height was not mentioned in the general record, but was entered into the surgical summary database
- 5 If a patient height neither was recorded in the general record nor entered into the surgical summary database

15. Other post-surgical complications [1-5]

- 1 If post-surgical complication (other than mediasthenitis and wound infection) was mentioned in both the surgical protocol and the surgical summary database and was the same regardless their recorded sequence
- 2 If post-surgical complication (other than mediasthenitis and wound infection) was mentioned in both sources of patient information, but was different by even one of the procedures
- 3 If post-surgical complication (other than mediasthenitis and wound infection) was mentioned in the general record, but was not entered into the surgical summary database
- 4 If post-surgical complication (other than mediasthenitis and wound infection) was not mentioned in the general record, but was entered into the surgical summary database
- 5 If post-surgical complication (other than mediasthenitis and wound infection) was neither recorded in the general record nor entered into the surgical summary database

16. Recurrent surgery (ReDo) [1-5]

- 1 If a both the surgical protocol and the surgical summary database mentioned that a patient underwent recurrent cardiac surgery (ReDo)
- 2 N/A
- 3 If ReDo was mentioned in the surgical protocol, but was not entered into the surgical summary database
- 4 If ReDo was not mentioned in the surgical protocol, but was entered into the surgical summary database
- 5 If ReDo was neither recorded in the surgical protocol nor entered into the surgical summary database

17. In hospital death [1/3-4]

- 1 If both the patient record and the surgical summary database mentioned that a patient underwent recurrent cardiac surgery (ReDo)
- 2 N/A
- 3 If ReDo was mentioned in the patient record, but was not entered into the surgical summary database
- 4 If ReDo was not mentioned in the patient record, but was entered into the surgical summary database
- 5 If ReDo was neither recorded in the patient record nor entered into the surgical summary database

18. Mediasthenitis [1/3-4]

- 1 If both the patient record and the surgical summary database mentioned that a patient had developed mediasthenitis
- 2 N/A
- 3 If mediasthenitis was mentioned in the patient record, but was not entered into the surgical summary database
- 4 If mediasthenitis was not mentioned in the patient record, but was entered into the surgical summary database
- 5 If mediasthenitis was neither recorded in the patient record nor entered into the surgical summary database

19. Wound infection [1/3-4]

- 1 If a both the patient record and the surgical summary database mentioned that a patient had developed a wound infection
- 2 N/A
- 3 If having a wound infection was mentioned in the patient record, but was not entered into the surgical summary database
- 4 If a wound infection was not mentioned in the patient record, but was entered into the surgical summary database
- 5 If a wound infection was neither recorded in the patient record nor entered into the surgical summary database

20. Intensive Care Unit (ICU) Stay [1-5]

- 1 If a patient ICU stay could be calculated in hours from the data in the ICU chart and was the same, as it was entered into the surgical summary database
- 2 If a patient ICU stay could be calculated in hours from the data in the ICU chart and was different from that entered into the surgical summary database
- 3 If a patient ICU stay could be calculated in hours from the data in the ICU chart, but was not entered into the surgical summary database
- 4 If a patient ICU stay could not be calculated in hours from the data in the ICU chart, but was entered into the surgical summary database
- 5 If a patient ICU stay could not be calculated in hours from the data in the ICU chart and it was not entered into the surgical summary database

Note: the difference of 1 hour is considered acceptable and the item is evaluated as the same.

21. Duration of intubation [1-5]

- 1 If the intubation time (in minutes or hours) was recorded in the ICU chart and surgical summary database and was the same by hours
- 2 If the intubation time was recorded the ICU chart and surgical summary database, but it was different by hours
- 3 If the intubation time was recorded in the ICU chart, but was not entered into the surgical summary database
- 4 If was not recorded the ICU chart, but was entered into the surgical summary database
- 5 If the intubation time was neither recorded in the ICU chart and not it was entered into the surgical summary database

22. Blood use [1/3-4]

- 1 If a both the patient record and the surgical summary database mentioned about the blood use (the amount of used blood)
- 2 N/A
- 3 If blood use was mentioned in the patient record, but was not entered into the surgical summary database
- 4 If blood use was not mentioned in the patient record, but was entered into the surgical summary database
- 5 If blood use was neither recorded in the patient record nor entered into the surgical summary database

