What is the impact of accreditation recommendations on healthcare organisations?

A pilot study of accreditation data

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For several years, the Haute Autorité de Santé has undertaken to strengthen the evaluation of the impact of its programs, in order to meet two objectives that are also two commitments to HAS stakeholders:

❖ Give a fully transparent account of the results obtained;
❖ Inform the debate on the development of systems implemented by HAS and enable these systems to become more effective in improving patient care.

The accreditation of healthcare organisations, which has been an established part of the healthcare landscape for more than 12 years, is particularly concerned by these requirements.

The study presented here plays an important role in the quest to understand the effects of accreditation and its limitations, which requires a diverse range of approaches and a combination of different types of study.

HAS wished to analyse the data gathered at national level during accreditation procedures. Processing these data in a pilot study enables questions to be asked about the effectiveness of accreditation recommendations, and the progress made by healthcare organisations between cycles of accreditation to be analysed.

Accreditation has had the great merit of encouraging healthcare organisations to implement systems for managing the quality and safety of care. As a result of accreditation, organisations have taken it to the next level in terms of developing these systems. This study highlights the role of HAS reservations and recommendations as a lever for improvement. The study shows that the majority of changes needed are only implemented progressively because they concern the practices of all professionals. These changes may be delayed by problems involving barriers to adaptation within the healthcare system. Through the continuity provided by its follow-up system and its gradual increases in requirements, accreditation helps healthcare organisations to engage in and maintain improvement initiatives.

This impact study has led to the following actions by HAS:

- Continuity of approach will be one of the features of the next version of accreditation. The aim is to ensure that systems are in place to prevent or correct any steps backward in key areas of risk management.
- Provisions will be made for monitoring the impact of accreditation recommendations. This monitoring will enable HAS, healthcare organisations and users to note the positive developments related to accreditation, and also to more easily identify barriers to improvement in healthcare organisations.

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Summary

Since its implementation in France 12 years ago, accreditation\(^1\) has resulted in several thousand recommendations or reservations for French healthcare organisations. Almost 18,000 recommendations or reservations were issued during the second cycle of accreditation, which began in 2005 and was completed in 2012.

What is the outcome of these recommendations and reservations once they have been issued? Do healthcare organisations take them on board? Are they implemented and do they lead to improvements in organisational management and patient care?

The study presented here tackles the issue of the effects of accreditation recommendations, using data from accreditation visits.

This study aims to follow up the outcome of 4,109 reservations and recommendations issued during the “V2” cycle of accreditation to the first 612 organisations to have also undergone “V2010”. Quantitative and qualitative analysis of these recommendations, from their formulation until their follow-up evaluation four years later at recent V2010 accreditation visits, demonstrates that accreditation recommendations have mobilised these organisations and play a role as a lever for improvement in patient care.

The study shows that in some organisations, certain recommendations and reservations were reiterated from the previous accreditation procedure.

These cases arise from several different situations:

- Increasing requirements or changes to the accreditation assessment methods in some fields often explains the maintaining of recommendations from one procedure to the next.
- The study suggests that progress is slower and more difficult in some fields where particularly complex issues must be tackled through improvement initiatives involving all professionals in the organisation and entailing a substantial change in professional practices.
- More rarely, these cases are related to a stagnating drive for improvement in an organisation, with accreditation facing managerial and cultural barriers that are worth analysing.

\(^1\) See box “The accreditation of healthcare organisations”.

HAS / Division for the Improvement of Quality and Safety of Care / November 2012
Introduction

To meet the challenges of regulating the quality and safety of care in healthcare organisations, many countries have set up accreditation and external evaluation systems for healthcare organisations, inspired directly or indirectly by Canadian or American models. In recent years, healthcare providers in many countries have started to ask legitimate questions about the effectiveness of these mechanisms, and a field of applied research has gradually developed in response to these questions, despite the methodological challenges of evaluating this type of intervention.

Impact studies in France and abroad demonstrate the positive effects of accreditation/certification on the development of improvement initiatives, in particular in terms of risk management, the dissemination of good practice and an open style of management. Studies that gather professionals’ perceptions also point to some limitations in the approach, particularly its formality, which is sometimes inappropriate to an organisation’s professions and activities, and the burden of work generated by implementing the procedure.

The impact of accreditation/certification is related to all aspects of the process: the publication of standards, communication as to their meaning, the self-assessment phase, the accreditation/certification visit, observations and recommendations, and the publication of results.

The recommendations resulting from an accreditation/certification procedure and outlining the fields where the organisation must improve do not constitute the whole approach. But they are a substantial component, aiming to fulfil the aim of accreditation/certification to act as a lever for improvement in patient care in each organisation assessed.

This evaluation of the impact of accreditation/certification therefore also aims to examine how effectively the recommendations made during the process are implemented: are these decisions acted upon by the organisation? Are improvement initiatives put into place and do they have the desired results?

Paradoxically, despite its importance, this more specific question about the impact of recommendations is rarely tackled in studies of the impact of accreditation/certification.

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Studies of the impact of recommendations made during the accreditation of healthcare organisations

A review of the literature on the impact of accreditation reveals three studies which focus more particularly on analysing the effects of accreditation/certification recommendations:

- **The 2003 annual report of the ANAES accreditation board** includes a qualitative study of 30 reports of targeted visits conducted as part of the first French accreditation/certification procedure. This study illustrates the mobilisation generated by accreditation reservations within the organisations concerned.

- **A 2004 study by L. Benson, A. Boyd and Kieran Walshe** evaluated the effectiveness of clinical governance reviews, an external evaluation process that is very comparable with healthcare organisation accreditation systems and which was implemented in Great Britain in the early 2000s by the Healthcare Commission. The researchers chose to evaluate the effectiveness of this approach by focusing their questions on the effects of recommendations made following visits. To analyse these effects, they used mixed methodologies combining document analysis, analysis of data from standardised questionnaires and qualitative reports.

- **An internal HAS study on the impact of recommendations from the first cycle of accreditation** (“V1”), published in 2006, provides quantitative analysis of accreditation data on the improvements made following V1 recommendations and reservations. The 100 first V2 reports were analysed.

These three studies show:

- that data from accreditation procedures provide substantial material for evaluating the effect of recommendations and reservations. One of the aims of accreditation is to monitor the actions taken following the identification of problems, and accreditation provides pertinent data on this follow-up;
- that these data can be quantified despite the methodological challenges of:
  - processing aggregated data that is only partially standardised and was collected to give an account of the particular situation and particular follow-up in each organisation studied;
  - analysing changes over time, which assumes continuity within the structures evaluated and the system for collecting and evaluating data – continuity that does not always exist;
- that mixed methodologies based on quantitative and qualitative data are valid.

In order to demonstrate the effects and consequences of accreditation procedures in France, the questions first asked about the impact of accreditation recommendations in 2006 must be repeated and extended.

Since its implementation in France 12 years ago, accreditation has resulted in several thousand recommendations or reservations for healthcare organisations. Almost 18,000 recommendations and reservations were issued during the second cycle of certification, which began in 2005 and was completed in 2012.

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7 See box “The accreditation of healthcare organisations”.

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What is the impact of accreditation decisions? A pilot study

What is the outcome of these recommendations and reservations? Do healthcare organisations take them on board? Are they implemented and do they lead to improvements in organisational management and patient care?

The study presented here tackles the issue of the effects of accreditation recommendations, using data from the second cycle of accreditation in France, from a very similar perspective to that of the 2006 study. This study aims to follow up the outcomes of recommendations and organisations between the V2 cycle, now completed, and the V2010 cycle that is currently under way.

What is the accreditation of healthcare organisations?
The accreditation of healthcare organisations, implemented by HAS, aims to ensure continuous improvement in the quality and safety of care in healthcare organisations.

The accreditation of healthcare organisations was established in France by the decree of 24 April 1996. It is compulsory for all public and private healthcare organisations. It engages each healthcare organisation in a process of improvement, including internal assessment and an independent external evaluation of quality in the organisation or, where applicable, in one or more of its departments or activities.

Transparency is intrinsic to the process, with accreditation reports published so that the public and stakeholders can be informed.

The procedure involves the following steps:

- a self-assessment phase, during which professionals and patient representatives are invited to evaluate the functioning of the organisation with reference to the Accreditation Manual;
- an on-site visit, called the initial visit, conducted by healthcare professionals who have been appointed and trained by HAS, known as surveyors;
- the production of a report including observations and any recommendations or reservations. These indicate improvements that need to be made, and are classified according to their severity: recommendations, reservations or major reservations;
- validation and publication of the report, any recommendations or reservations, and the corresponding level of decision made by the HAS Board;
- in the case of reservations or major reservations, the implementation of follow-up measures: the organisation submits a follow-up report or an on-site visit (follow-up visit or targeted visit) is conducted by the surveyors. After these follow-up measures, reservations may be either removed, maintained or changed (for example, a reservation may be downgraded to a recommendation).
French healthcare organisations have been subject to several rounds of the procedure. The first cycle of accreditation (V1) dates back to June 1999. The second cycle of accreditation (V2 and V2007) began in 2005, and the initial visits in this cycle were completed in the latter half of 2010. The V2 manual was updated (to V2007) midway through the cycle. The first visits in the third cycle of accreditation (known as V2010) began in January 2010. In total, 974 accreditation reports from V2010 initial visits had been validated by 1 July 2012. On this date, 1,347 visits had been conducted out of the 2,644 planned for this cycle of accreditation.
Figure 2. Accreditation visits conducted since 1999 and planned for 2012-2014
1. Method

The Impact of Recommendations study concerns the first “wave” of organisations to have undergone both the second accreditation procedure, known as V2, and the third procedure, known as V2010. These organisations have been evaluated twice in four or five years, during the V2 visit and the V2010 visit. In the case of organisations that had to respond to a reservation, a third assessment was conducted as a follow-up measure between these two visits. Through these reference points, it is possible to observe changes that have occurred during the four years between an organisation’s V2 visit and its V2010 visit.

