EFFICIENCY AND EFFECTIVENESS OF IT TOOLS IN DATA QUALITY MANAGEMENT: A CASE STUDY IN MODERN MEDICAL IMAGING

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Abstract - This paper starts from an observation drawn from practice: the same lesion, examined at two different imaging centres, reaches the neurosurgeon as datasets that do not behave in the same way when loaded into a neuronavigation system. The difference does not lie in the diagnostic quality of the images, but in the conformity of the acquisition metadata with the technical requirements of the system that receives the data. We developed a software tool that verifies this conformity automatically, reading only the header of standardised imaging files, and applied it retrospectively to 255 cranial magnetic resonance examinations performed during the first quarter of 2024 at two centres, one public and one private. The rule set comprises fourteen rules, distributed across the three dimensions of data quality defined by the international data quality standard, and was frozen before the validation set was analysed. The results show two qualitatively different patterns. The first centre produces conforming datasets whenever it runs the volumetric sequence, but the sequence is absent from 28 of 44 contrast-enhanced examinations. The second runs the sequence almost every time, yet only 8.8% of candidate series meet the requirements, and in 18 examinations a conforming volume exists but was acquired before injection. The management consequence is counter intuitive. The centre with the apparently weaker result could move from 11.7% to 41.7% of examinations that are directly usable for navigation by shifting an already existing sequence to after contrast administration, at a cost of five minutes of scanner time and with no investment. Without measurement, the likely decision would have been to purchase equipment. The tool processed 186,000 files in approximately seven minutes, which places the cost of verification well below the threshold at which it might be considered an administrative burden.

Keywords: Data quality management, Imaging metadata conformity, Neuronavigation, retrospective comparative study, Efficiency and effectiveness, Medical imaging.

1. Introduction

A neurosurgeon planning an image-guided procedure does not look at the image; he loads a volume. The neuronavigation system takes a single series, reconstructs it in three dimensions and registers it to the operative space. If the series fails to meet certain acquisition requirements, the system either rejects it or accepts it with a degraded accuracy that the operator does not always discover in time.

This creates a dissociation that practice experiences but that the literature rarely measures. An examination may be diagnostically impeccable, with a complete and correct radiological report, and at the same time unusable for surgical planning. The two qualities are not the same quality. The first is a property of interpretation; the second is a property of the data.

The distinction becomes operational when viewed through the framework of quality management. Donabedian showed that the

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assessment of care quality decomposes into structure, process and outcome, and that each of the three can degrade independently [1]. An imaging dataset belongs to structure: it is the resource with which subsequent work is carried out. When structure is deficient, the surgical process absorbs the deficiency and the outcome reflects it.

The problem has an immediate economic dimension. Imaging centres in Romania, both public and private, purchase high-performance equipment but configure protocols locally, each according to its own practice. The result is a heterogeneity that is invisible in the radiological report and becomes apparent only at the moment of use. Those who pay for it are the hospital that reschedules the examination, the patient who receives a second dose of contrast agent, and the operating theatre that loses time.

Recent literature has produced tools capable of verifying automatically whether imaging datasets conform to a reference protocol. Sinha and Raamana demonstrated the extent of protocol non-compliance across more than twenty open neuroimaging datasets [2], while Keaveney and colleagues integrated a similar check into an imaging repository used in a multicentre study [3]. These works validate tools within research consortia, where the protocol is negotiated in advance and where any departure from it is, by definition, an error.

The question we raise here is different and, we believe, closer to the reality of a health system. What happens when there is no negotiated protocol, but two centres working independently, each correct by its own criteria, while the requirement originates in a subsequent use that neither of them controls? How far do the results diverge, where exactly does the chain break, and, above all, what would it cost to repair it?

We make three contributions. The first is a purpose-built software tool for automatic conformity verification, based on acquisition metadata and designed to survive data protection procedures. The second is its comparative application to real data from two centres, with the results translated into management indicators rather than technical rates alone. The third, and the most important in practice, is the demonstration that measuring data quality can reverse the direction of an investment decision.

2. State of the Art

2.1. Data Quality as an Object of Management

Data quality became a field in its own right only after organisations began to reuse data collected for one purpose in entirely different ones. ISO 8000-8:2015 [4] offers the conceptual framework best suited to the problem addressed here, because it separates three dimensions that degrade independently: syntactic quality, that is, the degree to which data conform to the syntax imposed by their own metadata; semantic quality, that is, the extent to which data correspond to the reality they represent; and pragmatic quality, that is, fitness for the purpose of use.

The separation has practical consequences. A dataset may be syntactically impeccable, with every attribute present and correctly encoded, and entirely inadequate pragmatically, because the values of those attributes fail to meet the requirements of subsequent use. This is precisely the situation documented in the sections that follow.

In the medical field, the literature on data quality has developed almost exclusively around the electronic health record. Lewis and colleagues systematised assessment approaches and tools in a review extending an analysis published a decade earlier, finding that although the dimensions assessed remain consistent, no standard approach has emerged [5]. Their conclusion regarding the need for scalable and flexible guidance applies in full to imaging as well.

Automation of assessment was addressed separately by Ozonze and colleagues, who identified a small number of programmes actually deployed in real settings and observed that effort in the field remains fragmented and insufficiently grounded in theory [6]. Penev and colleagues reached a convergent finding in a scoping review, concerning incomplete reporting and poor reproducibility of published assessments [7].

