

# Concept and implementation of a single source information system in nuclear medicine for myocardial scintigraphy (SPECT-CT data)

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## Keywords

Single source information system, hospital information system, nuclear medicine, myocardial - scintigraphy (SPECT/CT-data)

## Summary

**Objective:** Data for clinical documentation and medical research are usually managed in separate systems. We developed, implemented and assessed a documentation system for myocardial scintigraphy (SPECT/CT-data) in order to integrate clinical and research documentation. This paper presents concept, implementation and evaluation of this single source system including methods to improve data quality by plausibility checks.

**Methods:** We analyzed the documentation process for myocardial scintigraphy, especially for collecting medical history, symptoms and medication as well as stress and rest injection protocols. Corresponding electronic forms were implemented in our hospital information system (HIS) including plausibility checks to support correctness and completeness of data entry. Research data can be extracted from routine data by dedicated HIS reports.

**Results:** A single source system based on HIS-electronic documentation merges clinical and scientific documentation and thus avoids multiple documentation. Within nine months 495 patients were documented with our system by 8 physicians and 6 radiographers (466 medical history protocols, 466 stress and 414 rest injection protocols). Documentation consists of 295 attributes, three quarters are conditional items. Data quality improved substantially compared to previous paper-based documentation.

**Conclusion:** A single source system to collect routine and research data for myocardial scintigraphy is feasible in a real-world setting and can generate high-quality data through online plausibility checks.

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## 1. Background

At present medical data are often documented twice, once in an electronic healthcare record (EHR) and again in an electronic data capture (EDC) system for research purposes despite existing overlap between data items. “Electronic data capture (EDC) tools provide automated support for data collection, reporting, query resolution, randomization, and validation, among other features, for clinical trials” [1]. This documentation approach is called dual source [2] and its concept is shown in ►figure 1. Clinical data input takes place in the HIS and is separated from data input in (electronic) case report forms for research.

In contrast, a single source system reuses routine healthcare data for clinical research (►figure 2). Clinical and research data entry takes place in the HIS. Research data are available in the research database after export from the HIS.

A separate documentation system possesses quite a few disadvantages, for instance “Inefficiencies in clinical trial data collection cause delays, increase costs, and may reduce clinician participation in medical research” [3]. Moreover, “Routine data are potentially cheaper to extract and analyze than designed data...” and “... have the potential to identify patient outcomes captured in remote systems that may be missed in designed data collection” [4]. Furthermore, transcription errors are eliminated and patient recruitment for clinical trials is facilitated [5].

In our setting, the clinical database shall enable several studies concerning cardiovascular diseases. In particular, the system was designed for a study on cardiovascular risk stratification by combination of risk factor analysis, in-vitro diagnostics and SPECT/CT in order to be able to predict individualized risk concerning coronary events. It focuses on the concordance between non-invasive imaging and traditional risk factors and extends the Framingham [6] and the Prospective Cardiovascular Münster (PROCAM) [7] study in which algorithms were developed for assessing risk of myocardial infarction and stroke with epidemiological approaches to heart diseases on the basis of traditional risk factors such as age, LDL cholesterol, HDL cholesterol, smoking and hypertension. Data items to calculate Framingham and PROCAM risk scores are collected using the medical history form. Patients without known coronary heart disease (CHD) but with suspicion of CHD and patients with known CHD and their course of disease are included. The intent of the medical study is to evaluate the prognostic value of SPECT/CT examinations in comparison to the Framingham and PROCAM studies.

## 2. Objectives

This manuscript assesses technical and clinical feasibility of the single source documentation concept for a study in nuclear medicine. It addresses data modeling and implementation of a single source information system to collect routine and research data for myocardial scintigraphy on SPECT/CT to replace predominant paper-based or unstructured electronic documentation.

## 3. Methods

We analyzed the process from the initial patient encounter in nuclear medicine to the following bicycle stress test with tracer injection, subsequent post-stress SPECT/CT image acquisition as well as repeated injection and data acquisition at rest (one or two-day stress-rest protocol) with focus on the clinical documentation. At first, data for medical history, medication and symptoms are collected. When the electrode pads are affixed to the patient, the venous indwelling catheter is placed for the stress electrocardiography (ECG) examination. If the patient has adequate exercise capacity an exercise stress test is performed on a bicycle ergometer, otherwise a three-minute adenosine infusion is performed (140 micrograms per kg body weight). The radiotracer is injected at peak exercise at least one minute before exercise termination or 1.5 minutes after the start of the adenosine infusion, respectively. During the examination the ECG is continuously printed and blood pressure, pulse and stress level are documented as well as stress-induced symptoms such as pectoral angina or shortness of breath. After half an hour waiting time – to allow distribution of the tracer –

a SPECT/CT examination is performed. A specific scintigraphic camera (SYMBIA® [8]), a two-head gamma camera combined with a two-slice CT (SYMBIA T2) measures myocardial tracer accumulation as well as calcium deposition in the coronary arteries. The image analysis software 4DM-SPECT [9] is used to display and quantify regional perfusion defects at stress and rest, software from the scanner manufacturer is used to quantify the “calcium score” in the different branches of the coronary tree. The process of clinical examination and documentation is presented as sequence diagram in ►figure 3. The patient’s consent or refusal to participate in studies as well as clinical information such as medical history and exercise results are documented electronically within HIS forms. Only personnel with treatment context within the department is authorized to access the electronic health record (EHR). Authorization is covered by HIS-functionality.

We also analyzed the research process. A nuclear medicine specialist defines and runs a query for a defined time span on data of patients whose informed consent is available. The resulting data are analyzed by a statistician and at last the research team publishes research results. These sequences are shown in ►figure 4.

Before implementation of the single source system, documentation processes were predominantly paper-based and contained only clinical routine data. ►Figure 5 shows an example of the previously used paper form. After analyzing these processes we designed and implemented three complex electronic forms using tools of our HIS (ORBIS® from Agfa Healthcare) [10]. Checkboxes, lists and number fields with only few narrative text fields were used in order to provide structured data for research analysis. To speed up documentation, checkboxes are preferred data entry elements. Furthermore, many conditional attributes were implemented which are merely visible in context to superordinate questions. To improve data quality, online plausibility checks were implemented. For instance, mandatory items need to be completed before a form can be finalized. For clinical acceptance the protocols can be saved and closed any time in draft mode. A work list contains all uncompleted forms for physician’s review.