On 23 May 2012, 817 organisations had undergone V2010 and had a validated V2010 accreditation report.

Six hundred and twelve (612) of these 817 organisations are included in the study. These are the 612 organisations:

- that have undergone both the second (V2) and third (V2010) accreditation procedures;
- that have had to respond to one or more recommendations or reservations resulting from V2;
- for which it was possible to establish statistical links between V2 and V2010.

In total, 4,109 recommendations or reservations were issued to these 612 organisations following the second accreditation procedure and were analysed in this study. There were 1,193 reservations or major reservations and 2,916 recommendations.

The study is divided into two parts:

- a reservations substudy focusing on outcomes from V2 reservations. This involves 1,193 reservations and 385 organisations;
- a recommendations substudy focusing on outcomes from V2 recommendations. This involves 2,916 recommendations and 546 organisations.

Three hundred and nineteen (319) organisations are included in both substudies as they had to respond to both recommendations and reservations.

The organisations in the sample were accredited through the V2 procedure between November 2005 and January 2009. Their V2010 accreditation took place between February 2010 and March 2012.

More detail about the methods for selecting the study sample and the exclusion criteria is provided in Appendix 1 as well as in the sections devoted to the two substudies.

1.1 Substudy 1: What is the impact of reservations?

The first substudy is intended to analyse the outcomes of reservations and major reservations from V2, i.e. those recommendations which indicate more severe problems and are subject to follow-up. The methodology used aims to facilitate understanding of how organisations have changed over the complete process, from the formulation of reservations in V2 to observations on the improvements made in the area concerned during V2010, including the results of follow-up measures in the interval between these two visits.
On 23 May 2012, at the start of the study, 385 healthcare organisations had completed this process, i.e. they met the following criteria defining the sample for the first substudy:

- has undergone the V2 procedure;
- has been notified by HAS of at least one reservation or major reservation during the V2 or V2007 procedure;
- has undergone the V2010 procedure, i.e. has a validated V2010 (initial visit) accreditation report.

Some information about these 385 organisations was available in a standardised format enabling quantitative analysis, namely:

- **reservations and major reservations** issued during the V2/V2007 procedure and the V2 manual criteria to which they relate;
- **results of follow-up measures**, with an examination of the follow-up report or a targeted visit leading to the reservations being removed, maintained or changed;
- **recommendations and reservations** issued during V2010 and the V2010 manual criteria to which they relate.
In order to examine how recommendations and reservations have been followed up between V2 and V2010, and in particular to identify in what proportion of cases a V2 recommendation or reservation was the subject of a renotification\(^8\) at the V2010 visit, a table of corresponding V2 and V2010 criteria, organised into categories, has been drawn up (see Appendix 2).

It should be noted that establishing correspondence across different versions of the accreditation manual presents some methodological challenges. There is continuity “in broad strokes” between the fields tackled in different versions, but the requirements of accreditation are evolving: new fields are introduced and others are deepened and broadened. In addition, the matter of continuity between two versions in terms of requirements and the follow-up of recommendations has not, to date, been a priority when developing the manuals and information system. Neither the different manuals, nor the accreditation data, have been structured \textit{a priori} so as to establish a link between two cycles of accreditation. This correspondence table should therefore be viewed as an \textit{ad hoc} tool, intended to meet the needs of this study, which provides the best possible approximation of correspondence between the requirements of V2/V2007 and of V2010. The correspondence table was created from work carried out internally\(^9\) and externally, particularly involving the MARQ BN (Method for Regional Analysis of Quality of Care) tool, a method created by ARS Basse-Normandie that enables summary analysis and real-time follow-up of the results of accreditation in all healthcare organisations in the Basse-Normandie region.\(^{10}\)

Anomalies in the file containing information on the 385 organisations in this substudy were detected and removed, and processing difficulties linked to the V2 multiple indexing system in particular were resolved. To simplify the way results are presented, differences between clinical departments were not taken into account in this initial pilot study. A reservation was only counted once even if it concerned several clinical departments within the same organisation. The correspondence table was applied automatically. \textbf{Descriptive quantitative analysis} was performed. This was supplemented by quantitative analysis of the grades achieved by organisations in V2010 in two fields particularly affected by V2010 renotifications: medication management and patient records.

\textbf{Qualitative analysis} of 30 files (reports and follow-up reports) on organisations complemented the quantitative approach. These files were selected randomly (see Appendix 3).

- In order to understand the leverage effect of reservations and their possible limitations:
  - five follow-up files were analysed (V2 accreditation reports and targeted visit reports).
- In order to understand cases where a reservation is maintained from one cycle of accreditation to the next:
  - 25 files on organisations with a V2 reservation in the two fields most commonly affected by renotifications in V2010, medication management and patient records, were analysed.

The material provided by the textual data from accreditation and follow-up reports is often rich and, as it is collected by a third party, has a high level of validity. However, this material has its limitations: the aims of the visit and the accreditation report are not the same as those of a study specifically looking at the impact of accreditation. Although this document analysis

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\(^8\) This is the terminology used in the Abdelmoumène N \textit{et al.} (2006) study, which refers to “renotification” when an organisation is notified of a decision in the same area during V1 and V2. We shall use this term in the same way to designate cases where organisations are issued with reservations in certain areas during V2, then are again issued with recommendations or reservations in the same areas during V2010.

\(^9\) Dominique Ferréol, HAS.

\(^{10}\) ARS files, ARS Basse-Normandie, no. 1 March 2011.
cannot claim to meet the study’s aims comprehensively, it has enabled recurring themes and meaningful examples to be identified.

1.2 Substudy 2: What is the impact of recommendations?

Unlike reservations, recommendations resulting from V2 accreditation were not subject to HAS follow-up between the two procedures. External follow-up of V2 recommendations is carried out during the V2010 visit.

For each recommendation, the surveyors evaluate the actions taken since the V2 visit. Following this evaluation, a written observation is made and a standardised answer is selected: taking into account the organisation’s progress towards improvement, the team of surveyors must answer “yes”, “no” or “in progress” to the question of whether the recommendation has been followed up. These items are included in the V2010 accreditation report in a follow-up table.

The recommendations substudy is based on data from the follow-up tables in V2010 reports. As with the reservations substudy, the analysis combines:

- descriptive quantitative analysis of the standardised answers in the follow-up tables, which is supported by the category correspondence table also used in the reservations substudy;
- qualitative analysis of the surveyors’ written observations in the follow-up tables. This allows situations to be identified that would be hidden by the standardised “yes”, “no” and “in progress” answers. In total, 80 randomly selected observations were examined.

The sample of organisations in the recommendations substudy was determined in a similar manner to the sample in the reservations substudy, as here too the first wave of organisations to complete the whole process from V2 to V2010 was followed up.

The organisations in this substudy met the following criteria:

- has undergone the V2 procedure;
- has had at least one recommendation from the V2 procedure (excluding recommendations on evaluation of professional practices\(^{11}\));
- has undergone the V2010 procedure and has a recommendations follow-up table.

Six hundred and forty-eight (648) organisations met these criteria on 23 May 2012.

\(^{11}\) Recommendations on evaluation of professional practices are not subject to follow-up, and were not examined by the surveyors as part of their assessment of outstanding V2 decisions. The decision follow-up tables included in the V2010 reports do not include data on the follow-up of recommendations in this category. An evaluation of the results of any recommendations in this category is performed during the V2010 visit.
It was not possible to use the follow-up data from all 3,624 recommendations made to these 648 organisations in this study. Analysis of the recommendations follow-up data, and in particular the use of a thematic analysis grid, requires each V2 recommendation to be linked with its respective data in the V2010 report follow-up table. There is no a priori “chain” within the information system between recommendations made after the V2 accreditation visit and the corresponding observations in the V2010 follow-up table. This link has been reconstructed through a customized computer program. This program has been able to overcome a large number of problems related to the weakly standardised nature of the accreditation data, and in particular their indexing.

In total, 80% of the recommendations, that is 2,916 recommendations, were able to be matched with their follow-up data. 546 organisations were therefore ultimately included in this substudy, which equates to almost 85% of the organisations in the original sample.

| Linking V2 recommendations with V2010 follow-up tables – results by recommendation | No. of recommendations | % of recommendations |
|:|---|---|
| Successful V2 – V2010 follow-up table link | 2,916 | 80.46% |
| Failed V2 – V2010 follow-up table link | 708 | 19.54% |
| Total | 3,624 | 100% |

| Linking V2 recommendations with V2010 follow-up tables – results by organisation | No. of organisations | % of organisations |
|:|---|---|
| HCOs with no V2-V2010 linking | 102 | 15.74% |
| HCOs with partial V2-V2010 linking | 131 | 20.22% |
| HCOs with complete V2-V2010 linking | 415 | 64.04% |
| Total | 648 | 100% |

As with the sample in the reservations substudy, duplicate data and anomalies were identified and removed.
2. Results

2.1 Substudy 1: What is the impact of V2 reservations?

2.1.1 Organisations studied

The 385 organisations included in this substudy have:
- undergone the V2 procedure;
- been notified of a reservation or major reservation following the V2 accreditation visit;
- undergone the initial phase of the V2010 procedure.\footnote{That is, whose accreditation report from the V2010 initial visit has been validated by the HAS Board.}

Of these 385 organisations:
- 349 organisations had to respond to at least one reservation in V2 and were awarded “accreditation with follow-up”;
- 36 organisations had to respond to at least one major reservation and were awarded “conditional accreditation”.