Two empirical studies deserve attention for designs close to our own. Wiley and colleagues quantified data quality by comparing two contexts of care delivery, telehealth and office-based consultation, across the dimensions of timeliness, completeness and information density [8]. Fraser and colleagues assessed data quality across fifty health facilities, identifying organisational factors that influence it and demonstrating that automated alerts measurably improve completeness [9].

On the imaging side, Willemink and colleagues described the preparation of data for machine learning, noting that metadata heterogeneity is the dominant practical obstacle [10]. The European network for artificial intelligence in health imaging (AI4HI) formulated, through Kondylakis and colleagues, a position on metadata models for imaging biobanks, arguing that without harmonised metadata the reuse of data remains theoretical [11].

2.2. Automated Conformity Verification in Imaging

Existing tools fall into two families, according to what they verify.

The first verifies the technical integrity of acquired data. Oguz and colleagues proposed, in DTIPrep, a quality control solution for diffusion-

weighted images that has become a reference in the field [12]. Kim and colleagues developed a semi-automated web environment for comprehensive quality control of neuroimaging data [13].

The second family verifies compliance with a predefined acquisition protocol, which is closer to the object of the present work. Hristova and colleagues formalised a set of quality control rules for positron emission tomography combined with computed tomography examinations within a multicentre clinical study [14]. Nagy and colleagues built a tool that automatically monitors the metadata of the Digital Imaging and Communications in Medicine (DICOM) standard and stated explicitly that such monitoring is an instrument of quality management, not merely a technical check [15]. Their results, obtained across more than nine thousand examinations in two nuclear medicine departments, show that systematic errors arise from organisational practices rather than from equipment faults.

Sinha and Raamana brought the problem to the scale of large consortia, demonstrating that protocol non-compliance is widespread and that frequent sources are deviations in repetition time, echo time, flip angle and phase encoding direction [2]. Keaveney and colleagues carried verification into the operational workflow of a multicentre study, achieving a nil rate of technical failure and a significant correlation between protocol compliance and the overall radiological quality of the examination [3].

The consequences of non-compliance for quantitative results were documented by Nguyen and colleagues, who showed how data entry inconsistencies affect quantification in positron emission tomography [16]. In a different register, Baccei and colleagues analysed patient safety events in radiology systemically, showing that patterns of risk become visible only when incidents are viewed at system level rather than as isolated episodes [17].

The benchmark against which verification is performed derives, in these works, from published consensus protocols. Ellingson and colleagues proposed the standardised brain tumour imaging protocol for clinical trials [18], subsequently complemented for perfusion sequences by Boxerman and colleagues [19]. For epilepsy, the task force of the International League Against Epilepsy formulated, through Bernasconi and colleagues, a harmonised protocol built around three-dimensional acquisitions [20].

Interoperability of medical information systems, as a precondition for any automated verification, was analysed systematically by Torab-Miandoab and colleagues [21], and its effect on the safety and quality of care was assessed by Li and colleagues [22].

2.3. Efficiency and Effectiveness: Operational Definitions

The title of this paper calls for a distinction that everyday language blurs. Donabedian separated the two notions on the same page, among the seven attributes of care quality: effectiveness is the degree to which attainable improvements are actually achieved, while efficiency is the ability to obtain the same improvement with a lower consumption of resources [23].

Transposed to a software verification tool, the definitions become operational at once. The effectiveness of the tool is the extent to which it identifies genuinely existing non-conformities. Its efficiency is the resource consumed to obtain the same result. A tool may be highly effective and practically unusable, if verification takes longer than manual correction; and it may be highly efficient and useless, if it misses precisely the deviations that matter.

The methodological framework for quantifying defects comes from the Six Sigma literature, where Pyzdek and Keller consolidated the calculation of defects per million opportunities and their conversion into a Sigma level [24]. The application of this apparatus in healthcare has consistent precedents. McLaughlin and Kaluzny discussed the conditions under which total quality management functions in health organisations [25], Mazzocato and colleagues analysed the mechanisms through which Lean thinking produces effects in healthcare [26], and Knechtges and Decker documented the application of the kaizen methodology within a radiology department itself [27].

The link between quality management practices and organisational performance in healthcare was tested empirically by Lee [28], while Tonjang and Thawesaengskulthai proposed an integrated quality and innovation framework for hospitals [29]. Quality management systems in health organisations, viewed through the principles of intellectual property, have been addressed previously by the authors [30].

General system requirements derive from ISO 9001:2015 [31], and those specific to medical devices from ISO 13485:2016 [32], both relevant to the positioning of the tool developed here.

The comparison between public and private provision of health services was synthesised by Basu and colleagues, who found that the available evidence does not support the view that the private sector is systematically more efficient or more effective, although the public sector frequently shows deficits in timeliness [33]. Their conclusion recommends caution in interpreting any comparison of this kind, including the present one.

3. Materials and Methods

3.1. Study Design and Setting

The paper presents a retrospective observational study with a comparative design, carried out on cranial magnetic resonance examinations performed at two imaging centres in Romania between 3 January and 29 March 2024.

The research question does not concern the diagnostic quality of the images, but a distinct and rarely measured property: the extent to which the dataset resulting from an examination can be used further, without additional processing, by a neuronavigation system. This distinction is essential to understanding the results. An examination may be diagnostically impeccable and at the same time unusable for planning an image-guided procedure, because the acquisition parameters do not meet the technical requirements of the neuronavigation system.