Conditional items with related plausibility checks were applied to improve data quality. For example: The attribute “cardiac transplantation” is a mandatory item. If “cardiac transplantation” equals “yes”, the date of cardiac transplantation must be filled in. Implausible date values such as future dates or dates before the patient’s birth are rejected; otherwise the date field is invisible. Range checks are also implemented, for instance regarding systolic blood pressure with a range from 70 to 300 mmHg. Error messages occur if data items are invalid or missing. Missing items are marked red.

To differentiate between missing data entry and clinically not available information, checkboxes “unknown” are provided. For instance, the medical history form is based on the medical report sent by the patient’s cardiologist and the patients’ answers. Sometimes precise information is not available like location of right coronary artery (RCA) stenosis or degree of stenosis.

Repetitive data elements like multiple values for blood pressure and heart rate were implemented as lists.

To minimize data entry efforts, item values are calculated automatically wherever possible. For instance, injected activity of the applied tracer is calculated from initial activity and decay time depending on selected isotope (technetium-99m, fluorine-18 or nitrogen-13) according to:

$$A(t) = A(0) \cdot e^{(-\ln 2 \cdot t / T_p)}$$

where  $T_p$  = physical decay time, unit: Bq “Becquerel”: 1 Bq = 1 decay/second [11].

Laboratory data are provided by a dedicated laboratory information system (LIMS) (OPUS-L from OSM [12]), transferred by a communication server (egate from SUN [13]) using health level seven (HL7)-messages and imported into the clinical information system (ORBIS), therefore no manual entry of laboratory data is necessary. The report generator of ORBIS® [10] was used to extract HIS data for quality control and research purposes. This tool enables to prepare data reports by drag-and-drop of the relevant items. Authorized study physicians perform these queries. The report tool generates csv-files suitable for import in statistic software packages such as SPSS [14]. HIS reports are pseudonymized to protect patient data privacy by numeric identifiers without patient names. A data management team performs monitoring – supported by specific HIS reports – to verify data validity in the research database.

## 4. Results

A single source system based on HIS documentation merges clinical and scientific documentation and thus avoids multiple documentation. ▶Figure 6 presents a section from the medical history form which requires structured data entry and many conditional items. To speed up documentation, radio buttons and check boxes are preferred data elements. After export from the HIS and import into a statistic software package (SPSS) these data are represented in ▶figure 7. Each form corresponds to one record.

▶Figure 8 presents another example of the implemented forms including repetitive data elements which contain structured data like check boxes, radio buttons, lists and number fields with additional narrative text fields. To enable statistical data analysis, entry is highly structured.

The previous paper-based routine documentation consisted of 74 attributes. This is a subset of the new single source information system which contains 295 attributes where 47 (16%) are required, 215 (73%) conditionally required, 8 (3%) optional, 3 (1%) conditionally optional and 21 (7%) calculated and initialized items respectively. Patient demographics and a subset of medical history are examples for overlapping items. Several attributes are refined in order to be used in research, for example medication or vessel status. In supplement 2 we provide a table with details on all attributes and their use for routine or research documentation. Because almost three quarters of the total number of items in our system are conditional, data entry efforts are reduced. 201 attributes are subject to plausibility checks.

We assessed the documentation period from February till October 2009. ▶Figure 9 shows the frequency of documentation forms by month and form type. Nuclear medicine specialists started to document medical histories and stress injection protocols on HIS forms in February 2009. The use of the rest injection protocol began in March. Documentation raised from about 25 forms per month to about 65 forms per month. Since July 2009 it is in steady state. ▶Figure 10 and the supplementary ▶figures A and B present the number of forms per month and protocol with their rate of completeness. In the analyzed period the number of medical history forms (466 of 456 distinct patients) and stress injection protocols (466 of 451 distinct patients) is balanced. The fact that the total number of the rest injection protocols (414 of 407 distinct patients) is lower can be explained with the delayed start of this electronic form. 81% of the total protocols were completely documented. For comparison, we assessed the completeness of the previous paper-based documentation. Therefore, we took 19 random samples in February and March 2009. It became apparent that no patient (0 out of 19) was completely documented. The median proportion of incompletely documented and illegible items per protocol was 15%.

In the analyzed period 495 patients were documented by 8 physicians and 6 radiographers. We collected user feedback by unstructured interviews and found a good level of acceptance. A complete documentation comprises at least one medical history form, one stress injection protocol and one rest injection protocol and each protocol must be finalized. Overall, documentation of 181 (37%) patients was complete. ▶Figure 11 presents the number of recruited patients per month itemized by completeness. Since July the completeness rose considerably. The increased number of examinations presented in ▶figure 9 corresponds to the number of documented patients (▶figure 11).

## 5. Discussion

Design and implementation of this system show that a single source information system is technically feasible and accepted in the clinical setting. It is integrated into existing clinical workflow without disruption. It provides highly structured documents with only a few narrative text fields. Thus, there are possibilities for applying plausibility checks to improve data quality. Paper-based entries are error-prone, for instance due to legibility problems. In contrast to that electronic forms have a significantly reduced error rate [15–17] which was demonstrated for instance in a laboratory setting [15]. Data quality is improved, if electronic forms are provided with checks for correctness and completeness [3, 18–20]. This was confirmed for instance in documentation of cardiovascular disease [3], emergency [18] and in primary care [19]. In our setting, a random sample of the previ-

ous paper-based documentation showed poor data quality (none of 19 random patients was completely documented), so 37% completeness is a relevant step forward.

Because clinical routine documentation usually contains less structured items than research case report forms (CRFs), it is necessary to transform the data in coded items in order to analyze them for research. This process is difficult and also error-prone so that inconsistencies of data will follow [19]. In a single source system this action is dispensable because redundant data entry is eliminated [3, 17, 21, 22]. Consequently the documentation on EHR and eCRF is in time [23].

Due to the fact that a physician spends nearly a quarter of his working time on clinical routine documentation [22], additional documentation efforts for research purposes are relevant, especially in a university hospital setting.

In order to increase interoperability data standards are necessary which are used in medical care and in research [24]. Ohmann [25] states in the future a “Trial protocol-based workflow... has interfaces to laboratory information systems, hospital information systems, EHRs, tools for capturing, coding and analyzing adverse events, manage participant recruitment and randomization...”. HIS data can be used to recruit patients for studies [2, 5, 26]. In the repository of our single source system queries can be performed in order to recruit patients for several studies on heart diseases. To comply with data privacy protection rules, patient’s consent or refusal to participate in studies is documented electronically in the HIS [27].