![Figure 5. Levels of V2 decision – reservations substudy sample](image)

Reading guide: of the 385 organisations in the reservations substudy sample, 349 obtained accreditation with follow-up in V2.

The number of reservations per organisation ranges from 1 to 11.
Three hundred and seventy-eight (378) of the organisations in the sample had undergone V2 and seven had undergone V2007. The organisations in this substudy were distributed among the following categories:
2.1.2 Reservations studied

The organisations in the sample were notified of a **total of 1,193 reservations or major reservations** following the V2 initial visit. These reservations and major reservations involve the following categories:

**Figure 7. Types of HCO – reservations substudy**

*Reading guide: 39% of organisations in the reservations substudy sample are general hospitals.*

**Figure 8. Reservations by category**

*Reading guide: of the 1,193 V2 reservations in the study (reservations substudy), 222 concerned medication management.*
The distribution across categories of the reservations studied in this sample is comparable to the distribution of all reservations from the V2 procedure, which frequently emphasised:

- medication management;
- patient records;
- management of the quality and safety of care;
- patient rights and the role of patients;
- certain specific issues regarding the quality or safety of care (for example, infection control and pain management).

Thus, 57% of the organisations studied here had to respond to a reservation or major reservation on patients’ medication management, 30% to a reservation on patient records and almost 25% to a reservation on risk management.

2.1.3 Outcomes from V2 reservations: overall results

V2: What are the results of accreditation follow-up measures?

Reservations or major reservations in V2 are subject to follow-up within a time period specified by HAS in its decision (3 to 18 months). Depending on the situation, these follow-up measures take the form of either a follow-up report submitted by the organisation, or a targeted visit conducted by surveyors. At the end of the follow-up, as a result of the improvements observed in the fields affected by reservations, the reservations may be removed, changed (a reservation becomes a recommendation) or maintained. The reservations examined in this study (n = 1,193) were mostly removed after follow-up.

Figure 9. Results of V2 follow-up measures

Reading guide: 82% of V2 reservations in the study (reservations substudy) were removed.
V2 accreditation follow-up measures: analysis of five follow-up cases

Five files (accreditation reports and targeted visit reports) from organisations that have had a targeted visit were examined. This sample comprised one university hospital, one general hospital, one specialist hospital, one private non-profit healthcare organisation and one private healthcare organisation. Each organisation was randomly selected from its category within the study sample. This analysis shows that reservations and follow-up measures have a similar effect to those identified in studies of the impact of all aspects of accreditation (standards, self-assessment, etc.).

Initiatives to improve the quality and safety of care have been developed and standardised. For example, during the V2 accreditation visit of Organisation A in October 2007, the surveyors observed that the organisation had not defined any initiatives to improve the quality and safety of care. In particular, there was no structure that would enable the organisation to take an overall view of its risks. Professionals were insufficiently involved, and there was no communication about improvement initiatives. During the targeted visit, in April 2009, the surveyors’ observations revealed significant changes: they noted that management, the leadership and professionals were involved in defining initiatives to improve the quality and safety of care. Risk management was in place: aims had been drawn up and prioritised through risk mapping, there was a structure enabling information on risks to be pooled together and disseminated, communicative actions were taken, etc.

A collective learning process and a culture of evaluation have been instilled. Professionals in Organisation B could not meet the accreditation criterion concerning evaluation of the appropriateness13 of care during the organisation’s V2 accreditation visit. The surveyors observed a lack of objectives, methodology and tools (external recommendations, investigative projects, action plans) in this field. The targeted visit report reveals greater competence in the professional community and the setting up of a “loop” of learning and improvement: the appropriateness of indications for hospitalisation and admissions to old age psychiatry was selected and studied by a multidisciplinary working group. HAS tools for reviewing the appropriateness of care were adapted and implemented. This evaluation initiative led to a study of the connections between different providers of care to the elderly and to actions being taken (cooperation with referring doctors in order to improve patient orientation, weekly medical team meetings on requests for admission, meetings between doctors and the management of organisations working with the population concerned, etc.).

A positive impact on the organisations and their professional practices. For example, as the surveyors had observed non-compliant practices in the primary decontamination of equipment (endoscopes) in March 2006, Organisation C had to respond to a reservation on medical device risk management. The targeted visit in June 2007 showed that the professionals responsible for pre-treating and disinfecting endoscopes had been trained and now used validated protocols.

The accreditation visit of Organisation D in May 2006 highlighted a number of organisational problems that affected perioperative safety (poor communication of information between the different providers of surgical care). One year later, the surveyors observed that corrective actions and improvement initiatives had been implemented: the communication of information among the professionals involved was ensured in the pre-, per- and postoperative periods.

The sample revealed cases where reservations were changed (the decision was maintained but in the form of a recommendation). These were, for the most part, linked to structural constraints such as geographical or architectural issues. This was the case for a reservation on respect for personal dignity issued following the V2 initial visit in Organisation E: during the targeted visit, the “humanisation” work had not yet started and, although awareness-raising initiatives and a partial reorganisation of the premises had been put into place, a recommendation was issued

► V2010: Are the problems noted during V2 accreditation observed again?

The use of the category correspondence tool for V2 and V2010 requirements and recommendations enables the outcomes of reservations to be followed up beyond follow-up

13 The appropriateness of care concerns whether care (preventative measures, diagnostic and therapeutic procedures, admissions, length of hospitalisation and type of hospitalisation) is suited to the patients’ needs.
measures, all the way to V2010 accreditation, which takes place approximately four years after notification of the V2 reservation.

It seems that the majority of problems noted during the V2 procedure and resulting in reservations or major reservations are no longer evident during the V2010 procedure and accreditation visit.

![Figure 10. Reservations renotified in V2010](image)

Reading guide: 63% of the reservations issued during V2 and examined in the reservations substudy were not renotified in V2010. In 63% of cases of reservations studied, the category that was subject to a reservation in V2 was no longer subject to a reservation or recommendation in V2010.

<table>
<thead>
<tr>
<th>Type of Renotification</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>V2 reservations not renotified in V2010</td>
<td>746</td>
<td>63%</td>
</tr>
<tr>
<td>V2 reservations renotified in V2010 as recommendations</td>
<td>296</td>
<td>25%</td>
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<tr>
<td>V2 reservations renotified in V2010 as reservations</td>
<td>138</td>
<td>12%</td>
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<tr>
<td>V2 reservations renotified in V2010 as major reservations</td>
<td>13</td>
<td>1%</td>
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<tr>
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</tbody>
</table>

Thus, 63% of reservations issued during V2 and examined as part of this study were not renotified following the V2010 initial visit. In these cases, the fields that the reservations identified as “areas of weakness” in V2 were no longer subject to reservations following the V2010 visit. In 25% of cases, the category was re-implicated in V2010 in the form of a recommendation, suggesting that the problem was less significant than it had been during V2. Finally, in 12% of cases, the same category was subject to a reservation in V2 and in V2010. This could be viewed, in the initial analysis, as the V2 reservation being reiterated. As we shall see in the rest of the study, this apparent continuity between the two cycles of accreditation is complex to interpret, and covers situations that are very varied in nature.
Two case studies: one reservation removed following the V2 targeted visit and not renotified in V2010, and one reservation maintained after the targeted visit and renotified in V2010

A reservation as a lever for improvement

In late 2006, the V2 accreditation visit at Organisation F, a private medical, surgical and obstetrics clinic with 145 beds, revealed that the medication management system was poorly organised: there were fragmented prescription formats, requiring prescriptions to be re-transcribed several times without being validated by a pharmacist. In addition, IMDS (implantable medical devices) were managed by the theatre without pharmacy control. There was insufficient traceability of IMDS to respond to a safety alert from medical devices vigilance. The organisation’s policy on medication management was the subject of some internal debate and had not been defined.

Two reservations were issued in June 2007. These were followed up in 2008 with a targeted visit that showed progress: a single form for prescription and administration had been implemented throughout the organisation, and administration was documented systematically in real time. The way implantable medical devices were managed had been changed: the pharmacist was responsible for referencing IMDS, managing stock, and validating orders and invoice files. A specific prescription pad had been introduced and the traceability of IMDS was computerised, becoming the pharmacist’s responsibility.

The report shows that a genuine policy was put into place, with information available to professionals via the intranet (hospital formularies for drugs and IMDS, good practice guidelines for drugs e.g. analgesics, antibiotics), the Vidal drug database online, secure transportation, plans to bring certain facilities up to standard, computerisation plans, the introduction of a policy for the management of adverse events, etc.