The two centres were included on the basis of existing collaboration agreements. The first is a public emergency hospital, which used a single magnetic resonance scanner throughout the study period. The second is a private imaging centre, where two scanners were in operation: 165 of the 166 examinations were performed on the first, and a single examination, dated 30 January 2024, on the second. The isolated examination was retained in the sample but supports no comparison between scanners. Neither centre replaced equipment during the study interval, which allows the observed differences to be attributed to protocol configuration rather than to renewal of the scanner fleet.

One clarification, which conditions the entire interpretation, must be made at the outset. The two centres do not constitute samples of the public and private sectors respectively, and the results do not generalise to those categories. One centre and one protocol do not represent a sector. What is compared are two concrete protocol configurations, applied at two concrete centres, over the same interval of time. The ownership form of the centre is, in this paper, an element of context, not an explanatory variable.

3.2. Data Governance and Ethical Considerations

The retrospective analysis of data from the public hospital was conducted under a favourable opinion issued by the institution's Ethics Committee. Access to data from the private centre was granted with the institutional agreement of the clinic's management, within the collaboration contract currently in force.

The tool reads only the technical acquisition metadata contained in the file header. It does not access pixel data and does not extract, process or store patient identifying information. The identifiers appearing in the generated reports are cryptographic fingerprints computed locally, without meaning outside the analysis session, and the keys linking them to the actual examinations are kept separately from the working set.

The sub-analysis of lesions with a surgical indication, presented in Section 4.6, required the addition of a clinical label at examination level. This label was applied by the lead author, a consultant neurosurgeon, to the local copy of the already exported data, on the basis of imaging appearance. The label does not originate from the issuing centres and was not transmitted back to them.

3.3. The Automated Verification Tool

Conformity verification was performed with a software tool developed by the authors, named *dicom_qc* and written in Python. The tool traverses a file archive recursively, reads the header of each file without loading pixel data, aggregates the information at series level, classifies each series by its clinical role and applies a set of conformity rules. Figure 1 presents the complete workflow.

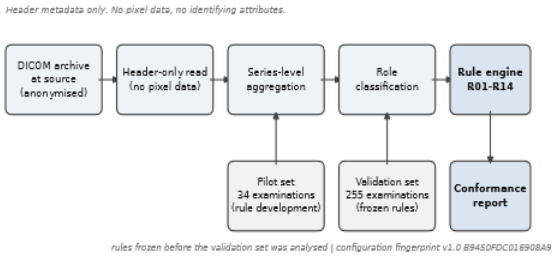

Figure 1: Processing workflow, from the file archive to the conformity report, showing the separation of the development set from the validation set.
Source: personal contribution of the author.

The choice to read only the header has two consequences, both relevant to the theme of the paper. The first concerns efficiency and is quantified in Section 4.7. The second concerns governance: the tool has no technical access to imaging content, which substantially simplifies the data protection framework under which it may operate.

Four auxiliary utilities were developed around the main tool: a generator of synthetic datasets containing known non-conformities, used for validation; a module comparing the original and de-identified datasets; a module merging batches of results, with verification of the configuration fingerprint; and a module that maintains, strictly locally, the correspondence between fingerprint and actual examination.

3.4. The Conformity Benchmark and the Rule Set

The benchmark against which verification is performed is not a published acquisition protocol, but the set of technical requirements a dataset must satisfy in order to be loaded and used by a neuronavigation system. This choice deserves justification, since it departs from customary practice.

Published consensus protocols define requirements oriented towards diagnostic comparability and towards use in multicentre studies [18], [19], [20]. They constitute the conceptual background of the present work. The requirement of use we study here is, however, different and stricter along certain dimensions: the navigation system does not compare, it reconstructs a volume and registers it to the operative space. The benchmark adopted therefore derives from the import requirements of neuronavigation systems in current use.

The set comprises fourteen rules, designated R01 to R14, distributed across the three dimensions of data quality defined by ISO 8000-8:2015: the syntactic dimension, that is, the presence of the attribute and the validity of its encoding; the semantic dimension, that is, the correspondence between the recorded value and the reality it describes; and the pragmatic dimension, that is, the fitness of the value for the declared purpose of use. The attributes verified and their meaning are those defined by the DICOM standard, published by the National Electrical Manufacturers Association of the United States [34].

Figure 2 presents the correspondence between the three dimensions, the parts of the DICOM standard that define the attributes verified, and the requirements of use in neuronavigation.

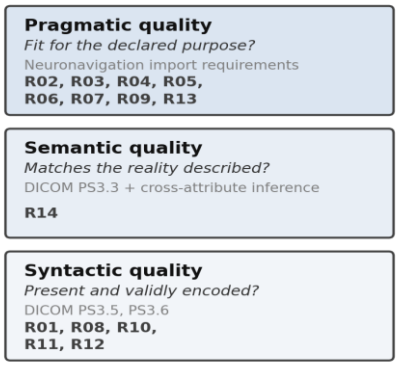

Figure 2: Three-layer conformity model, showing the correspondence between data quality dimensions, the normative source of each requirement and the rules applied.

Source: personal adaptation by the author after ISO 8000-8:2015 and NEMA [34].