Our single source system is extensible and builds the technical basis for several studies in nuclear medicine. An advantage of the single source system is that the repository assembled by the reports is independent from the statistical tool. There are some disadvantages of our approach, for instance the technical dependence from the HIS and the effort to develop complex HIS-forms. In a multicentric study, CRFs need to be adapted to the different HIS environments, which requires additional implementation efforts. The architecture of a single source system for a multicentric study is demonstrated in ► figure 12. “Each different HIS is communicating with the research database for this study: Study data are exported from each HIS, monitoring requests are sent back to each HIS by the data management team of the study. To support data consolidation and synchronization for multicentre studies, the research database needs a mapping between each data element and its associated HIS” [2]. Unfortunately, a single source information system depends on the used HIS at present. For integration with other HIS there are two prerequisites: Firstly, standards for (e)CRFs are needed. The non-profit organization Clinical Data Interchange Standards Consortium (CDISC) currently develops a global accessible electronic library called CDISC SHARE which contains standardized data element definitions for the use in applications across studies in order to improve biomedical research and thereby, in the end, healthcare [28]. And secondly, HIS functionality has to be improved in order to allow import and export of standardized (e)CRF-schemes.

At present, literature regarding single source information systems is quite limited. A first proof-of-concept study concerning a cardiology trial was published in 2007 [3]. It was indeed integrated into the clinical environment, but there was no integration into an existing inter-departmental CIS in contrast to our approach. Furthermore, the proof-of-concept study was tested in only two live patient encounters. In our approach the total emergence of cardiological patients of the department was involved into documentation in the single source system.

The introduction phase with parallel documentation – paper and electronic – required only a few days because the physicians were familiar with the HIS. User acceptance is a key prerequisite for electronic documentation systems [29]. Therefore we involved the users in the design of the documentation system, discussed and improved it with them.

In the future we intend to develop a monitoring system which notifies study physicians about incomplete forms to further improve data quality.

## 6. Conclusions

A single source system based on the HIS connects medical research and clinical documentation, avoids thereby redundant data entry, is technically feasible and well accepted in the clinical setting.

**Clinical Relevance Statement**

Integrated documentation of routine and research data is technically feasible and can help to avoid redundant data entry. This single source approach is clinically relevant due to high documentation workload of physicians and enables timely data capture with high quality.

**Conflict of Interest**

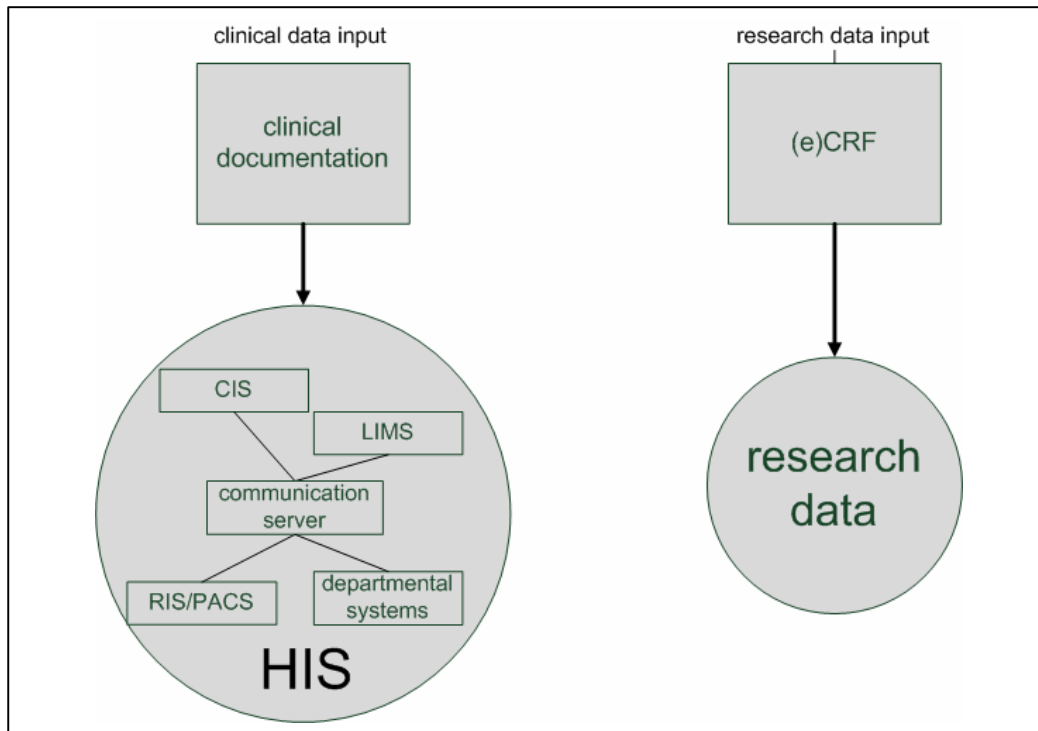
The author(s) declare that they have no competing interests.

**Human Subject Research**

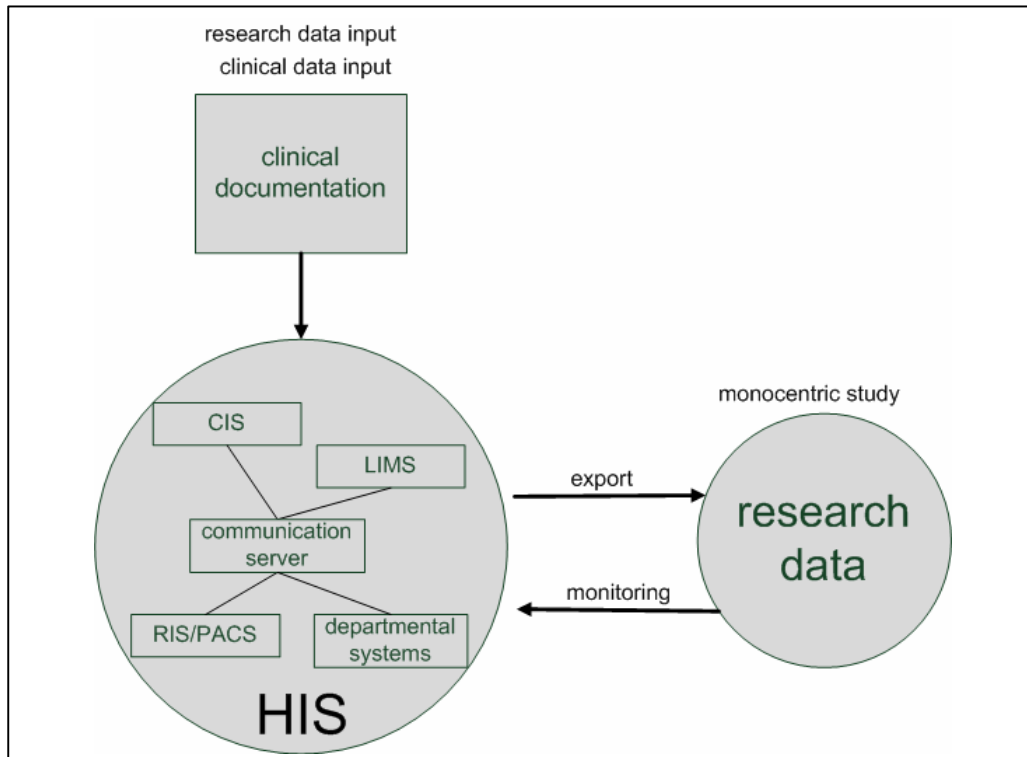
The study was performed in compliance with the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects. Informed consent was obtained in all cases.