In 2011, the V2010 accreditation visit showed that this progress had been consolidated: the computerisation plans had been completed and professionals had been trained, in particular making prescription and drug administration safer; a policy for improving the quality of medication management had been drawn up and integrated into the organisation’s main strategic aims.

This can be impeded by unfavourable organisational cultures and/or situations

Organisation G is a psychiatric hospital with 177 beds and spaces. In 2007, the V2 accreditation visit showed that there were no policies or tools for pain management. This omission had already been identified during the first cycle of accreditation and was the subject of a recommendation in 2004. A reservation about pain management was therefore issued in V2. In 2008, the V2 targeted visit did not reveal sufficient progress for the reservation to be removed: there were intentions to form a pain management committee, and a doctor had been appointed to lead it. A plan had been drawn up, but not implemented or even validated by the hospital's medical committee. Only one department had put pain evaluation tools into place. The reservation therefore remained. In 2011, the V2010 visit revealed that the situation was “deadlocked”: the pain management committee had only been formed in January 2010, and the pain management plan had still not been validated on an institutional level, nor examined by the medical committee. Only one department had tackled the issue with a number of initiatives: training professionals, distributing evaluation tools, patient education, sharing experience with the general hospital, etc. HAS declared “deferred accreditation” as a result of several problems, including the lack of a pain management policy. To fully understand this situation, an on-site investigation would be necessary. There are several possibilities. Mental health care providers in France often indicate that mental health professionals have poor awareness of the importance of physical care for psychiatric patients. Analysis of this organisation’s file also suggests a difficult situation locally, with high staff turnover and an institutional history marred by strategic problems and internal conflicts; in 2004, the Accreditation Board issued this organisation with the following reservation: “Restore the conditions for dialogue between medical staff and management as a matter of priority.”

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14 In V2010, in the case of major reservation(s), HAS may suspend the decision to accredit the organisation (when at least one major reservation has been identified in the organisation). The organisation will not be accredited until there is significant improvement of the point(s) leading to the major reservation, with a maximum time limit of twelve months set by the Haute Autorité de Santé.
The results of follow-up measures (whether reservations are removed, maintained or changed) are not entirely superimposable on results from the analysis of V2010 renotifications, even though, as one might expect, reservations removed after V2 follow-up are less frequently renotified in V2010 than reservations that are maintained or changed. Although 70% of reservations removed were not renotified following the V2010 visit, there are nonetheless 102 reservations that were removed during V2 follow-up and were renotified in V2010 in the form of a reservation or major reservation. These situations will be analysed later in the report. They are mostly related to changes in the requirements of accreditation which have not been taken into account by the correspondence table that enables renotifications to be identified.

Figure 11. Results of V2 follow-up vs. renotifications in V2010
Reading guide: 643 reservations removed after the V2 follow-up were not renotified in V2010. Two hundred and thirty-two (232) reservations removed after the V2 follow-up were renotified in the form of recommendations.
2.1.4 Outcomes from V2 reservations: results by category

The rates of renotification in V2010 vary considerably depending on the category. Some categories are more affected by renotifications in V2010 than others, as the following table shows:

![Renotification rates in V2010 – by category](image)

**Figure 12. Renotification rates in V2010 – by category**

*Reading guide: 54% of reservations issued in V2 in the patient records category were renotified in V2010 either as a reservation or a recommendation.*

Patient rights and the role of patients, medication management, and patient records were the categories particularly affected by renotifications in V2010. The 2006 study revealed a similar hierarchy, likewise observing that the medication management and patient records were the fields most commonly affected by renotifications between V1 and V2.  

Nonetheless, as the graph below shows, most renotifications are in the form of recommendations, suggesting that positive changes are occurring over time. More rarely, a reservation issued in V2 is renotified as a reservation in V2010.

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2.1.5 Explaining cases of renotification in V2010 recommendations

The results of this study suggest that, in the majority of cases, reservations in V2 have played their role as a lever for improvement. Qualitative analysis of institutional files shows how, in a concrete way, a reservation helps to mobilise providers significantly and prompts improvement initiatives to be put into place.

However, there are cases of “renotification” where a recommendation or reservation has been issued in the same category in V2 and V2010. Cases where a reservation is maintained and is then reiterated in the next cycle of accreditation are rare, and the most common situation, as we have shown, is where a reservation is reiterated as a recommendation.

Nonetheless, cases of renotification need to be interpreted, in particular with the aim of separating out what stems from the assessment system (1) (characteristics and changes in the requirements of the accreditation procedure) from what stems from the functioning of organisations themselves (2).

The issue can be summarised as follows: why is a recommendation in the same category reiterated from one cycle of accreditation to the next? Is it because the assessment system has changed and, in particular, has become more demanding (1) or is it because improvement within the healthcare organisation is stagnating (2)?
(1) In the fields most commonly affected by renotifications, a change in requirements and methods of assessment has been observed between V2 and V2010:

- firstly, because the level required has increased, particularly in fields that have been identified as priorities in V2010;\(^\text{16}\)
- secondly, because the standards go into more depth in the revised accreditation manual, incorporating dimensions that did not exist in previous manuals;
- finally, the methods of assessment have changed. In particular, the assessment draws on national indicators.

These changes in the requirements and methods of assessment help explain some cases where reservations were renotified in V2010, even though there had been a satisfactory response to reservations in V2. *Cases of renotification may therefore not, at least in part, be related to inertia within the organisation, but to the more in-depth requirements of accreditation and to changes in the methods of assessment.*

(2) Cases of renotification may also be linked to problems faced by organisations and to the slow nature of progress in some fields. As the 2006 study of V1 recommendations\(^\text{17}\) underlines, renotifications often concern complex problems with technical, organisational and cultural facets that require transverse improvement initiatives involving all professions. Progress is slower and more difficult in these cases than in other fields.

An examination of the three categories most affected by renotifications in V2010, “medication management”, “patient records” and “patient rights and the role of patients”, demonstrates the validity of both explanations.

- The first explanation (the effects of changes in accreditation) predominates in cases of renotification in the category “patient rights and the role of patients”.
- Both explanations must be combined to account for cases of renotification in the categories of medication management and patient records.

Qualitative analysis of organisations’ files can flesh out each of these explanations and show how they are connected in the case of individual organisations. Cases where an organisation does not respond are rare; rather, it is for insufficient progress that organisations are penalised when a recommendation is renotified.

In order to establish this, it was necessary to conduct a more in-depth analysis beyond the broad categories set out in the correspondence table and:

- focus on results by criteria and by the “assessment items”\(^\text{18}\) (AIs) that make up each criterion in the V2010 manual;
- complement this with qualitative analysis of these cases.

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\(^{16}\) V2010 designates some criteria as “priority required practices” with the aim of reinforcing the leverage effect of accreditation on the quality and safety of care. These priority required practices are criteria for which considerable expectation is reported. These practices have been selected based on the identification of areas judged fundamental to improving the quality and safety of care, by HAS, stakeholders and national and international experts, as well as on the capacity of accreditation to bring about changes in these areas. Failure to achieve a significant level of compliance with these requirements leads systematically to an adverse accreditation decision.


\(^{18}\) Assessment items break down the criteria of the accreditation manual, which appear as headings in the V2010 manual, into specific objectives. Sample criterion: criterion 1a, “Values, mission and strategy of the organisation”; sample assessment item from this criterion: “The values and mission of the organisation are communicated to the public and to professionals.”
This analysis concerns the three categories most frequently affected by renotations in V2010: patient rights and the role of the patient, medication management, and patient records.

► Patient rights and the role of patients: new awareness

The impact of changes in accreditation is very obvious in cases of renotification involving the category “patient rights and the role of patients”.

When the 64 V2010 renotifications in this category were examined (whether these were in the form of recommendations or reservations), it appeared that 32 of these primarily concerned the issue of disclosure of adverse events (criteria 11c of the V2010 manual).

 Disclosure of adverse events is not a new issue in accreditation. However, until V2010, it was rarely the subject of a recommendation. The requirements of accreditation have become more detailed in this area, as accreditation reflects general changes in awareness of the role of the patient in risk management. Users and medical institutions in France19 and abroad20 have raised awareness of the need to have a structure in place for responding to adverse events, in particular for informing and supporting the patient and their family. This development is reflected in V2010 accreditation recommendations, which very frequently involve criterion 11c, “Disclosure of adverse events”, the third most common criterion involved in recommendations in V2010.

Here, the cases of renotification are linked to the more in-depth requirements of accreditation. The correspondence table, which was drawn up to take a “panoramic” view, does not reflect this phenomenon.

► Medication management: the old and the new

Analysis of the answers obtained by the organisations in the sample to the assessment items from the medication management criterion in the V2010 manual can elucidate cases of renotification in this category.