The thresholds applied are as follows: effective spacing between slices of at most 1.5 mm; maximum voxel dimension along any axis of at most 1.5 mm; in-plane pixel size of at most 1.0 mm; a minimum of 100 slices; coverage of at least 150 mm measured along the axis perpendicular to the slice plane; and an interslice gap of at most 0.1 mm. These values reflect the requirements of neuronavigation systems in current use and may differ between manufacturers, which is why they are declared explicitly and are parameterised within the tool. Table 1 summarises the complete set.

Table 1. Conformity rule set, with the quality dimension covered and the normative source of each requirement.

Source: personal contribution of the author.

Rule	Dimension	What it verifies	Threshold
R01	syntactic	eligible modality	magnetic resonance or computed tomography
R02	pragmatic	volumetric acquisition	3D type declared
R03	pragmatic	effective spacing between slices	≤ 1.5 mm
R04	pragmatic	contiguity, no dead space	gap ≤ 0.1 mm
R05	pragmatic	maximum voxel dimension	≤ 1.5 mm
R06	pragmatic	in-plane resolution	≤ 1.0 mm
R07	pragmatic	number of slices	≥ 100
R08	syntactic	orientation present and consistent	attribute present, constant within series
R09	pragmatic	gantry tilt	≤ 0.5 degrees, computed tomography only
R10	syntactic	patient position declared	attribute present
R11	syntactic	absence of lossy compression	lossless transfer syntax
R12	syntactic	uniform spacing within series	deviation ≤ 0.1 mm
R13	pragmatic	cranial coverage	≥ 150 mm
R14	semantic	post-contrast series present in study	redundant detection

Two rules are remediable in software, without reacquisition: those concerning the declared patient position and compression. The remainder flag information that was not acquired and that cannot be recovered by post-processing. Interpolation creates the appearance of resolution, not resolution.

3.5. Classification of Series by Role

Applying the rules indiscriminately to every series within an examination would produce a meaningless conformity rate. A diffusion sequence or a T2 sequence is never loaded into a neuronavigation system and judging them against navigation criteria would distort the measurement entirely.

For this reason, each series is classified by role before the rules are applied. The roles defined are: navigation candidate, for T1-weighted series acquired volumetrically after contrast administration; native candidate, for volumetric T1-weighted series without contrast; two-dimensional post-contrast; diagnostic series; series belonging to another anatomical region; and technically excluded series, a category comprising derived images, reconstructions and calibration series.

The conformity rules are applied in full only to series in the first two categories. The rates reported in Section 4 therefore refer to candidate series, not to the total number of archived series.

Identifying post-contrast series raised a significant methodological difficulty, addressed in Section 4.5, since the two centres use different marking conventions and, in a substantial proportion of cases, the administration of contrast agent is not recorded in any header attribute. Detection was designed redundantly, along three independent paths: the dedicated header attribute, the series naming convention and, in the absence of both, the time difference between identically named series within the same examination, with a threshold of two minutes.

3.6. Separation of the Development set from the Validation Set

The rules and thresholds were built and adjusted iteratively on a pilot set of 34 examinations. During this stage, four systematic measurement errors were identified and corrected; these are described in Section 4.7.

Once the development stage was complete, the rule set was frozen as version 1.0 and the configuration was sealed by an automatically computed fingerprint, which the tool records in the configuration file generated at each run. The validation set, comprising 255 examinations distinct from those in the pilot set, was analysed with the rules thus frozen.

This separation is declared explicitly because, without it, the results would be circular: rules calibrated on the very data they are to judge inevitably produce a good fit. The fingerprinting mechanism allows subsequent verification that the validation set was analysed with the rules fixed beforehand.

3.7. Indicators

The immediate navigability rate is the proportion of examinations yielding at least one series directly usable for navigation, without further processing. The denominator consists exclusively of examinations in which contrast agent was administered, since navigation does not arise for an unenhanced examination. Reporting against the total number of examinations would artificially understate the performance of both centres.

Bottleneck analysis identifies the rules whose breach produces the greatest number of non-conformities. The analysis is built on root causes rather than on individual rules, since a single acquisition deficiency may trigger several rules at once. Counting at rule level would overstate the scale of the problem.

Defects per million opportunities are computed at the level of candidate series, relating the number of root causes identified to the product of the number of series and the number of rules applicable to the role of each series. The number of opportunities per unit is declared explicitly, as a condition of reproducibility. **The Sigma level** is derived through the customary conversion, with the conventional 1.5 sigma shift [24].

The effectiveness of the tool is defined as the extent to which it identifies genuinely existing non-conformities [23]. It was documented through validation on synthetic datasets containing known non-conformities, through analysis of the four measurement errors identified and eliminated during the development stage, and through targeted clinical confirmation of flagged cases. **The efficiency of the tool** is defined, in the same sense, as the resource consumed to obtain the same result, and was measured as processing time per series and per total file volume.

3.8. Analytical Approach

Results are presented descriptively, with absolute numbers and proportions. No tests of statistical significance were applied, and this choice is deliberate rather than an omission.

Two reasons require it. First, the comparison involves two centres, hence two terms, each with a single protocol configuration. The true unit of variation is the protocol, and the number of protocols compared is two. Second, series originating from the same examination are not independent observations: they share the patient, the scanner and the protocol applied. Applying tests that assume independence of observations would produce probability values that are meaningless yet apparently rigorous.

Consequently, all three levels of counting are reported consistently, namely examinations, protocols and series, and the observed differences are presented as such, without any claim of inference towards a population.

4. Results

4.1. Characteristics of the Samples

The validation set comprised 255 cranial magnetic resonance examinations, of which 89 at the public centre and 166 at the private centre. Table 2 summarises the characteristics of the two samples.