**Abbreviations**

SPECT: single photon emission computed tomography; HIS: hospital information system; LIMS: laboratory information systems; HL7: health level 7; PROCAM: prospective cardiovascular Münster study; LDL: low density lipoprotein; HDL: high density lipoprotein; ECG: electrocardiogram; RCA: right coronary artery; LCA: left coronary artery; LAD: left anterior descending artery; RCX: ramus circumflex; St. p.: status post; COPD: chronic obstructive pulmonary disease; CHD: coronary heart disease; EHR: electronic health record; CRF: case report form

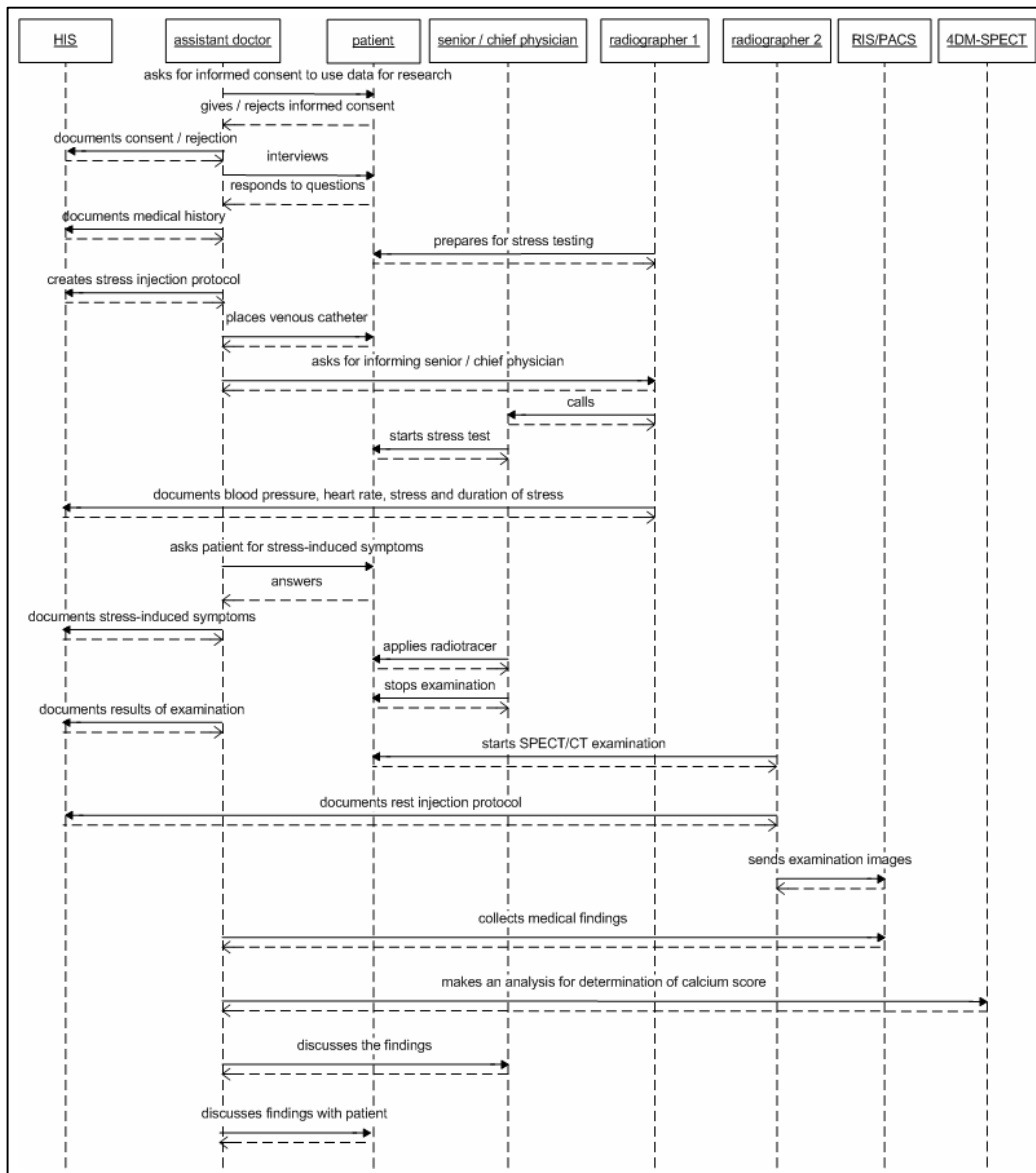


**Fig. 1 Architecture of dual source information systems.** HIS and research database are separated systems. (Electronic) case report forms ((e)CRFs) are entered into the research DB and are not available in HIS [2].



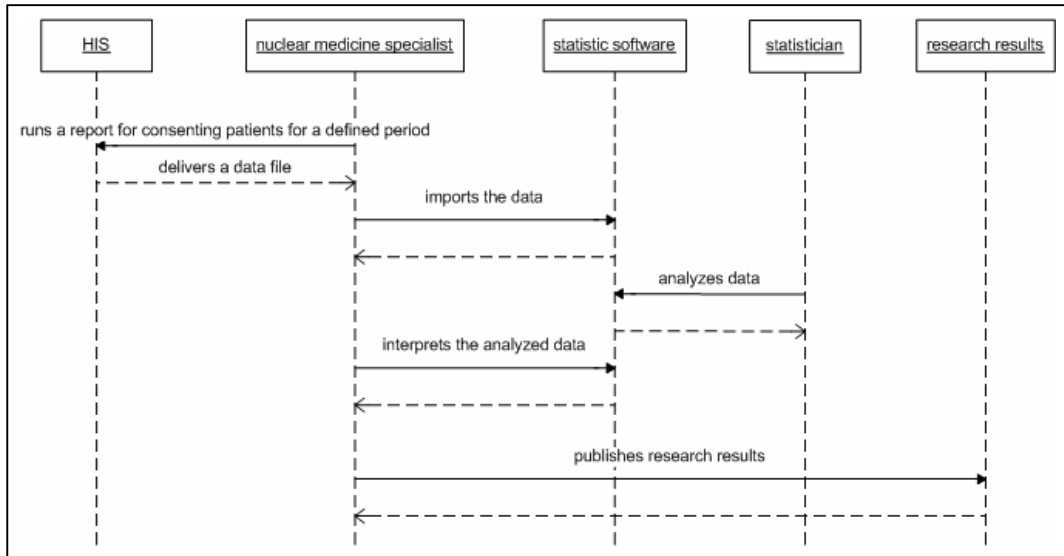
**Fig. 2 Architecture of single source information systems.** Routine and research data are collected within HIS. Research data are being exported into the research DB. Monitoring takes care of incomplete or incorrect data elements [2].