In V2010, each assessment item is “marked”, based on the situation observed, using the following scale: “yes”, “on the whole”, “partially” and “no”; each answer corresponds to a certain number of points. These points are added together to determine a grade of A, B, C or D for the criterion. A C grade or D grade leads to a recommendation or reservation being issued.21

The assessment items from V2010 criterion 20a, “medication management”, are as follows:

<table>
<thead>
<tr>
<th>Tools</th>
<th>Tools</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up-to-date and validated tools are available to professionals.</td>
<td>Tools</td>
</tr>
<tr>
<td>Continuity of medication management is ensured from admission until discharge, including transfers.</td>
<td>Continuity of drug therapy</td>
</tr>
<tr>
<td>Plans to computerise all medication management are defined and integrated into the hospital information systems.</td>
<td>Computerisation plans</td>
</tr>
<tr>
<td>Procedures to ensure the safe dispensing of drugs have been defined.</td>
<td>Dispensing procedures</td>
</tr>
<tr>
<td>Rules for administering drugs have been defined, with a framework in place to ensure traceability.</td>
<td>Rules for administration</td>
</tr>
<tr>
<td>Prescribing rules and validated prescription forms are in place for all prescribers.</td>
<td>Prescribing rules and prescription forms</td>
</tr>
<tr>
<td>The healthcare organisation has formalised its quality improvement policy for patient medication management in consultation with the professionals involved.</td>
<td>Improvement policy</td>
</tr>
<tr>
<td>Actions are taken to raise awareness of and train professionals in the risks of drug errors.</td>
<td>Professional awareness – Drug errors</td>
</tr>
<tr>
<td>The traceability of drug administration in patient records is ensured.</td>
<td>Traceability of administration</td>
</tr>
<tr>
<td>Pharmaceutical analysis of prescriptions and named-patient dispensing of drugs are being developed.</td>
<td>Named-patient dispensing and pharmaceutical validation</td>
</tr>
<tr>
<td>Best practices for preparation are applied (anticancer drugs, radiopharmaceuticals, paediatrics, etc.).</td>
<td>Best practices – Preparation</td>
</tr>
<tr>
<td>Health professionals ensure patients are informed of how to use their drugs correctly.</td>
<td>Patient information</td>
</tr>
<tr>
<td>Prescribing rules are implemented.</td>
<td>Prescription compliance</td>
</tr>
<tr>
<td>Medication management is computerised.</td>
<td>Computerisation</td>
</tr>
<tr>
<td>Improvement initiatives are put into place following each assessment conducted and following the analysis of errors, with feedback to professionals.</td>
<td>Improvement initiatives</td>
</tr>
<tr>
<td>Initiatives targeting the appropriate use of drugs are implemented (in particular regarding the appropriateness of prescriptions, etc.).</td>
<td>Appropriate use</td>
</tr>
<tr>
<td>Drug errors are recorded and analysed with the professionals concerned.</td>
<td>Analysis of errors</td>
</tr>
<tr>
<td>A periodic audit of the medication management system is conducted, focusing especially on the quality of administration.</td>
<td>Drug cycle audit</td>
</tr>
<tr>
<td>Quantitative and qualitative evaluation indicators are monitored</td>
<td>Monitoring of indicators</td>
</tr>
</tbody>
</table>

21 As a general rule. Feedback from V2010 has highlighted the need to make a certain number of exceptions, formalised by “case law”.

HAS / Division for the Improvement of Quality and Safety of Care / November 2012
The graph below concerns 124 organisations whose V2 recommendation in the broad category of medication management was renotified (as a recommendation or reservation) in V2010. It shows, for these 124 reports, the proportion of “yes”, “on the whole”, “partially” and “no” answers obtained for each assessment item in criterion 20a.

![Graph showing the proportion of answers for each assessment item in criterion 20a.](image)

Figure 15. Answers to assessment items for criterion 20a (drugs) in V2010

Reading guide: in the 124 files examined, the response to the “prescription compliance” assessment item was “partially” in 74 files, “on the whole” in 21 files and “yes” in 29 files.

The results presented in this graph enable the “areas of weakness” observed during the V2010 accreditation visits in these 124 organisations to be identified. The assessment items that received the highest numbers of “partially” and “no” answers point towards these areas of weakness.

If we examine the four subcategories with the lowest relative scores, that is with the highest number of “partially” and “no” answers across all organisations, a combination of “the old” and “the new” is noted:

- “The old” involves fields such as prescription compliance and named-patient dispensing which have been included as requirements of accreditation for a long time, but which are slowly evolving fields, as they strike at the heart of professional practices and cultures (prescription compliance) or are hindered by major problems with resources (named-patient dispensing and pharmaceutical validation).
- “The new” involves changing requirements that attest to the technological and social developments in this field. Thus, the level required for accreditation in terms of professional awareness of the risks of drug errors, or in terms of computerising the drug management cycle, has increased between one accreditation procedure and the next. New requirements in the field of informing and involving patients have been introduced.

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22 There is a greater number of organisations affected by a renotification in the medication management category. However, at the time of this study, some V2010 reports were not yet available from the accreditation infocentre.
In addition, the particularly low scores for the assessment item concerning prescription compliance reveal an “indicator effect” that helps to explain cases of renotification. Prescription compliance is measured through the HAS indicator on patient records. The use of a national performance measure makes assessments more acute and often more severe. This change in assessment methods partially explains renotifications from one procedure to the next.

Qualitative analysis confirms these hypotheses. The files on organisations that received a renotification in the medication management category are complex and demonstrate several interlinked phenomena:

- **Progress in certain areas:** in particular, V2 reservations have often resulted in the abolition of the practice of transcribing prescriptions, and more broadly in the development of quality assurance in this area, with drug management integrated into the organisation’s main strategic aims.
- **Stagnation in certain areas:** computerisation has barely been implemented, and plans announced in 2006 or 2007 are sometimes still in their infancy four years later. Professional practices are slow to change, as shown by the results of the prescription compliance indicator.
- **The appearance of new problems linked to changes in accreditation requirements:** professional awareness, patient information, etc.

On the other hand, the files that do not include any renotifications in the medication management category are unambiguous: a lack of renotification always indicates that very significant progress has been made, sufficient for the surveyors to judge that this field is under control.
Old and new, change and stagnation: three case studies

In Organisation H, an obstetric clinic with 94 beds accredited in 2007, the surveyors’ observations indicate the practice of re-transcribing prescriptions, little development in the named-patient dispensing of drugs, and a lack of efforts to raise awareness among the medical profession of declaring adverse events. A reservation concerning the medication management system was issued. One year later, the follow-up report showed progress: a single prescription form had been introduced with transcription abolished. A computerisation project had been started, and a system for reporting adverse events was in place. The reservation was removed. In early 2011, the V2010 accreditation report showed that the organisation had succeeded in mobilising professionals around the improvement initiatives for medication management. An evaluation system based primarily on risk mapping and detailed, multidisciplinary audits underpinned the policy, enabling training objectives and improvement initiatives to be defined. Restructuring (implementing a quality manual, a training programme, analysis of adverse events, etc.) had taken place. However, the surveyors highlighted some issues:

- stemming from old problems...
  - named-patient dispensing was only very partially implemented and the organisation’s human resources prohibited any correction of this in the short term;
  - prescription compliance as measured by the HAS national indicator was very poor;
  - drug administration was not always documented in real time.
- ...or more recent:
  - the management of patients’ individual treatment was not secure (no pharmaceutical checks, no management of patient discharge, etc.);
  - there was insufficient support for computerisation among professionals.

A reservation concerning medication management was renotified in V2010.

In this case, accreditation and the associated follow-up measures did contribute to the organisation’s development in terms of medication management. As in many other organisations, accreditation also facilitated initiatives that are essential to the safety of drug management, in particular the introduction of a single form for prescription and administration. In the case of Organisation F, however, some problems persisted and issues related to changes in knowledge and requirements were highlighted, leading to a reservation being renotified. Document analysis reveals that there are frequent cases of renotification that combine changes within the organisation, the resolution of some issues, the appearance or persistence of other problems and the effect of changes in the “focus” of accreditation. These interlinked factors can often explain cases where a reservation is renotified after it has been removed.

If cases where a reservation is removed but followed by renotification in V2010 (102 reservations) often point to an evolving organisation and the conjunction of several factors, as analysis of Organisation H’s file shows, the rare cases where a reservation remains after V2 follow-up measures and is renotified in V2010 (10 reservations) often indicate a deadlock related to managerial failings. In these cases, the apparent continuity between the two accreditation procedures does reflect reality.

For example, Organisation I, a medical, surgical and obstetrics clinic with 172 beds, was issued with a reservation concerning medication management following its V2 accreditation procedure in October 2006. In the organisation’s file, medication management appeared to be an “orphan” issue. It was not subject to quality assurance, and a number of problems were noted: prescriptions were not written and signed by all doctors; when they were written, prescriptions were re-transcribed; no consideration of named-patient dispensing and pharmaceutical analysis had been undertaken. The formulary was not up to date and no professional information policy had been implemented.

The targeted visit one year later showed improvement: drug management was now one of the priorities of the 2007-2009 overall risk management plan and assessments had been introduced. However, progress was limited: computerisation and the development of pharmaceutical analysis were under way, but remained in their infancy, and information and guidance for professionals had been insufficiently developed. Above all, the practice of re-transcription remained except in one computerised department (gynaecology). The institutional context was that of a merger with another clinic. This merger played an ambivalent role: although it helped to launch some new projects (such as
computerisation), it also seemed to act as a brake, with some improvements apparently on hold while waiting for restructuring. The reservation was maintained following the targeted visit.

In V2010, the situation had changed little. In particular, with the exception of the computerised department, there were still multiple prescription forms and the re-transcriptions continued. In the vast majority of other organisations studied, the reservations issued in V2 that were examined as part of this study and concerned transcriptions resulted in the introduction of a single form for prescription and administration. This step towards a safer drug management system had been taken, even if the system still had some weaknesses. The persistence of this problem indicates a “deadlock”. During the V2010 visit of Organisation I, other problems were revealed: oral prescriptions, patients self-managing their own treatment, and unsafe management of urgent requests. The rest of the accreditation report gives the impression that the organisation’s leadership had invested little in quality improvement. The section on evaluation of professional practices (EPP) highlighted that coordination of EPP within the organisation was entrusted to the only quality manager, with no clear mandate and without the support of the medical leadership. A reservation concerning medication management was renotified and accreditation was deferred in May 2011.