23. Insulin Administration [1/3-4]

- 1 If a both the patient record and the surgical summary database mentioned about the insulin administration
- 2 N/A
- 3 If insulin administration was mentioned in the patient record, but was not entered into the surgical summary database
- 4 If insulin administration was not mentioned in the patient record (the amount of insulin), but was entered into the surgical summary database
- 5 If insulin administration was neither recorded in the patient record nor entered into the surgical summary database

8a. Patient Diagnosis [1-5]

- 1 If a patient diagnosis was mentioned in both the surgical protocol and the surgical summary database and was the same regardless the recording sequence of primary disease and comorbidities

- 2 If a patient diagnosis was mentioned in both sources of patient information, but was different by primary disease or even one of the comorbidities
- 3 If a patient diagnosis was mentioned in the surgical protocol, but was not entered into the surgical summary database
- 4 If a patient diagnosis was not mentioned in the surgical protocol, but was entered into the surgical summary database
- 5 If a patient diagnosis was neither recorded in the surgical protocol nor entered into the surgical summary database

Note: Patient diagnosis is entered into the surgical summary database in the abbreviation format. The data collector will use the list abbreviations used at NMMC in English and respective diagnosis in English and Armenian.

10a. Surgical procedure [1-5]

- 1 If a surgical procedure was mentioned in both the surgical protocol and the surgical summary database and was the same regardless the recording sequence of procedures
- 2 If a surgical procedure was mentioned in both sources of patient information, but was different by even one of the procedures
- 3 If a surgical procedure was mentioned in the surgical protocol, but was not entered into the surgical summary database
- 4 If a surgical procedure was not mentioned in the surgical protocol, but was entered into the surgical summary database
- 5 If a surgical procedure was neither recorded in the surgical protocol nor entered into the surgical summary database

Note: Surgical procedure is entered into the surgical summary database in the abbreviation format. The data collector will use the list abbreviations used at NMMC in English and respective procedures in English and Armenian.

15a. Other post-surgical complications [1-5]

- 1 If post-surgical complication (other than mediathenitis and wound infection) was mentioned in both the surgical protocol and the surgical summary database and was the same regardless their recorded sequence
- 2 If post-surgical complication (other than mediathenitis and wound infection) was mentioned in both sources of patient information, but was different by even one of the procedures
- 3 If post-surgical complication (other than mediathenitis and wound infection) was mentioned in the surgical protocol, but was not entered into the surgical summary database
- 4 If post-surgical complication (other than mediathenitis and wound infection) was not mentioned in the surgical protocol, but was entered into the surgical summary database
- 5 If post-surgical complication (other than mediathenitis and wound infection) was neither recorded in the surgical protocol nor entered into the surgical summary database

APPENDIX 11. Heart Chart

Heart chart #					
Name		Date Of Birth	Date Of Adm.	Date Of Disch.	Date Of Surg.
Weight	Height	History #	Age	Cardiolog.	
Diagnosis:					
Procedure:					
Complications:					
CPB <input type="checkbox"/>	Heart denervation <input type="checkbox"/>	Intubation time		ICU stay	
ReDo <input type="checkbox"/>	Left pleural top <input type="checkbox"/>	Right pleural top <input type="checkbox"/>	Drips -		
Valve	Aorta	Mitral	Tricuspid	CABG	
Repair	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Number of distal anastomosis:	
Anuloplasty	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Arterial <input type="checkbox"/>	
By Ring	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Venous <input type="checkbox"/>	
Autograft	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Sequential <input type="text"/>	
Homograft	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Free mammaria <input type="text"/>	
Bioprosthesis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Aorta	
Mechanical	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Parch <input type="checkbox"/>	
Other IHD			Pacemaker		Pericardium
Myocardial resection <input type="checkbox"/>	Endocardial <input type="checkbox"/>		Pericardiotomy <input type="checkbox"/>		
Post MI VSD <input type="checkbox"/>	Epicardial <input type="checkbox"/>		Pericardiectomy <input type="checkbox"/>		
			Defibrillator <input type="checkbox"/>		
Circulatory Assist					
IABP	VAD	BIVAD	Myoplasty	TAH	
Asplenia/Polysplenia <input type="checkbox"/>	Visceral situs inversus <input type="checkbox"/>		Atrial situs inversus <input type="checkbox"/>		
Right isomerism <input type="checkbox"/>	Left isomerism <input type="checkbox"/>				
Comments					