**Fig. 3** UML sequence diagram of examination and documentation process. Physicians, radiographers and the patient as actors and the HIS, RIS/PACS and 4DM-SPECT as systems are involved into the scenario.





**Fig. 4** UML sequence diagram of research process. The nuclear medicine specialist and a statistician as actors and the HIS and statistic software as systems are involved into the scenario.

Age: <u>58</u> years		Height: <u>188</u> cm		Weight: <u>101</u> kg	
Medication:					
<b>Medical history + ICD 10</b> <input checked="" type="checkbox"/> Not medicated today <input checked="" type="checkbox"/> Empty-stomached today <input checked="" type="checkbox"/> Stress ECG Watt <u>150</u> Termination caused by: <u>muscular</u> <input checked="" type="checkbox"/> Myocardial scintigraphy <u>03/08</u> <u>63. Dent</u> <input checked="" type="checkbox"/> PTCA <u>+ 21VA</u> <u>(2) 10/08</u> <input type="checkbox"/> Bypass <input type="checkbox"/> Heart transplantation date <u>142.0</u>			<input checked="" type="checkbox"/> Family history <b>!</b> <input checked="" type="checkbox"/> Hypertension I10 <input checked="" type="checkbox"/> Hyperlipidemia E78.5 <input type="checkbox"/> Nicotine <u>Ex</u> F17.1 <input checked="" type="checkbox"/> Diabetes mellitus E14.90 <input checked="" type="checkbox"/> Myocardial infarction I25.2 location: <u>IV</u> , date: <u>10/08</u> <input checked="" type="checkbox"/> Cardiac arrhythmia I49.9 type: <input type="checkbox"/> Cardiac syncope R55 <input checked="" type="checkbox"/> Angina pectoris I20.9 since: <input checked="" type="checkbox"/> at stress <input checked="" type="checkbox"/> Dyspnea R06.0 <input checked="" type="checkbox"/> Asthma		
Adenosine <input type="checkbox"/> ml min ml/min max. predicted heart rate (220 - age) <u>162</u> % of max. heart rate ICD shock threshold			Resting ECG <u>SR, AV-Block E<sup>o</sup></u> Stress <input type="checkbox"/> ST depression <input type="checkbox"/> asc in <u>0.2 mV</u> <u>V3-S, II, aVF</u> mV <input type="checkbox"/> SVES <input type="checkbox"/> VES <input type="checkbox"/> monomorphous <input type="checkbox"/> polymorphous		
Duration [min]   Stress [watt]   Heart rate [1/min]   RR [mmHg]		<input checked="" type="checkbox"/> Angina pectoris <input checked="" type="checkbox"/> Dyspnea <input checked="" type="checkbox"/> Muscular exhaustion <input type="checkbox"/> General exhaustion <input type="checkbox"/> Other			
0		0		71 150 / 100	
2'		50		96 160 / 90	
2'		100		110 180 / 90	
2'		150		/	
1'		175		136 230 / 100	
Gravidity is not available.					
Patient's signature: _____			Physician: _____		

**Fig. 5** Screenshot of the previous paper-based documentation. The previous paper form contained only data for clinical routine. Additional information was documented as free text.

### Indication/question

Suspicion of CHD:  yes  no

Suspicion of toxic cardiomyopathy:  yes  no

St. p. heart transplantation:  yes  no Heart transplantation date: 01.06.2006

Known CHD:  yes  no

1 vessel CHD  
 2 vessel CHD  
 3 vessel CHD

Last cardiac catheter examination: 

<input checked="" type="radio"/> < 1 month	<input type="radio"/> 1 - 3 months	<input type="radio"/> 3 - 6 months
<input type="radio"/> 6 - 12 months	<input type="radio"/> > 12 months	<input type="radio"/> unknown

St. p. infarction:  yes  no

St. p. stent implantation:  yes  no

St. p. bypass surgery:  yes  no

Vessel status: Degree of stenosis: Therapy:


<input checked="" type="checkbox"/> RCA <input type="checkbox"/> unknown <input checked="" type="checkbox"/> proximal RCA <input type="checkbox"/> medial RCA <input type="checkbox"/> distal RCA <input type="checkbox"/> posterior descending artery  <input type="checkbox"/> LCA <input type="checkbox"/> LAD <input type="checkbox"/> RCX	<input type="checkbox"/> unknown	70%	yes	PTCA, Stent
---	----------------------------------	-----	-----	-------------

Cardiomyopathy:  yes  no

Fig. 6 Section from the medical history form. Structured data items are used, most of them are conditional. For instance, the type of CHD is only collected if "Known CHD" equals "yes". Radio buttons and check boxes are preferred item types to speed up documentation.

	creation_date	patient_id	case_id	suspicion_of_CHD_yes	suspicion_of_CHD_no	suspicion_of_toxic_cardiomyopathy_yes	suspicion_of_toxic_cardiomyopathy_no	st_p_heart_transplantation_yes	st_p_heart_transplantation_no	heart_transplantation_date	known_CHD_yes	known_CHD_no	CHD_1_vessel	CHD_1_yes
1	31.08.2009	76543210	12345678	1	0	0	1	1	0	01.06.2006	1	0	1	
2														
3														
4														
5														

Fig. 7 Data section from the medical history form imported into the statistic software SPSS. Each HIS form from figure 6 corresponds to one row of data in the statistic analysis.



**UKM**  
 Universitätsklinikum  
 Münster

**Department of nuclear medicine**  
 Director: Univ.-Prof. Dr. Dr. med. O. Schober

**Name:** 2009 Test  
**Date of birth:** 04.04.1960, M  
**Case ID:** 02009010201

The patient accepts the processing of collected data for research.