Table 2. Characteristics of the samples analysed, with the volume of archived series and the contrast marking conventions

Source: personal contribution of the author.

Characteristic	Public centre	Private centre
Examinations	89	166
Archived series	1,101	2,690
Series analysed	849	1,451
Derived series, excluded	252 (22.9%)	1,239 (46.1%)
Equipment	one scanner, unchanged over the period	two scanners, one of which in 165 of 166 examinations
Contrast-enhanced examinations	44	60
Contrast marking	prefix in the series name	suffix, or no marking at all

The proportion of derived series differs substantially. At the private centre, almost half of the data retained and transferred consists of computed images rather than primary acquisitions. This finding has direct implications for storage cost and network traffic, independent of the conformity problem.

4.2. Navigability and the two Modes of Failure

We report the principal result against contrast-enhanced examinations, the only ones in which use for navigation genuinely arises.

Of the 44 contrast-enhanced examinations at the public centre, 16 yielded at least one directly navigable series, that is 36.4%. The remaining 28 contained no volumetric sequence at all. Of the 60 contrast-enhanced examinations at the private centre, 7 yielded a directly navigable series, that is 11.7%; in 18 examinations a conforming volume existed but had been acquired before injection; in 15 a post-contrast candidate was present but failed to meet the requirements; and in 20 no volumetric sequence existed. Figure 3 presents the complete distribution.

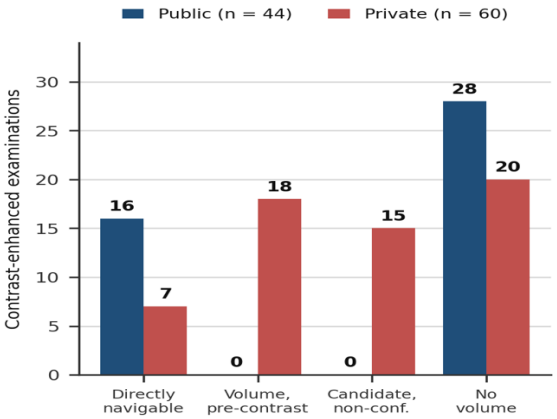

Figure 3: Distribution of outcomes across the four categories, for contrast-enhanced examinations, at the two centres.

Source: personal contribution of the author.

The figures describe two qualitatively different patterns, and the difference between them matters more than the difference between the percentages.

The public centre behaves in a binary fashion. Whenever the post-contrast volumetric sequence is run, it conforms. The centre's single protocol proved conforming in all 16 examinations in which it was applied, which represents one configuration validated sixteen times rather than sixteen independent observations. The deficit is one of protocol completeness: the sequence is simply absent.

The private centre behaves diffusely. The volumetric sequence is present almost everywhere but varies so widely that only 8 of the 91 navigation candidate series, that is 8.8%, meet the requirements. The situation is all the more striking in that, of the 48 native volumetric series, 20 conform. The technical capability exists; what is missing is correct sequencing relative to contrast administration.

4.3. Bottlenecks

Grouping non-conformities by root cause produces a distribution that is remarkably flat. Four root causes account for the 296 occurrences recorded across the 155 candidate series: insufficient slice count and cranial coverage, 105 occurrences or 35.5%; acquisition that is too thick, meaning effective slice spacing and maximum voxel size together, 103 or 34.8%; insufficient in-plane resolution, 85 or 28.7%; and the absence of any post-contrast series in the study, 3 or 1.0%. Counting is performed on root causes rather than on rules, since R03 and R05 express the same physical deficiency and would otherwise be recorded twice. Figure 4 presents the distribution.

There are no vital few here. Less than seven percentage points separate the three leading causes, and reaching eighty per cent of the occurrences requires three categories out of four. Ranking them by frequency yields no order of priority. It merely restates that they are almost equally common.

The reason becomes visible once the three are read together. Slice spacing and voxel size, cranial coverage and slice count, in-plane resolution: these are not independent defects but facets of one decision, the choice of an acquisition protocol built for diagnostic reading rather than for navigation. A protocol optimised for a radiologist scrolling through images will favour thicker sections over a limited region, because that is what shortens the examination without harming the diagnosis. Judged against the import requirements of a navigation system, the same protocol fails on every parameter at once.

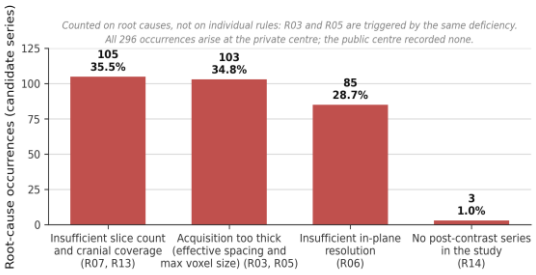

Figure 4: Root causes of non-conformity across the candidate series (n = 155). Occurrences are counted per root cause rather than per rule: R03 and R05 express the same physical deficiency and are therefore counted once. All 296 occurrences arise at the private centre; the public centre recorded none.

Source: personal contribution of the author.

The consequence for management follows from this. The remedy is not a point correction on one parameter but the redesign of the acquisition protocol, and such a redesign has to be specified jointly, which returns to the missing feedback loop between radiologist and surgeon taken up in Section 5.3. One further observation belongs here. All 296 occurrences arise at the private centre; the public centre recorded no non-conformity across its 16 candidate series. What this section describes is therefore a property of one protocol, not of the two centres taken together.