APPENDIX 12. INSTRUMENT for evaluation of surgical summary database

1 = present in both sources/the same	The item exists in both sources of patient information and it is the same
2 = present in both sources/different	The items exists in both sources of patient information, but it is different
3 = present in the record/not in the database	The item is recorded in the patient record, but it is not entered into surgical summary database
4 = not present in the record/ present in the database	The item is not recorded in the patient record, but it is entered into the surgical summary database
5 = none	The item is neither recorded in the patient record, nor it is entered into surgical summary database

* Response 2 for this item is not applicable (N/A)

Patient ID	Item	Information source	Response [1-5]
	Patient record #	Patient record	
	Patient name	Patient record	
	Date of birth	Patient record	
	Gender	Patient record	
	Date of admission	Patient record	
	Date of discharge	Patient record	
	Date of surgery	Patient record	
	Diagnosis**	Patient record	
	Heart failure class	Patient record	
	Procedure**	Patient record	
	Cardiologist	Patient record	
	Surgeon	Patient record	
	Patient weight (kg)	Patient record	
	Patient height (sm)	Patient record	
	Other post-surgical complications	Patient record	
	ReDo (re-operation)*	Patient record	
	In-hospital death*	Patient record	
	Mediasthenitis*	Patient record	
	Wound infection*	Patient record	
	ICU stay	ICU chart	
	Duration of intubation	ICU chart	
	Blood*	ICU chart	
	Insulin*	ICU chart	

#	Item	Information source	Score [1-5]
8a.	Diagnosis	Surgical protocol	
10a.	Procedure	Surgical protocol	
15a.	Other complications	Surgical protocol	

** If item is inconsistent between patient record and surgical summary database

APPENDIX 13/1. List of abbreviations for diagnoses

Abbreviation	Definition (English)	Definition (Armenian)
Anomalous Origin of L.C.A.	Anomalous Origin of Left Coronary Artery	Չախ կորոնար զարկերակի անոմալ ծագում
Ao Aneurism	Aortic Aneurysm	Աորտալ անևրիզմա
Ao Coarctation	Aortic Coarctation	Աորտային կոարկտացիա
Ao Insuf.	Aortic Insufficiency	Աորտալ անբավարարություն
Ao-LV Tunnel	Aortic-Left Ventricle Tunnel	Աորտա-թոքային թուննել
Ao-Pulmonary Window	Aortic-Pulmonary Window	Աորտա-թոքային պատուհան
AS	Aortic Stenosis	Աորտալ ստենոզ (նեղացում)
ASD	Atrial Septum Defect	Նախասրտային միջնապատի դեֆեկտ
Cardiac Myxoma	Cardiac Myxoma	Սրտի միքսոմա
Common Atrium	Common Atrium	Ընդհանուր նախասիրտ
Common AV Valve	Common Atrio-Ventricular Valve	Ընդհանուր նախասիրտ-փորոքային փական
Complete AVC	Complete Atrio-Ventricular Canal	Նախասիրտ-փորոքային ամբողջական կանալ
Core Triatriatum	Core Triatriatum	Եռնախասրտային սիրտ
Corrected TGA	Corrected Transposition of Great Arteries	Խոշոր անոթների վերականգնած/ուղղած տրանսպոզիցիա
DILV	Double Outlet Left Ventricle	Երկնուտք ձախ փորոք
DIRV	Double Inlet Right Ventricle	Երկնուտք աջ փորոք
Dissecting Ao Aneurysm	Dissecting Aortic Aneurysm	Աորտալ անևրիզմա
DOLV	Double Inlet Left Ventricle	Երկելք ձախ փորոք
DORV	Double Outlet Right Ventricle	Երկելք աջ փորոք
Ebstein Anomaly	Ebstein Anomaly	Էբշտեյնի անոմալիա (անկանոնություն)
HLHS	Hypoplastic Left Heart Syndrome	Հիպոպլաստիկ ձախ սրտի Համախտանիշ
Hypoplastic Ao	Hypoplastic Aorta	Հիպոպլաստիկ աորտա
Hypoplastic Ao Arch	Hypoplastic Aortic Arch	Աորտաի հիպոպլաստիկ Աղեղ
Hypoplastic PA	Hypoplastic Pulmonary Artery	Հիպոպլաստիկ թոքային զարկերակ
Hypoplastic RV	Hypoplastic Right Ventricle	Հիպոպլաստիկ աջ փորոք
IHD	Ischemic Heart Disease	Սրտի իշեմիկ հիվանդություն
III Degree AV Block	III Degree Atrio-Ventricular Block	III աստիճանի նախասիրտ-փորոքային պաշարում
LVOT Obstruction	Left Ventricle Outflow Tract Obstruction	Չախ փորոքի արտահանող տրակտի օբստրուկցիա
MA	Mitral Atresia	Միտրալ աթրեզիա (բացակայություն)