**Protocols:**
 At rest    
  Ergometry on stress    
 Cameras for the protocols: **Symbia**  
 Not at rest    
  Adenosine on stress    
 Isotop: **TC-99m**  
 At rest depending on stress

**Marked area for the electrode pads:**  
 Calibrated activity (stress): 123.00 MBq     Calibration time: 10:00

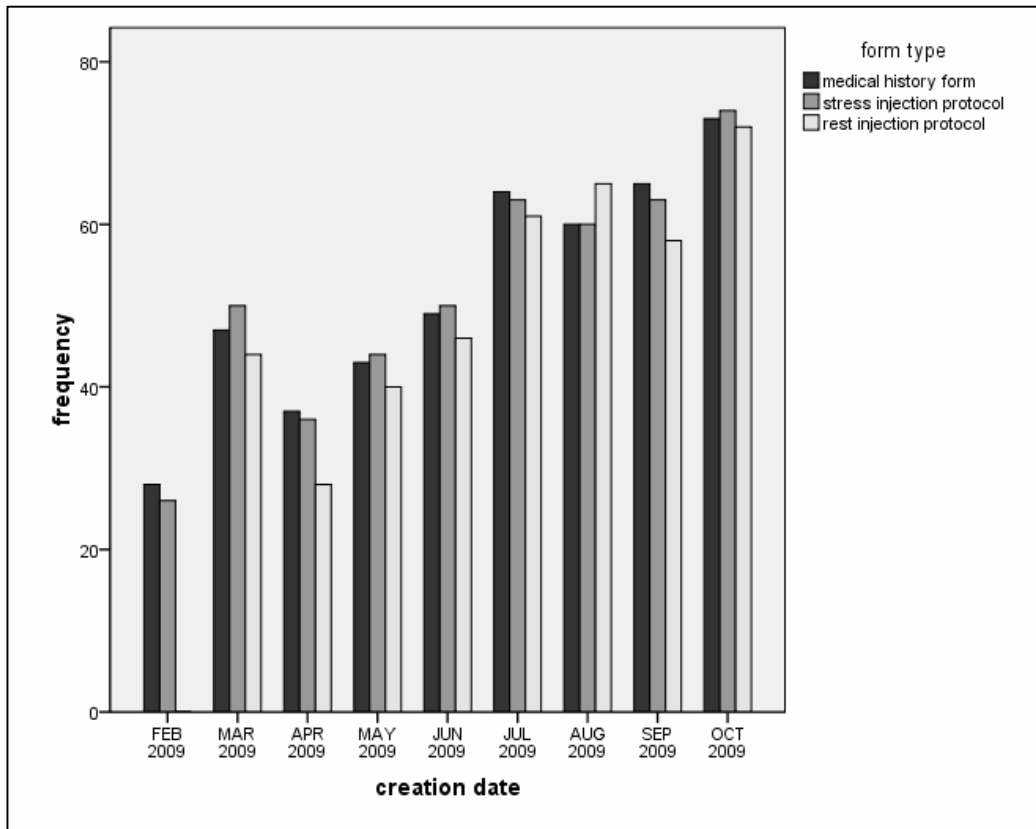
**Resting ECG:**  
 Inconspicuous ECG  
 Sinus rhythm  
 AV block    
  Level 1    
  Level 2    
  Level 3  
 Atrial fibrillation  
 ST depression  
 ST elevation  
 VES    
  monomorphous    
  polymorphous    
 Blood pressure at rest: 130 / 80  
 SVES     Heart rate at rest: 75  
 RBBB  
 LBBB  
 Negative T wave

**Comments:**

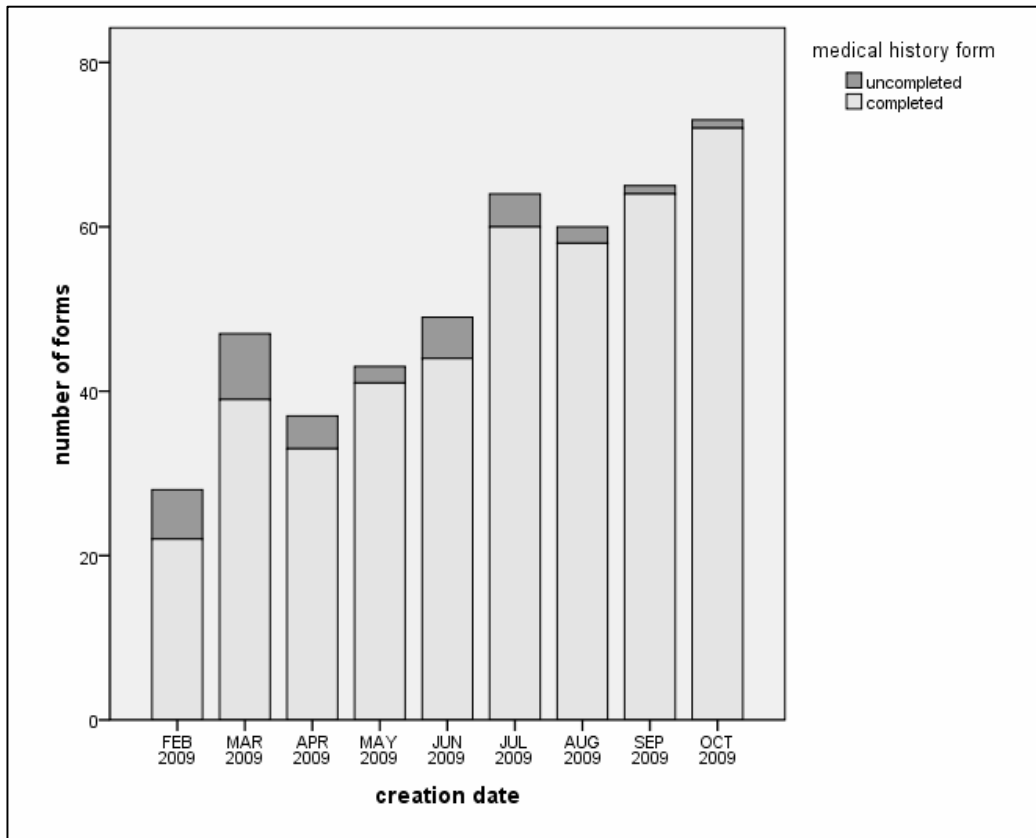
Nr	Injection time	Duration (hh:mm:ss)	Stress (watt)	RR systole	RR diastole	Heart rate
1	<input type="checkbox"/>	00:02:00	30	130	80	75
2	<input type="checkbox"/>	00:02:00	75	140	80	100
3	<input checked="" type="checkbox"/>	00:01:00	100	150	85	110