4.4. Defects per Million Opportunities and the Sigma Level

Six Sigma indicators were computed at the level of candidate series, counting root causes and declaring explicitly the number of rules applicable to each role. Table 3 presents the results.

Table 3. Summary conformity indicators, by centre

Source: personal contribution of the author

Indicator	Public centre	Private centre
Contrast-enhanced examinations	44	60
Immediately navigable	16 (36.4%)	7 (11.7%)
Navigation candidate series	16	91
Conforming candidate series	16	8 (8.8%)
Conforming native volumetric series	not applicable	20 of 48
Opportunities (applicable rules)	208	1,807
Defects	0	472
DPMO	0	261,206
Sigma level	≥ 3.69 *	2.14

** An opportunity is a rule actually applicable to a given candidate series (any verdict other than N/A); a defect is an applicable rule that is not met. With no defects observed in 208 opportunities, the sigma level of the public centre cannot be estimated as a point value. The figure quoted is the lower bound derived from the one-sided 95% upper confidence limit on the defect rate (rule of three), namely 1.44%. The conventional 1.5σ shift is applied throughout, as defined in Section 3.7.*

The indicators are reported per centre. The public centre recorded no defect across 208 applicable opportunities, so its sigma level cannot be given as a point estimate and appears in Table 3 as a lower bound, derived from the one-sided upper confidence limit on the defect rate. The private centre stands at 261,206 defects per million opportunities, which corresponds to 2.14 sigma.

No aggregate value is reported for the two centres taken together, and the omission is deliberate. Averaging a process in which no defect was observed with one that fails roughly a quarter of its opportunities yields a figure that describes neither of them. What is compared here is two protocols rather than one population, so the indicators are kept at the level at which they carry meaning.

Interpreting these indicators calls for an explicit reservation. Series originating from the same examination share the patient, the scanner and the protocol, and are therefore not independent observations. The values are presented as a descriptive index of process maturity, useful for tracking over time within the same centre, rather than as a statistical estimate transferable to a population.

4.5. Information that does not Reach the Standardised Carrier

Two findings, which emerged independently, describe the same phenomenon and are, in our view, the result of widest applicability in this work.

The first concerns contrast marking. In 48 of the 60 contrast-enhanced examinations at the private centre, that is in four cases out of five, series acquired after injection are not identifiable as such from any header attribute. The sequence is repeated without renaming, and the dedicated attribute remains unpopulated. At the public centre the situation arises in 7 of 44 examinations. The information that contrast agent was administered, an indisputable clinical fact, simply does not exist in the data.

The second concerns the data protection procedure. Comparative verification on the de-identified dataset showed that the anonymisation profile removes the very attribute recording the contrast agent. Because detection had been designed redundantly, along three independent paths, the tool survived. Detection based on a single metadata source would have been invalidated, and the invalidation would have been silent: the programme would have run successfully, only the result would have been wrong.

The two situations share the same structure. The information exists within the organisation and is known to the staff who produced it, yet it is not carried by the standardised metadata. Any subsequent automated process misses it, without being able to signal that it has done so.

4.6. Subset of Lesions with a Surgical Indication

Among the contrast-enhanced examinations, eleven concern meningiomas, lesions for which a surgical indication is frequent and for which navigation is routinely used. Table 4 presents the results for individual cases.

Table 4. Results for the meningioma subset, in absolute numbers.

Source: personal contribution of the author.

Note: "Native volume" denotes a conforming volumetric series acquired before contrast injection; "Non-conf." denotes a post-contrast candidate that failed the requirements.

Centre	Exams	Navigable	Native volume	Non-conf.	No volume
Public	7	4	0	0	3
Private	4	0	2	1	1
Total	11	4	2	1	4

The subset faithfully reproduces the pattern observed at each centre. The public centre remains binary, with four fully conforming examinations and three with no volumetric sequence at all, and nothing in between. The private centre remains diffuse, with no fully correct examination but two that are a single sequence repetition away from conformity. The pattern observed across 255 examinations recurs in eleven independently identified cases, which suggests that it is not an artefact of aggregation.

The second finding is more important than the first. The presence of a lesion with a surgical indication did not alter the acquisition protocol. The proportion of navigable cases in this subset is virtually identical to that of the overall sample. The protocol is applied mechanically, regardless of what is observed on the images. What is missing is neither the equipment nor the written protocol, but the feedback loop between the radiological finding and the subsequent need to use the images. The information existed and the lesion had been identified, yet it triggered no adaptation.

On a human scale, the figure is as follows: of eleven patients with meningioma, seven would require re-examination before an image-guided procedure, entailing rescheduling, a further administration of contrast agent and delay, or would be operated on with degraded guidance.

These cases were identified opportunistically rather than through a systematic search, and do not represent all meningiomas within the study period. The subset is presented as an illustration, with documented clinical consequence, of the pattern established on the larger sample, not as a representative sample; the numbers involved do not support comparisons between centres.

4.7. Effectiveness and Efficiency of the Tool

Three levels of evidence support the effectiveness of the tool.

On the synthetic datasets, generated with known non-conformities, the tool identified all of them. The second level is more instructive. During the development stage, four systematic measurement errors were identified and eliminated, each with an effect on the result.