In general, the trajectory of organisations whose reservation was removed and not renotified (643 reservations, including 61 concerning medication management) differs from the two previous cases. This trajectory is a rising and linear progress curve, contrasting with the stalled or, more often, ambiguous changes in the other organisations. In this case, the effect of the increasing level of requirement between the two procedures is less noticeable, and does not result in renotification because the organisation’s trajectory has followed the same “gradient” as accreditation.

For example, a reservation was issued in Organisation J’s accreditation report, a private aftercare and rehabilitation clinic with 220 beds, where the surveyors observed multiple prescription and drug administration forms and widespread practices of transcribing prescriptions. The follow-up report in November 2008 states that a system has been put into place to eliminate prescription transcribing. In parallel with this, computerised prescribing has been started. The V2010 report, dated May 2011, shows very positive development. The entire cycle of prescribing, pharmaceutical validation, dispensing, administration, stock management and order management has been computerised and brought under control. The computerisation project was driven by a strong policy, a programme that trained, informed and involved professionals, a very comprehensive assessment system including the collection and dissemination of indicators, audits of the entire cycle and daily checks on 8% of pills by the pharmacist. Criterion 20a, “medication management”, was awarded the maximum grade (A).
Patient records: the indicator perspective and the surveyor perspective

Renotifications in the patient records category are mostly related to the “indicator” effect identified above. One of the assessment items for the V2010 “patient records” criterion is assessed using the national indicator on patient records.

When the answers to assessment items for criterion 14a (patient records management) are examined for organisations who had a reservation in V2010 in the patient records category, it can be seen that the weakest scores, that is the answers “no” and “partially”, come from the assessment item evaluated through the HAS indicator.

![Figure 16. Answers to assessment items for criterion 14a (patient records) in V2010](image)

*Reading guide: in the 169 files examined, the answer to the “record keeping” assessment item was “partially” in 128 files, “on the whole” in 23 files and “yes” in 12 files.*

Qualitative analysis of these institutional files shows that, although cases of renotification in this category are related to an “indicator effect”, other factors are also involved. In particular, the surveyors’ assessment changes depending on the type of visit. The field of a targeted visit is narrower than that of an initial visit. During an initial visit, the surveyors tend to expand their focus. They are therefore likely to detect policy issues and overall organisational problems that were not spotted during targeted visits.
The indicator perspective and the surveyor perspective

In September 2006, following the V2 procedure, a reservation concerning patient records was issued to Organisation K, a public healthcare organisation with 867 beds. It was worded as follows: “Define the rules for record keeping.” It was supplemented by two recommendations, one on policy and one on evaluating patient records. The reservation was more specifically linked to the observation that there was no definition, supported at institutional level, of the medical staff’s responsibilities in terms of keeping patient records.

The targeted visit showed that a paper records protocol had been drawn up and implemented. This included the composition of records, rules for managing and accessing files, and the means of evaluating them. New formats were tested. The reservation was removed in June 2008.

The V2010 report, published in November 2010, includes a recommendation concerning patient records. The surveyors noted that although patient records were organised in a way that enabled satisfactory coordination between professionals, the evaluation and improvement system was only loosely structured. In particular, the relationship between the results of evaluations and improvement initiatives was not always coherent. The follow-up of improvement initiatives and information for professionals were insufficiently structured. In addition, the HAS indicator on patient record ranked the organisation as one of the weakest performers in this field.

The V2010 perspective was therefore both:
- broader than during the V2 targeted visit, with the assessment not only focusing on the specific aspects (record-keeping rules) that had led to the reservation issued in V2, but more widely on the “governance” of patient records within the organisation;
- more precise and “objective” with the contribution of the indicator results.

These two shifts in the assessment approach, the contribution of the broad perspective of an initial accreditation visit and the contribution of objectiveness from the indicators, can be seen in a significant proportion of the files studied, and help to explain cases where recommendations are renotified.
2.2 Substudy 2: What is the impact of V2 recommendations?

Organisations studied

The 546 organisations included in the recommendations substudy have:

- undergone the V2 procedure;
- had at least one recommendation following the V2 accreditation visit;
- undergone the V2010 procedure in its initial phase\(^{23}\).

In addition, data from the V2 accreditation report could be statistically linked to follow-up data from the V2010 report for these organisations.

These 546 organisations are distributed as follows across the different levels of V2 accreditation:

- 30 organisations had “conditional accreditation”;
- 290 organisations had “accreditation with follow-up”;
- 226 organisations had “straightforward” accreditation (with no follow-up measures between the V2 and V2010 procedures).

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![Figure 17. Levels of decision – recommendations substudy](image)

*Reading guide: 290 organisations in the recommendations substudy sample had accreditation with follow-up in V2.*

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The number of recommendations per organisation ranges from 1 to 27.

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\(^{23}\) That is, whose accreditation report from the V2010 initial visit has been validated by the HAS Board.
What is the impact of accreditation decisions? A pilot study

Figure 18. Number of recommendations per HCO – recommendations substudy
Reading guide: 34% of organisations in the recommendations substudy sample had one, two or three recommendations.

Within the sample, 519 organisations had undergone V2 and 27 had undergone V2007. The organisations in this substudy were distributed among the following categories:

Figure 19. Types of organisation – recommendations substudy
Reading guide: 29% of organisations in the recommendations substudy sample are general hospitals.
Recommendations studied

A total of 2,916 recommendations issued to the organisations in the sample following the V2 initial visit were analysed as part of the study. These recommendations involve the following categories:

![Distribution of recommendations among categories](image)

**Reading guide:** 374 of the 2,916 recommendations in the study concerned the organisation’s improvement policy.

A comparison of the hierarchies of categories for recommendations and reservations shows some “beacon” categories in common: policies and programmes for improving the quality and safety of care, risk management, patient rights and the role of patients, and patient records. But these hierarchies differ considerably on certain points. For example, the medication management category does not predominate in the hierarchy for recommendations as it does for reservations. The management category, on the other hand, takes second place in the ranking of recommendations. These are primarily recommendations concerning:

- human resources policy and management;
- internal communication and management of activity sectors;
- value for money policy;
- defining and implementing strategic aims.
Follow-up of recommendations: overall results

An examination of the standardised “yes”, “no” and “in progress” observations made in V2010 for the 2,916 V2 recommendations in this study gives the following results:

![Pie chart showing follow-up results]

Figure 21. Observations on the follow-up of recommendations

Reading guide: In 62% of cases of recommendations studied, the surveyors answered “yes” to the question, “Has the organisation implemented follow-up in the fields of the recommendation?”

It therefore appears that:

- according to the surveyors’ observations, almost all recommendations in V2 were followed up by organisations with improvement initiatives;
  - the majority of recommendations were followed up with improvement initiatives judged as durable and successful by surveyors (62% “yes”);
  - in a substantial minority of cases (36%), the improvement initiatives were still in progress;
- cases where a recommendation was ignored were very rare.
“No” (20 statements analysed): this answer was given by surveyors in the V2010 follow-up table in the rare cases where an organisation failed to respond to a HAS recommendation.

This “no” covers several situations:

- The surveyors note that no improvement initiatives have been undertaken since the previous visit. In this case, their observations are pithy.
  
  o The surveyors’ observation on Organisation L’s follow-up of the V2 recommendation “Define a patient records policy” is as follows: “The organisation has not defined a patient records policy.”

- Some actions have been taken, but they are considered to be insufficient.
  
  o The V2 recommendation “Analyse waiting times and undertake improvement initiatives” issued to Organisation M is followed by this observation in the V2010 follow-up table: “The healthcare teams are careful to respond within timeframes that are appropriate to patients’ needs. Initiatives such as an initial nurse consultation help to ensure a rapid response. Nonetheless, the organisation has not implemented a structured approach to measuring and analysing waiting times.”

- The organisation has made a plan, or even just expressed an intention, but cannot demonstrate that its implementation is under way.
  
  o The recommendation “Develop tools to control the costs of activities” issued to Organisation N in V2 was the subject of the following observation in V2010: “The organisation has planned, by late 2010, to implement cost accounting and expenditure control, and to send the costs of activities to managers. On the day of the visit, no deadline had been set […] The organisation is currently unable to know the precise costs of its activities.”

“Yes” (20 observations analysed): this answer is given when an organisation has fully and satisfactorily responded to the HAS recommendation. This answer is especially likely to be selected by surveyors when the organisation has completed the “improvement loop” by introducing an evaluation of its initiatives.

- The following observation was made regarding the actions taken following the recommendation “Reinforce adherence to hygiene rules in the infectious clinical waste terminal storage unit” issued in V2 to Organisation O: “Work has been carried out in accordance with the 2007 order (floors and walls tiled with an outlet in the floor and a water supply). A cleaning protocol for the infectious clinical waste unit was drawn up in January 2007, including documentation of cleaning of the unit. An evaluation of the implementation of the procedure by the hygiene department was conducted, including monitoring of the documentation sheets and unannounced inspections of the cleanliness of the unit.”