Nitro-spray after stress:    
  yes    
  no

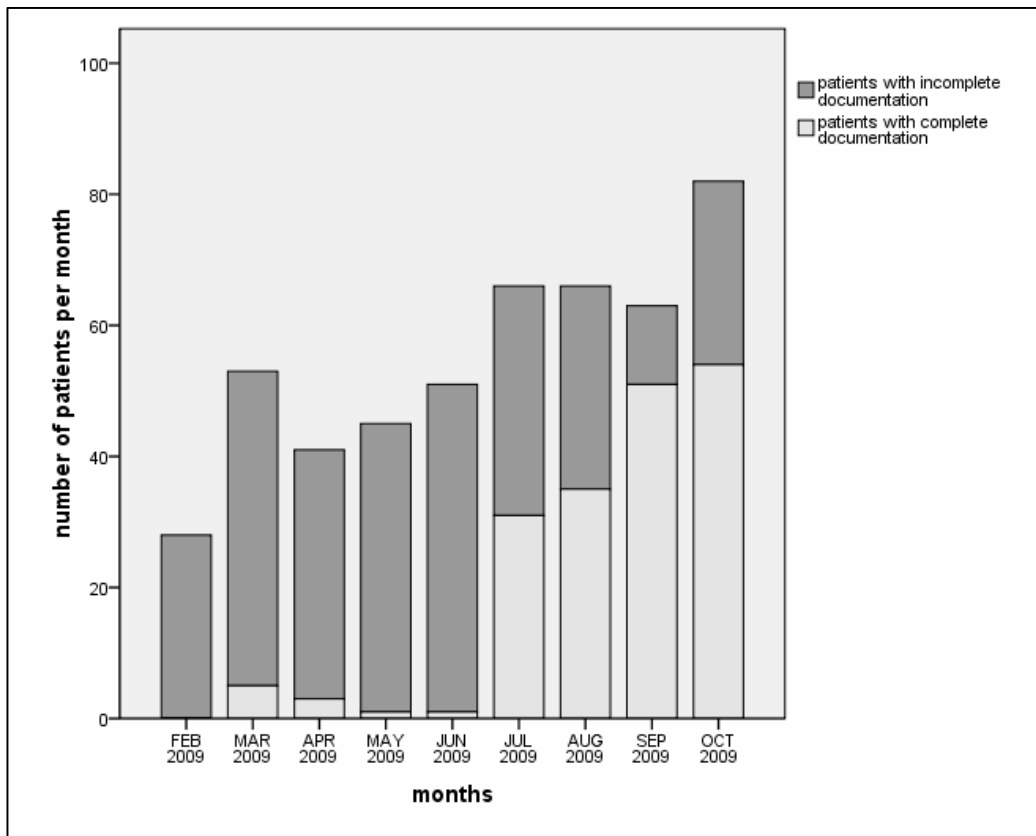
**Fig. 8** Section of the stress injection protocol. Structured data items and a few narrative text fields are used. Radio buttons and check boxes are preferred data items. Stress level, blood pressure (RR) and heart rate are repetitive data elements.



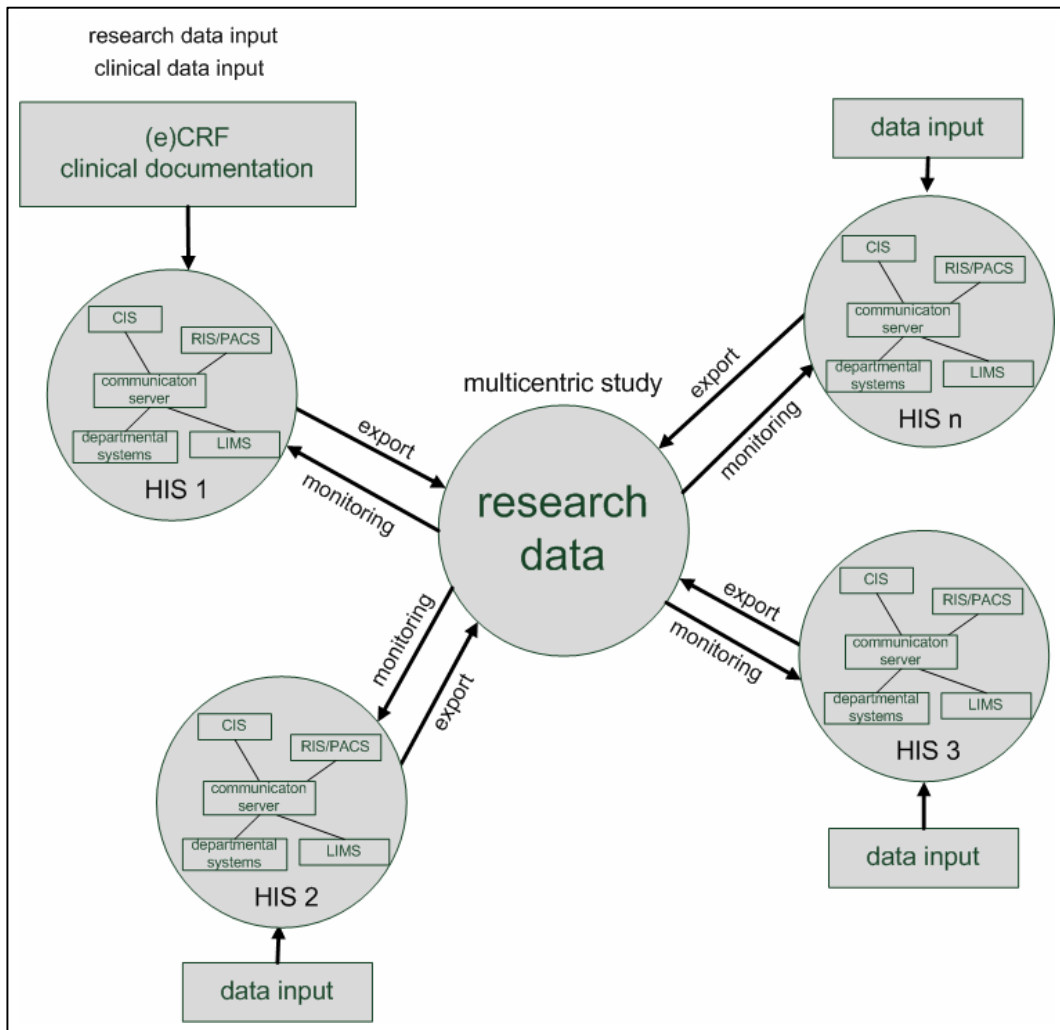
**Fig. 9** Bar diagram of created electronic forms per month. Documentation raised from about 25 forms per month to about 65 forms per month. Since July 2009 it is in steady state.