Cranial coverage was initially computed along the longitudinal axis of the patient, which measured every sagittal and coronal acquisition incorrectly; it was corrected to the axis perpendicular to the slice plane. The thickness check was applied to the declared nominal value, although many scanners acquire thick slices and reconstruct them with overlap, and the navigation system sees the effective spacing rather than the declared thickness. Isotropy was assessed as a ratio between voxel dimensions, which rejected excellent acquisitions with voxels of the order of 0.47 by 0.47 by 1.0 mm; it was replaced by the maximum physical dimension. In-plane resolution was judged by pixel count, which penalised perfectly usable matrices; it was replaced by the dimension in millimetres.

Each of these corrections altered the meaning of a measurement, not merely its precision. Listing them forms part of the validity evidence for the tool: a rule that measures something other than what it believes it measures produces figures that are stable and false. The third level was targeted clinical confirmation of cases flagged as unmarked post-contrast.

Efficiency ranged between 0.16 and 0.21 seconds per series, corresponding to a throughput of approximately 17,000 to 22,000 series per hour. The 186,000 files of the sample were processed in approximately seven minutes. The gain derives from reading the header alone, without loading pixel data.

The ratio between these two magnitudes is the practical argument of the paper. Verifying an examination costs a fraction of a second of computation; failing to verify it costs, in the cases documented above, a rescheduling and a second administration of contrast agent.

4.8. Operating Window

The hourly distribution of examinations, extracted from the metadata, is consistent with the declared operating schedule of the two centres. The window at the private centre is approximately 57% longer, and the load is remarkably uniform across it. Figure 5 presents the two operating windows.

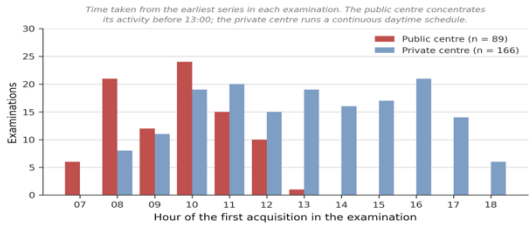

Figure 5: Distribution of examinations by the hour of the first acquisition, per centre. The public centre concentrates its activity before 13:00, while the private centre operates a continuous daytime schedule.

Source: personal contribution of the author.

The provision of imaging equipment varies substantially across European states, and Romania stands below the Union average in the number of scanners relative to population [35], which makes the operating time of an existing scanner all the more important as a management lever. The difference in volume, 1.87 times more cranial examinations at the private centre, decomposes into two factors: the longer operating window, with a factor of 1.57, and the number of cranial examinations per hourly interval, with a factor of 1.19. The second factor is not an indicator of productivity but reflects the structure of indications, that is, the share of cranial investigations within the total activity of each centre.

This finding is managerial in nature and is distinct from protocol quality. It is acted upon through entirely different levers: scheduling, staffing and the organisation of on-call cover.

The sample comprises cranial examinations only, and not the other anatomical regions examined on the same scanners within the same interval. Consequently, neither equipment utilisation nor true hourly throughput can be calculated.

5. Discussion

5.1. The Arithmetic of Remediation

The result of greatest practical relevance is none of the rates reported individually, but what follows from combining them.

At the private centre, 18 examinations already contain a conforming volume, acquired however before contrast administration. Moving that sequence to after injection, without altering any acquisition parameter, would take the centre from 7 to 25 navigable examinations out of 60, that is from 11.7% to 41.7%. The cost is approximately five minutes of scanner time per examination, on a sequence already present in the protocol. It requires no investment in equipment, no licence and no new training.

By comparison, the public centre, which currently achieves 36.4%, cannot improve through resequencing, because the sequence is absent. It requires an additional sequence in the protocol, which means scanner time added to every examination rather than redistributed. Figure 6 compares the three situations.

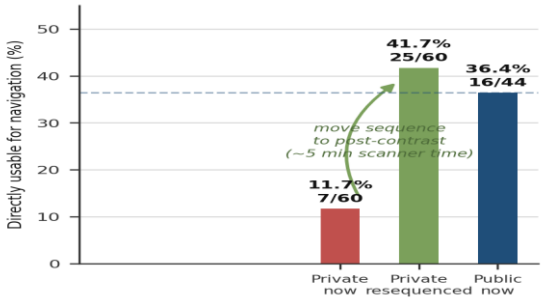

Figure 6: Effect of resequencing on the navigability rate at the private centre, compared with the situation at the public centre.

Source: personal contribution of the author.

The centre with the apparently weaker result therefore has the cheapest path to improvement, and following it would place it ahead of the centre that currently appears better. Without measurement, the intuitive ranking would have been the reverse, and the likely decision would have targeted equipment. This is, in essence, the added value of data quality management: it does not refine the precision of a decision already correctly oriented, it changes the direction of the decision.

5.2. Information that does not Reach the Standardised Carrier

The findings in Section 4.5 suggest a design principle that the literature on verification tools does not address explicitly.

In both documented situations, the information existed within the organisation and was not carried by the metadata. The consequence is identical, and it is the serious one: the automated process that receives the data fails silently. No error appears, no warning, no indication that the result might be incomplete. This is, in the terms of ISO 8000-8:2015, a deficiency of the semantic dimension, and its particularity is that it cannot be detected by syntactic checks, however rigorous.

The de-identification case deserves separate emphasis, because the procedure that destroyed the information is precisely the procedure intended to protect the patient. A tool that had derived the presence of contrast from a single metadata source would have been invalidated by its own compliance with data protection requirements.