- The long-term care unit in Organisation P responded to the following recommendation: “Assess patients’ nutritional status and take their specific needs into account.” In V2010, the following observation was made: “A malnutrition screening EPP was started in 2010 to systematise the assessment of nutritional needs. In order to do this, measuring tools (height/weight, calculation of height from knee-heal measurement) were made available, patients’/residents’ records were amended and an evaluation was carried out. Work was undertaken with CLAN [the Diet and Nutrition Liaison Committee], including a malnutrition screening sheet and an information sheet on dietary supplements. An appropriate diet is now offered.”
“In progress” (40 observations analysed): this answer is selected by surveyors when they note that improvement initiatives have been introduced, but these cannot be considered as completely successful:

- either because the professionals have not yet evaluated their effect:
  - Organisation Q responded to the V2 recommendation “Coordinate medical teams and teams of paramedical staff by ensuring the traceability of information communicated.” The following observation was made regarding the follow-up of this recommendation: “The introduction in January 2009 of a single patient record including dedicated files for each type of professional (medical, nursing, paramedical staff, occupational therapists, dieticians) enables care to be documented and traceable. In order to comply with professionals’ requests as closely as possible, some pages in the record have been adapted following evaluation. A patient records audit conducted in September 2010 is currently being analysed. The results of the traceability analysis are not known”;

- or because there are still minor or major constraints to implementing them:
  - Organisation U responded to the recommendation “Make appropriate antibiotic use widespread (16d)” issued during the second accreditation procedure. The observation on this follow-up in V2010 was as follows: “Prescriptions are issued in accordance with the recommendations in the antibiotic prophylaxis booklet written by the infectiologist working in the organisation. The booklet has been validated by the organisation’s medical committee and distributed among all practitioners for first-line treatment of community-acquired infections. There are also prescription guidelines for antibiotic prophylaxis in theatre. During the validation of computerised prescriptions, the pharmacists insert comments for the doctors and nurses. The widespread implementation of a re-evaluation of antibiotic treatment after between 24 and 72 hours is included in the Quality Assurance and Quality Control Plan.”

This answer covers the widest range of situations, because “in progress” can apply to improvement initiatives in very variable stages of development.

▶ Follow-up of recommendations: results by category

The following graph shows the distribution of the three observations “yes”, “no” and “in progress” in each category.
Cross-referencing the observations given in the follow-up table with their categories shows that the results are fairly homogeneous from one category to the next.

However, there is one variation worthy of examination:

The care plans category is the only category where follow-up of the majority of recommendations was judged as “in progress”, with a minority of recommendations receiving the answer “yes”. These are recommendations concerning the implementation and documentation of a risk-benefit assessment in the patient record. Other categories directly related to professional practices have a significant proportion of recommendations where follow-up by the organisation was considered as “in progress” four years after they were issued (for example, pain management).

The reservations substudy showed that progress was less evident and took longer to achieve in fields that directly concern the care of each patient and involve a change in professional practices. An examination of the outcomes of recommendations reinforces this hypothesis, which is in agreement with the results of other impact studies.24

Organisation V responded to the recommendation “Ensure the risk-benefit assessment is documented (29d)” issued during the V2 procedure. Four years later, surveyors noted that a number of actions had been taken. However, the answer “in progress” is given in the follow-up table. This answer is accompanied by the following observation:

“The organisation has introduced a specific form intended to ensure the risk-benefit assessment is documented for each invasive procedure. This form is included in patient records. The circumstances when the form is to be used are set out in the guide to patient record keeping rules [...] However, although the assessment is documented in multidisciplinary meetings in oncology, and in reviews in psychiatry, it does not appear in the majority of records consulted in surgery. In the majority of departments visited, the specific form described above is not used by professionals. These observations are corroborated by the results of patient records audits conducted in 2006 and 2008 which show that a risk-benefit assessment is carried out less than one time in four before an invasive procedure.”
Conclusion

What are the lessons learned from this study? What does it teach us about the impact of the accreditation of healthcare organisations?

1- Quantitative and qualitative analysis of the outcomes of reservations and recommendations show that accreditation recommendations play a major role as a lever for improvement in the quality and safety of care.

   a. **Reservations and recommendations create a positive “pressure” on healthcare organisations.** Accreditation recommendations push organisations to set as their top priority the implementation of improvement initiatives, which would not have had the same degree of urgency and necessity without accreditation. This study shows that the vast majority of organisations have a documented response to a HAS recommendation. Those that ignore these recommendations are a very small minority.

   b. Follow-up, which is implemented over several years as part of the accreditation process, and the reiteration of external evaluation at regular intervals enable the deployment over time of initiatives which, to be successful, must involve the mobilisation of several types of professionals and a long-term investment. The periodic external appraisal of accreditation provides essential reference points in this lengthy process. The very common cases of reservations concerning the quality and safety of medication management illustrate this synergy between internal dynamics and external pressure.

2- The methodological challenges of a comparison between the two versions of accreditation, and the analysis of cases of renotification, have highlighted the significant changes in the requirements of accreditation between accreditation procedures.

   a. **The level required has increased** and the requirements have become more in-depth with new dimensions, reflecting changes in perception, society, science and technology.

   b. **Objective elements are increasingly playing a role in accreditation assessments.** National indicators in particular allow specific points to be viewed objectively, and provide an additional perspective to that of the teams of surveyors, who conduct a more global evaluation of the organisation.

3- Certain barriers may limit the impact of reservations and recommendations. Some of these have been highlighted by the study:

   a. **Structural issues** and problems with resources may slow the implementation of the necessary improvements;

   b. The study suggests that **progress is slower and more difficult when it involves several sectors and implies significant and long-lasting changes in the practices** of all professionals. Prescription compliance and documentation of medical observations or drug administration: there are many examples of weak points
identified since the start of accreditation in France and these are sources of persistent difficulties.

c. There are a few rare cases of an organisation failing to respond to an accreditation recommendation. These rare cases show that the impact of reservations and recommendations is strongly conditioned by internal managerial dynamics and mobilisation.

This pilot study has some limitations which could be addressed by a more comprehensive study:

- Although it demonstrates the effects of accreditation empirically, the study does not meet all of the necessary methodological conditions to establish an exclusive causal link between accreditation and the improvements observed. In addition, the results cannot be interpreted as establishing complete equivalence between the absence of a recommendation and the absence of problems. The results will be combined and consolidated with results from other studies (perception studies, international research, etc.).
- Not all V2 recommendations and reservations could be analysed in this study, which only includes organisations that have also undergone V2010. The completion of the V2010 procedure in 2015 will enable an exhaustive view of organisations and recommendations.
- Because the requirements evolve over time, the linking of categories from two cycles of accreditation could only be approximate. This must be accompanied by identification and analysis of the changes in requirements and in how they are evaluated.
- The qualitative data from accreditation reports are very instructive, but a further study could supplement them and combine them with data from other sources (for example, interviews).
- This pilot study has been conducted internally but the issue of the independence of the analysis should be raised when subsequent reports are produced.
Appendix 1. Selection of the Sample for the Impact of Recommendations Study

On 23 May 2012, 817 organisations had undergone V2010 and had a V2010 accreditation report.

Six hundred and twelve (612) of these 817 organisations are included in the study. These are:

- 1. Organisations that have undergone both the second (V2) and third (V2010) accreditation procedures;

As this study follows the developments within organisations, they must have had a certain level of continuity during the period studied; organisations that have undergone major restructuring in the interval between the two procedures are not included in the sample (35 organisations).

- 2. Organisations that have had to respond to one or more recommendations or reservations following the V2 visit;

The 123 organisations that were accredited with no recommendations or reservations are not included in the sample.

- 3. Organisations for which it was possible to establish links between V2 and V2010.

47 organisations could not remain in the sample, as a link between V2 and V2010 could not be established. This exclusion concerns two types of files:

- Organisations excluded from the recommendations substudy because their only recommendation concerned evaluation of professional practices. Recommendations on evaluation of professional practices are not examined by the surveyors as part of their assessment of outstanding V2 recommendations. The recommendation follow-up tables included in the V2010 reports do not include data on the follow-up of recommendations in this category.

- Documents from organisations without reservations that would have been included in the recommendations substudy, but for which a link between V2 and V2010 could not be established. There is no a priori “chain” within the information system between recommendations made after the V2 accreditation visit and the corresponding observations in the V2010 follow-up table. This link has been reconstructed through a customized computer program. One hundred and two (102) organisations could not remain in the recommendations substudy sample for this reason. Fifty-five (55) of these organisations had one or more reservations and were included in the study as part of the reservations substudy. Forty-seven (47) organisations were not eligible for either substudy.
There were two samples corresponding to the two substudies:

- a reservations substudy focusing on the outcomes of V2 reservations. This involved 385 organisations;
- a recommendations substudy focusing on outcomes from V2 recommendations. This involved 546 organisations.