**Fig. 10** Bar diagram of medical history forms by month. In this period, the mean rate of completeness is 93%.

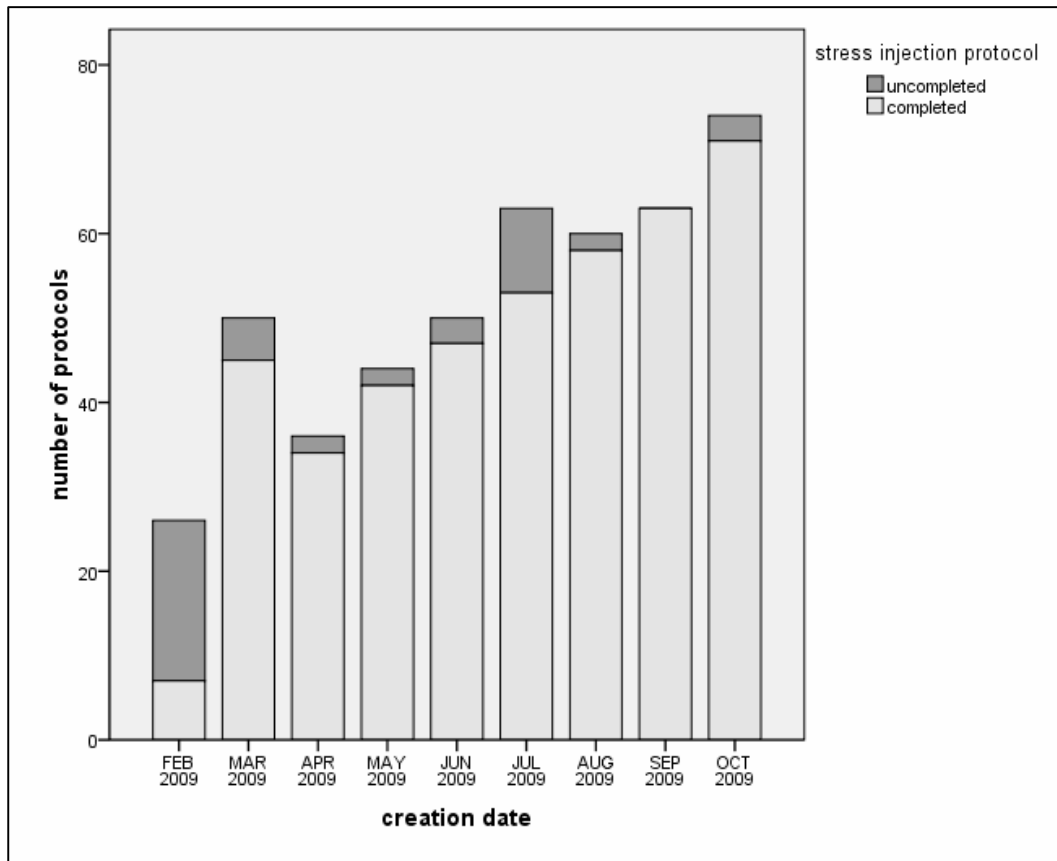


**Fig. 11** Bar chart: Number of recruited patients per month itemized by completeness. Since July the completeness of documentation rose.

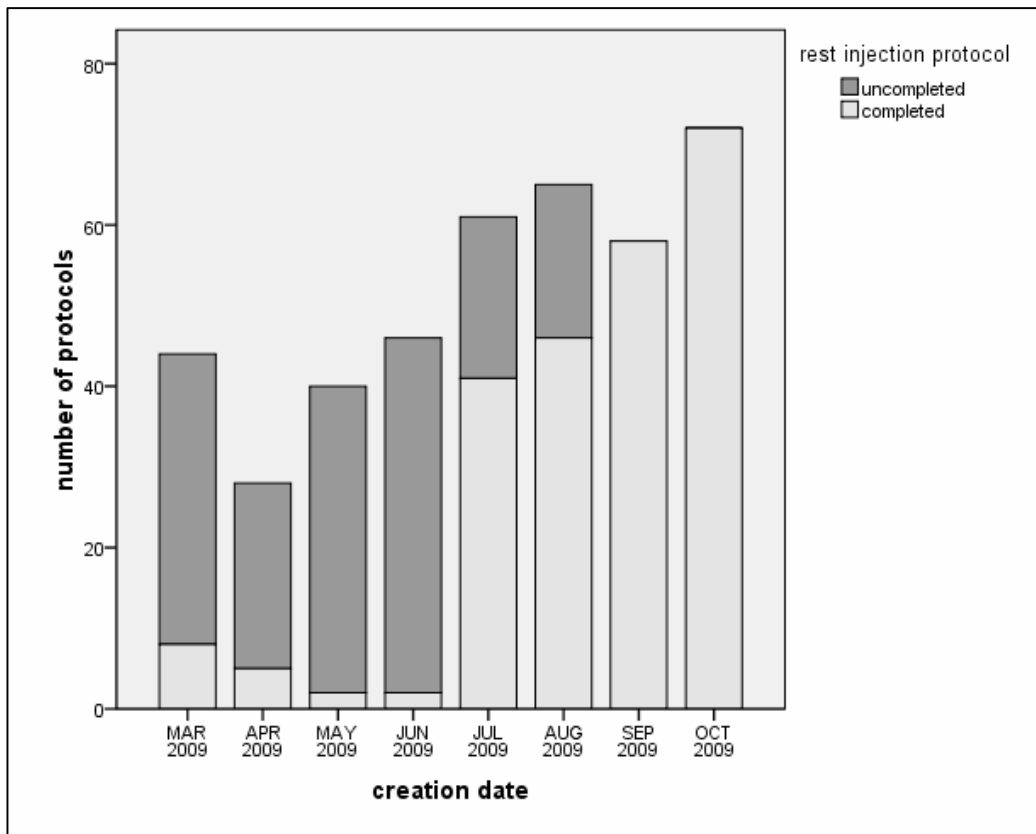


**Fig. 12** Single source information systems for multicentric studies. Routine and research data are collected within each local HIS. Research data are being exported into the common research database for each study [2].





**Supplementary Figure A** Bar diagram of stress injection protocols by month. In this period, the mean rate of completeness is 90%.



**Supplementary Figure B** Bar diagram of rest injection protocols by month. The mean rate of completeness of the period is only 57% but it rose since July 2009. In July 2009, it was 67% and in September and October 2009, it was 100%.

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