From this follows a design requirement: resistance to de-identification must be treated as a criterion from the outset, not as an afterthought. In practice, this means that any essential property of the data should be derived redundantly, from independent sources, and that the tool should report by which path each property was established. The recommendation complements, from a different direction, the argument for harmonised metadata models [11].

5.3. The Absent Feedback Loop

The subset of surgical lesions showed that the presence of an operative indication does not alter the acquisition protocol. The finding admits a richer management interpretation than it might appear.

Both centres possess the necessary equipment and have written protocols. Structure, in Donabedian's terms, is adequate. What fails is the process, more precisely the absence of a mechanism by which a finding made by the radiologist comes to modify that radiologist's own acquisition decision, in response to a need that arises later, with the surgeon. Information travels in one direction only, in the form of the report, while the technical requirement of the end user does not travel at all.

This asymmetry explains why purchasing equipment alone would have resolved nothing, and why writing a stricter protocol would not suffice either. The missing mechanism is one of feedback, not of provision or of regulation. The observation aligns with literature showing that quality improvement in healthcare depends on organisational mechanisms rather than on resources as such [26], and with the finding that systematic errors in imaging workflows arise from organisational practices [15].

5.4. Management Implications

Three consequences follow for the management of an imaging service.

The first is that an indicator of data conformity can be produced continuously, at negligible cost, and tracked like any other process indicator. The throughput measured allows a centre's entire daily output to be verified within a few minutes.

The second is that the indicator must be defined against the final use of the data, not against the internal protocol. A centre may be in perfect conformity with its own protocol and, at the same time, unable to deliver a surgically usable dataset. Internal conformity and fitness for purpose are different things, and the former can mask the latter.

The third concerns the ranking of interventions. Root cause analysis showed that a single acquisition parameter accounts for the majority of non-conformities at one centre. The correct order of interventions is resequencing, then adjustment of the dominant parameter, and only then, if necessary, extension of the protocol.

The comparison between the two centres neither supports nor refutes any hypothesis about the superiority of one form of organisation. It shows only that the determinant observed is the configuration of the protocol on the scanner. The caution recommended by the comparative literature on public and private provision of health services applies in full [33].

5.5. The Tool as an Object of intellectual Property

The tool developed constitutes a computer program, protected by copyright from the moment of its creation, without constitutive formalities. Protection covers the form of expression, that is the source code and its structure, not the idea of verifying metadata conformity automatically.

From the perspective of a health organisation, the distinction has practical consequences. The rule set and the thresholds, considered separately, constitute procedural know-how, and their economic value lies in their documentation and transferability rather than in a title of protection. The associated procedural documentation, including the rule version and the configuration fingerprinting mechanism, serves a dual role: it evidences the reproducibility of the results and fixes the concrete content of the know-how.

Depositing the program with the national copyright administration body, although it does not condition protection, provides a certain date and a means of proof in the event of litigation or of a technology transfer negotiation. For a public

institution, this formality is advisable ahead of any wider dissemination. The protection of results in health organisations, through intellectual property instruments integrated into quality management systems, has been addressed previously by the authors [30].

5.6. Limitations

The study is retrospective, covers a single quarter and includes one centre only for each arm of the comparison. The unit of variation is the protocol, and the number of protocols compared is two. At the private centre, a single examination was performed on a second scanner, which does not allow any difference between scanners to be assessed.

The conformity thresholds reflect the requirements of neuronavigation systems in current use and may differ between manufacturers. They are declared explicitly and are parameterised, so that the results can be recalculated for other requirements.

The rules were developed iteratively on a pilot set, and separation from the validation set was ensured by freezing the configuration. It remains possible that the rule set reflects particularities of the two centres on which it was built.

The sample includes cranial examinations only, which precludes any calculation of overall equipment utilisation. The subset of surgical lesions was constituted opportunistically and involves small numbers, which is why its results are presented exclusively in absolute terms.

Finally, the measurement concerns the technical usability of the data, not the surgical outcome. The relationship between dataset conformity and the actual accuracy of intraoperative navigation was not assessed here and constitutes the natural direction for continuation.

6. Conclusions

We have shown that the usability of an imaging dataset for neuronavigation can be verified automatically, at negligible cost, on the basis of acquisition metadata alone, and that the result of this verification carries management information that neither the radiological report nor volume indicators contain.

The two centres included in the study produced qualitatively different patterns. One achieves full conformity whenever it runs the appropriate sequence, but runs it rarely. The other runs it almost always, but seldom under the right conditions. The distinction between a completeness deficit and a sequencing deficit appears in no activity statistic and calls for entirely different interventions.

The finding of greatest practical consequence is that the centre with the apparently weaker performance holds the cheapest path to improvement, and that following it would place it ahead of the other. Measuring data quality did not refine a decision; it changed its direction, averting an investment that would have been unnecessary.

Conceptually, we identified a class of deficiencies that syntactic checks cannot detect: information that exists within the organisation and does not reach the standardised carrier. The case in which the anonymisation procedure itself destroys an essential attribute shows that resistance to de-identification must be treated as a design requirement for data quality management tools.

Three directions for continuation follow: extension to a longer interval and to more centres; correlation of dataset conformity with the actual accuracy of intraoperative navigation; and integration of the verification into the workflow, so that non-conformity is flagged before the patient leaves the scanner, the only moment at which remediation costs nothing.

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