Marfan`s Syndrome	Marfan`s Syndrome	Մարֆանի համախտանիշ
MI	Myocardial Infarction	Սրտամկանի ինֆարկտ
MR	Mitral Regurgitation	Միտրալ ռեգուրգիտացիա
MS	Mitral Stenosis	Միտրալ ստենոզ
PA Atresia	Pulmonary Artery Atresia	Թոքային զարկերակի արեզիա
PAPVR	Partial Anomalous Pulmonary Vein Return	Թոքային երակների մասնակի անոմալ դրենաժ
Partial AVC	Partial Atrio-Ventricular Canal	Ատրիովենտրիկուլյար մասնակի հաղորդակցություն
PDA	Patent Ductus Arteriosus	Բոտալյան ծորան (բաց զարկերակային ծորան)
Pericarditis (constrictive)	Pericarditis (constrictive)	Պերիկարդիտ (կոնստրիկտիվ)
PS	Pulmonary Stenosis	Թոքային զարկերակի ստենոզ (նեղացում)
SA	Single Atrium	Միակ նախասիրտ
Shone`s Syndrome	Shone`s Syndrome	Շոնի համախտանիշ
Sinus of Valsalva Aneurysm	Sinus of Valsalva Aneurysm	Վալսալվա ծոցի անևրիզմա
Sinus Valsalva Aneurysm and Fistulas	Sinus Valsalva Aneurysm and Fistulas	Վալսալվա ծոցի ֆիստուլա
SubAo Ring	Subaortic Ring	Ենթաաորտալ օղակ
SV	Single Ventricle	Միակ փորոք
TA	Tricuspid Atresia	Տրիկուսպիդ ատրեզիա
TAPVR	Total Anomalous Pulmonary Vein Return	Թոքային երակների տոտալ անոմալ դրենաժ
TGA	Transposition of Great Arteries	Մագիստրալ անոթների տրանսպոզիցիա
ToF	Tetralogy of Fallot	Ֆալոյի տետրադա
TR	Tricuspid Regurgitation	Տրիկուսպիդ Ռեգուրգիտացիա
Truncus Arteriosus	Truncus Arteriosus	Զարկերակային ցողուն
TS	Tricuspid Stenosis	Տրիկուսպիդ նեղացում
Vascular Ring	Vascular Ring	Անոթային Օղ
VSD	Ventricular Septum Defect	Փորոքային միջնապատի դեֆեկտ
WPW Syndrome	Wolf Parkinson White Syndrome	Վոլֆ-Պարկինսոն-Վայթի համախտանիշ