A total of 319 organisations were included in both substudies, as they had to respond to both recommendations and reservations.
Figure 24. Reservations sample and recommendations sample

Impact of recommendations study: Methodology

Study sample

612 organisations
Sample for the study of Impact of Recommendations

4,119 recommendations and reservations

66 with reservations
319 with reservations and recommendations
227 with recommendation(s) only

385 organisations
Reservations substudy
1,193 reservations

546 organisations
Recommendations substudy
2,916 recommendations

(1) HCOs which on May 23, 2012 had undergone V2-V2007 and V2010 (782)
- At least one recommendation or reservation (859)
- Analysable (chained) data (612)
### Appendix 2. Table of V2 – V2007 – V2010 Category Correspondence

<table>
<thead>
<tr>
<th>Category</th>
<th>V2010</th>
<th>V2007</th>
<th>V2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Medication management</td>
<td>20a, 20a bis</td>
<td>31a, 31b, 31c, 31d</td>
<td>36a, 36b, 36c, 36d, 36e</td>
</tr>
<tr>
<td>2 Risk management and vigilance</td>
<td>8b, 8d, 8e, 8f, 8i, 8j</td>
<td>11a, 11b, 11c, 11d, 11e, 12a, 12b, 12c, 12d, 41a</td>
<td>14a, 14b, 14c, 14d, 14e, 14f, 15a, 15b, 15c, 15d, 15e, 45a, 45b</td>
</tr>
<tr>
<td>3 Environmental risks (waste management, etc.)</td>
<td>7a, 7b, 7c, 7d, 7e</td>
<td>15a, 15b, 15c, 15d</td>
<td>18a, 18b, 18c, 18d</td>
</tr>
<tr>
<td>4 Patient records</td>
<td>14a</td>
<td>4b, 28a, 28b, 28c</td>
<td>4e, 21a, 21b, 21c, 24a, 24b, 24c, 24d, 24e, 29b, 34a, 34b, 34c, 34d, 49c</td>
</tr>
<tr>
<td>5 Continuity of care</td>
<td>18a, 18b</td>
<td>27a, 27b</td>
<td>33a, 33b, 33c</td>
</tr>
<tr>
<td>6 Policies and programmes for improving the quality and safety of care</td>
<td>1e, 8a</td>
<td>6a, 6b, 10a, 10b, 10c, 10e, 44d</td>
<td>6a, 6b, 6c, 13a, 13b, 13c, 13d, 13e, 13f, 13g, 50a, 50b, 50c</td>
</tr>
<tr>
<td>7 Logistics</td>
<td>6c, 6d, 6e, 6f</td>
<td>9a, 9b, 9c, 9d, 44b</td>
<td>11a, 11b, 11c, 12a, 12b, 12c, 48a, 48b</td>
</tr>
<tr>
<td>8 Infrastructure security</td>
<td>6b</td>
<td>16a, 16b, 16c</td>
<td>19a, 19b, 19c, 19d</td>
</tr>
<tr>
<td>11 Care plans</td>
<td>17a</td>
<td>24a, 24b, 24c</td>
<td>29a, 29c, 29d, 29f</td>
</tr>
<tr>
<td>12 Pain management</td>
<td>12a</td>
<td>26a, 26b, 26c</td>
<td>32a, 32b, 32c, 32d</td>
</tr>
<tr>
<td>13 Infection control</td>
<td>8g</td>
<td>13a, 13b, 13c, 13d, 13e</td>
<td>16a, 16b, 16c, 16d, 16e, 16f, 16g, 18e</td>
</tr>
<tr>
<td>14 Operating theatres and interventional activity sectors</td>
<td>26a, 26b</td>
<td>32a, 32b, 32c, 33a</td>
<td>37a, 37b, 37c, 37d</td>
</tr>
<tr>
<td>16 Patient identification</td>
<td>15a</td>
<td>18b</td>
<td>22a, 22b, 22c</td>
</tr>
<tr>
<td>17 Medical device risk management</td>
<td>8k</td>
<td>14a, 14b, 14c</td>
<td>17a, 17b, 17c</td>
</tr>
<tr>
<td>18 Evaluation of professional practices</td>
<td>1f, 28a, 28b, 28c</td>
<td>40a, 42a</td>
<td>44a, 44b, 44c, 44d, 46a, 46b, 46c, 46d, 46e, 46f</td>
</tr>
<tr>
<td>19 Patient rights and the role of patients</td>
<td>1c, 2b, 2c, 9a, 9b, 10a, 10b, 10c, 10e, 11a, 11b, 11c, 14b</td>
<td>2a, 2b, 2c, 19a, 19b, 19c, 19d, 20a, 21a, 21b, 21c, 24d, 28d, 43a, 43b</td>
<td>2a, 2b, 2c, 2d, 2e, 10a, 26a, 26b, 26c, 26d, 26e, 27b, 29e, 31a, 31c, 31d, 31e, 31f, 51a, 51b, 51c, 51d</td>
</tr>
<tr>
<td>20 Information systems</td>
<td>5a, 5b, 5c</td>
<td>4a, 18a, 18c, 44c</td>
<td>4a, 4b, 4c, 4d, 21d, 21e, 23a, 23b, 23c, 49a, 49b</td>
</tr>
<tr>
<td>21 Medical imaging and clinical laboratory sector</td>
<td>21a, 21b, 22a, 22b</td>
<td>29a, 29b, 29c, 30a, 30b, 30c</td>
<td>35a, 35b, 35c</td>
</tr>
<tr>
<td>22 Management of the organisation</td>
<td>1a, 2a, 2d, 3a, 3b, 3c, 3d, 4a, 4b</td>
<td>1a, 1b, 1c, 1d, 3a, 3b, 3c, 3d, 3e, 5a, 7a, 5b, 7a, 7b, 8a, 8b, 8c, 8d, 43c, 44a</td>
<td>1a, 1b, 1c, 1d, 3a, 3b, 3c, 3d, 5a, 5b, 5c, 7a, 7b, 7c, 8a, 8b, 9a, 9b, 9c, 9d, 9e, 25a, 25b, 25c, 25d, 25e, 25f, 25g, 47a, 47b, 52a, 52b, 53a, 53b, 53c</td>
</tr>
<tr>
<td>23 Safeguarding people and assets</td>
<td>6a</td>
<td>17a, 17b</td>
<td>20a, 20b, 20c</td>
</tr>
<tr>
<td>24 Patient admission and special care</td>
<td>13a, 16a, 19a, 25a, 27a, 22a, 22b, 22c, 22d, 23a, 23b, 23c, 23d, 25a, 25b, 25c, 25d, 25f, 34a, 34b, 34c, 35a, 36a, 37b, 38a, 38b, 38c, 39a, 39b, 39c</td>
<td>10b, 10c, 10d, 27a, 27c, 27d, 27e, 28a, 28b, 28c, 28d, 30a, 30b, 30c, 30d, 30f, 38a, 38b, 38c, 39a, 39b, 39c, 40a, 40b, 40c, 41a, 41c, 42b, 42c, 42d, 43a</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 3. Qualitative Sample – Reservations Substudy

Thirty institutional files were subject to qualitative analysis.

▲ In order to understand the leverage effect of reservations and their possible limitations: five files from organisations that have had at least one reservation and a targeted visit were examined. Each organisation was randomly selected from its category within the study sample. This sample comprises:
- one university hospital (1,700 beds and spaces);
- one general hospital (1,500 beds and spaces);
- one specialist hospital (177 beds and spaces);
- one private non-profit healthcare organisation (279 beds and spaces);
- one private healthcare organisation (180 beds and spaces).

▲ In order to understand cases where a reservation is maintained from one cycle of accreditation to the next: Twenty-five (25) files from organisations with a V2 reservation in the two fields most commonly affected by renotifications in V2010, medication management and patient records. These files were selected randomly.

<table>
<thead>
<tr>
<th>Situation</th>
<th>Result of V2 follow-up + renotification in V2010</th>
<th>Patient records</th>
<th>Medication management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reservation removed and not renotified</td>
<td>Medical, surgical and obstetrics clinic 145 beds and spaces</td>
<td>General hospital 250 beds and spaces</td>
<td>Private non-profit HCO Cancer centre 185 beds and spaces</td>
</tr>
<tr>
<td></td>
<td>General hospital 867 beds</td>
<td>General hospital 180 beds</td>
<td>Rehab clinic 220 beds and spaces</td>
</tr>
<tr>
<td>Reservation removed and renotified as</td>
<td>General hospital 698 beds</td>
<td>Private non-profit HCO 194 beds</td>
<td>General hospital 700 beds</td>
</tr>
<tr>
<td>recommendation</td>
<td></td>
<td>General hospital 325 beds</td>
<td>General hospital 175 beds and spaces</td>
</tr>
<tr>
<td>Reservation removed and renotified as reservation or major reservation</td>
<td>General hospital 1,263 beds and spaces</td>
<td>Maternity clinic 94 beds and spaces</td>
<td>General hospital 175 beds and spaces</td>
</tr>
<tr>
<td>Reservation changed to recommendation and renotified as recommendation</td>
<td>General hospital 800 beds</td>
<td>General hospital 492 beds and spaces</td>
<td>Local hospital 40 beds</td>
</tr>
<tr>
<td>Reservation changed to recommendation and renotified as reservation or major reservation</td>
<td>General hospital 824 beds and spaces</td>
<td>Medical, surgical and obstetrics clinic 113 beds and spaces</td>
<td>Local hospital 40 beds</td>
</tr>
<tr>
<td>Reservation maintained and renotified as reservation or major reservation</td>
<td>General hospital 824 beds and spaces</td>
<td>Private non-profit rehab clinic 25 beds</td>
<td>Medical, surgical and obstetrics clinic 142 beds</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>General hospital 117 beds</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>General hospital 321 beds</td>
</tr>
</tbody>
</table>
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