APPENDIX 13/2. List of abbreviations of surgical procedures

Abbreviation	Definition (English)	Definition (Armenian)
Ao arch angioplasty	Aortic arch angioplasty	Աորտալ աղեղի անգիոպլաստիկա
Ao commissurotomy	Aortic commissurotomy	Աորտայի կոմմիսուրոտոմիա
Ao valvuloplasty	Aortic valvuloplasty	Աորտալ փականի պլաստիկա
Ao-coronary and mammary-coronary bypass	Aortic-coronary and mammary-coronary bypass	Աորտո-կորոնար և մամմարո-կորոնար շունտավորում
Ao-coronary bypass	Aortic-coronary bypass	Աորտո-կորոնար շունտավորում
Arterial switch	Arterial switch	Զարկերակային տեղափոխում
Artificial chord making	Artificial chord making	Արհեստական խորդայի ստեղծում
Atrial septotomy	Atrial septotomy	Նախասրտային միջնապատի հատում
AVR	Aortic Valve Replacement	Աորտալ փականի փոխադրում
Bilateral mammary-coronary bypass	Bilateral mammary-coronary bypass	Երկկողմնային մամմարո-կորոնար շունտավորում
B-T shunt	Blellok-Tausig shunt	Բլելոկ-Տաուսիգի շունտ
Central shunt	Central shunt	Կենտրոնական շունտ
Closure of PFO	Closure of Patent Foramen Ovale	Բաց օվալ անցքի փակում
Closure of VSD	Closure of Ventricular Septum Defect	Փորոքային միջնապատի դեֆեկտի փակում
Direct closure of ASD	Direct closure of Atrial Septum Defect	Նախասրտային միջնապատի դեֆեկտի ուղղակի փակում
Fontan procedure	Fontan procedure	Ֆոնտենի վիրահատություն
Glenn shunt	Glenn shunt	Գլեննի շունտ
HemiFontan	HemiFontan	Հեմի-Ֆոնտենի վիրահատություն
Implantation of Pacemaker	Implantation of Pacemaker	Պեյսմեյկերի իմպլանտացիա
LA-isolation	Left Atrium isolation/denervation	Զախ նախասրտի մեկուսացում
Ligation of PDA	Ligation of PDA	Բոտալյան ծորանի (բաց զարկերակային ծորանի) կապում
Mammary-coronary bypass	Mammary-coronary bypass	Մամմարո-կորոնար շունտավորում
Mod.B-T shunt	Modified Blellok-Tausig shunt	Բլելոկ-Տաուսիգի մոդիֆիկացված շունտ
Mod.Ross procedure	Modified Ross procedure	Ռոսսի մոդիֆիկացված վիրահատություն

Mustard procedure	Mustard procedure	Մաստարդի վիրահատություն
MV anuloplasty	Mitral Valve anuloplasty	Միտրալ փականի անուլոպլաստիկա
MV commissurotomy	Mitral Valve commissurotomy	Միտրալ փականի կոմիսսուրոտոմիա
MV valvuloplasty	Mitral Valve valvuloplasty	Միտրալ փականի պլաստիկա
MVR	Mitral Valve Repair	Միտրալ փականի շտկում
PA banding	Pulmonary Artery banding	Թոքային զարկերակի նեղացում
PA commissurotomy	Pulmonary Artery commissurotomy	Թոքային զարկերակի կոմիսսուրոտոմիա
PA patch angioplasty	Pulmonary Artery patch angioplasty	Թոքային զարկերակի անգիոպլաստիկա
PA valvotomy	Pulmonary Artery valvotomy	Թոքային զարկերակի փականի հատում
Patch closure of ASD	Patch closure of Atrial Septum Defect	Նախասրտային միջնապատի պլաստիկա լաթով
Pericardiectomy	Pericardiectomy	Պերիկարդի հատում
Peripheral arteriovenous shunt	Peripheral arteriovenous shunt	Պերիֆերալ զարկերակ-երակային շունտ
Potts shunt	Potts shunt	Պոտտսի շունտ
RA denervation	Right Atrium denervation/isolation	Աջ նախասրտի դեներվացիա/մեկուսացում
RA isolation	Right Atrium isolation/denervation	Աջ նախասրտի մեկուսացում
Rastelli procedure	Rastelli procedure	Ռաստելլի վիրահատություն
Repair of Ao-Pulmonary window	Repair of Aortic-Pulmonary window	Աորտա-թոքային զարկերակի անցքի շտկում
Repair of complete AVC	Repair of complete Atrio-Ventricular Canal	Նախասիրտ-փորոքային ամբողջական կանալի շտկում
Repair of core triatriatum	Repair of core triatriatum	Եռնախասրտային սրտի շտկում
Repair of DORV	Repair of Double Outlet Left Ventricle	Երկելք աջ փորոքի շտկում
Repair of PAPVR	Repair of Partial Anomalous Pulmonary Vein Return	Թոքային երակների մասնակի անոմալ դրենաժի շտկում
Repair of partial AVC	Repair of partial Atrio-Ventricular Canal	Նախասիրտ-փորոքային մասնակի կանալի շտկում
Repair of sub-pulmonary stenosis	Repair of sub-pulmonary stenosis	Թոքային զարկերակի ենթափականային նեղացման շտկում
Repair of	Repair of Total Anomalous	Թոքային երակների ամբողջ

TAPVR	Pulmonary Vein Return	անոմալ դրենաժի շտկում
Repair of ToF	Repair of Tetralogy of Fallot	Ֆալոյի տետրադայի շտկում
Resection end to end anastomosis of Ao Coarctation	Resection end to end anastomosis of Aortic Coarctation	Աորտալ կոարկտացայի հատում և ծայրը ծայրին բերանակցում
Resection of cardiac myxomas	Resection of cardiac myxomas	Սրտի միքսոմայի հեռացում
Resection of sub-Ao ring	Resection of subaortic ring	Ենթաաորտալ օղի հատում
Ross procedure	Ross procedure	Ռոսսի միջամտություն
Senning procedure	Senning procedure	Սեննինգի վիրահատություն
Subclavian angioplasty	Subclavian angioplasty	Աորտայի կոարկտացիայի շտկում ենթաանրակային զարկերակի միջոցով
Total heart isolation	Total heart isolation	Սրտի ամբողջական մեկուսացում
Transanular PA patch angioplasty	Transanular Pulmonary Artery patch angioplasty	Տրանսանուլիար թոքային զարկերակի անգիոպլաստիկա
TV anuloplasty	Tricuspid Valve anuloplasty	Տրիկուսպիդ փականի օղի պլաստիկա
TV commissurotomy	Tricuspid Valve commissurotomy	Տրիկուսպիդ փականի կոմիսսուրոտոմիա
TV valvuloplasty	Tricuspid Valve valvuloplasty	Տրիկուսպիդ փականի պլաստիկա
TVR	Tricuspid Valve Replacement	Տրիկուսպիդ փականի փոխարինում/ պրոթեզավորում
Ventricular septum myotomy	Ventricular septum myotomy	փորոքային միջնապատի մկանահատում
Waterston-Cooley shunt	Waterston-Cooley shunt	Ուոտերսոն-Բուլեյի շունտ

APPENDIX 14. The agreement between medical records and database for each variable

Variable name	Percent agreement (%)	Agreement value (%)	Strength of agreement
Patient record #	81.97	81-100	excellent
Patient name	98.36	81-100	excellent
Date of birth	95.08	81-100	excellent
Gender	78.69	81-100	excellent
Date of admission	98.36	81-100	excellent
Date of discharge	93.44	81-100	excellent
Date of surgery	96.72	81-100	excellent
Diagnosis	47.54	41-60	poor
Heart failure class	77.05	61-80	good
Surgical procedure	93.44	81-100	excellent
Cardiologist	98.36	81-100	excellent
Surgeon	93.44	81-100	excellent
Patient weight	100	81-100	excellent
Patient height	95.08	81-100	excellent
Re-operation	98.36	81-100	excellent
In-hospital death	100	81-100	excellent
Mediathenitis	100	81-100	excellent
Wound infection	100	81-100	excellent
Other post-surgical complications	85.25	81-100	excellent
ICU stay	77.05	61-80	good
Intubation time	85.25	81-100	excellent
Blood used for treatment	47.54	41-60	poor
Insulin administered to patients	100	81-100	excellent

APPENDIX 15. Sensitivity, specificity, and positive predictive value (PPV) for each variable

Variable name	Sensitivity	Specificity	PPV
Patient record #	81.97	100	100
Patient name	98.36	100	100
Date of birth	95.08	100	100
Gender	100	0	78.69
Date of admission	98.36	100	100
Date of discharge	93.44	100	100
Date of surgery	96.72	100	100
Diagnosis*	47.54	100	100
Heart failure class	41.18	90.91	63.64
Surgical procedure	93.44	100	100
Cardiologist	98.36	100	100
Surgeon	93.44	100	100
Patient weight	100	100	100
Patient height	95.08	100	100
Re-operation	80	100	100
In-hospital death	100	100	100
Mediathenitis	100	100	100
Wound infection	100	100	100
Other post-surgical complications	100	84.75	18.18
ICU stay	77.05	100	100
Intubation time	85.25	100	100
Blood used for treatment	3.03	100	100
Insulin administered to patients	100	100	100

* Patient diagnosis documented in patient record