Haut Conseil de la Santé Publique

Assessment of the 2013-2017 National Patient Safety Programme

Collection
Evaluation

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The 2013-2017 national patient safety programme (NPSP) is the first programme in France to take a cross-cutting approach to patient safety throughout the patient's journey. Underpinned by ambitious targets mainly the improvement in the safety culture of all stakeholders including the users, this programme has enabled a strong regulatory framework to be defined, with the drafting of legal texts and development of educational guides and tools by the French National Authority for Health (HAS). The evaluation concerned three priorities of the programme (1: information for patients, getting patients actively involved in their safety; 2: improving the declaration and treatment of adverse events associated with care; 3: training, safety awareness, healthcare organization support). The evaluation of the NPSP by the HCSP proposes recommendations for the future patient safety policy, organized across 3 priorities:
1) promoting new targets for developing patient safety,
2) pursuing a highly-visible structured patient safety policy,
3) determining the terms behind the future governance of the patient safety policy.
These recommendations particularly bear on consolidating the adverse event reporting systems, continuing to develop common culture of patient safety and improving communication.
Given the current public health challenges, the HCSP urge for a swift follow-up to the 2013-2017 NPSP.

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Haut Conseil de la santé publique
14 avenue Duquesne
75350 Paris 07 SP
www.hcsp.fr

Summary note of the assessment of the 2013-2017 National Patient Safety Programme

The 2013-2017 NPSP's coherence and relevance

The coherence and relevance of the National Patient Safety Programme (2013-2017 NPSP) general and operational goals were analysed by means of five evaluative questions. The analysis resulted in the following four main findings:

- The absence of any specific goal and monitoring indicator as regards reduction of anticipated risks;
- A high relevance of goals, which aimed at overall development of a safety culture of patients and professionals;
- A design stage that did not enough involve primary care and medicosocial sectors;
- The drafting of a programmatic document (rightly called "programme" rather than "plan"), a reference text composed of actions whose granularity and timescales are heterogeneous.

These actions would appear to be relevant and useful overall, even though they are almost impossible to assess without predefined monitoring indicators. The coherence between the different NPSP focuses assessed was limited by the fact that involvement of patients, training and experience feedback might rather have been regarded as crosscutting to all focuses. External coherence in terms of links between the 2013-2017 NPSP and other existing programmes and schemes related to patient safety (health surveillance programmes, medicinal and healthcare-associated infectious risks in particular) was not particularly explicit. Lastly, international comparisons with initiatives carried out show marked differences compared with France: specific risk reduction goals, an integrated overall approach combining quality with safety, prioritisation of goals, assessment by predefined crosscutting indicators, and a communication plan defined *a priori*.

Implementation and observed effects of the 2013-2017 NPSP

In the absence of monitoring indicators and goals specifying expected improvements, findings are based on actors' perception of implementation of three of the NPSP's four focuses. The various health professionals and patient associations interviewed considered that they had not been sufficiently informed or involved, and were therefore not really committed to the programme. This suggests that the national programme did not succeed in bringing about convergence of or greater synergy between the various safety cultures inherent to each profession, "corporate cultures" that are still all too frequently compartmentalised, as they are in initial training courses, and still largely unfamiliar with crosscutting approaches to risk management during a patient's care pathway. Hence, the ways in which the programme's goals and measures were communicated were seen as inadequate. The result was a lack of information and appropriation from concerned stakeholders, a weak point of the programme.

More specifically,

• Focus 1 of the programme (the patient as an actor of his/her health) was seen as useful and ambitious as its aim was a far-reaching radical cultural change: bringing about "a culture of partnership" that went beyond the "patient-centred" model, turning patients and, more generally, users into health professionals' partners, including in the area of safety. Acknowledged emblematic measures, such as the annual implementation of a "patient safety week" in November and making communication tools

available, were highlighted. The goal of better informing and involving patients and users on the quality and safety of care does not seem to have been achieved, except for the most well informed individuals belonging to associations with knowledge of actions carried out in the context of the 2013-2017 NPSP.

• Focus 2 enabled publication of the Decree on adverse events (AEs) issued in late 2016 with the mandatory reporting of the adverse events (events resulting in death, or life-threatening conditions or definitive incapacities) occurring in healthcare and medico social organisations and in primary care. The opening of the national unique reporting portal in March 2017 (for these AE reports, along with the vigilances and the patient's reports) was too recent to enable any assessment to be made, as data on numbers of reports recorded in 2017 was not available at the time the High Council for Public Health (HCSP) drew up its assessment report. The scheme was seen as a sign of progress by most of the actors involved, who nonetheless highlighted the ambivalence of the role of the Regional Health Authorities (ARS), sometimes experts, sometimes patient safety regulators. By interviewing medical actors in the community during the HCSP evaluation, this web reporting access was not known and used by a large majority of general practitioners.

• Focus 3 was largely devoted to training courses: funding of training on feedback and medical simulation, regulatory texts aiming to bring additional content on risk management and non-technical skills into medical and paramedical initial education and continuing professional development (CPD), translation of the World Health Organisation's (WHO) Patient Safety Curriculum Guide, consolidation of regional support structures (SRAs) and creation of Regional Vigilance and Support Networks (RREVA). Among the less advanced actions, the assessment report cited insufficient development of tools and methods for teamwork, despite the promising Programme for Continuous Improvement in Teamwork (PACTE) National Authority for Health (HAS) experimentation, which has been recently assessed, and the inadequacy of CPD programmes' risk management content, which does not enable public health institutions to take a full part in the initiative.

Management of the 2013-2017 NPSP

As regards management, initial pioneering of the 2013-2017 NPSP, mainly under the aegis of the Ministry of Health's departments, prioritised definition of a robust regulatory framework, with drafting of decrees, orders and instructions, and development by the HAS of various educational tools and guides intended for actors in the field. Creation of a regulatory corpus constitutes a founding structural phase that forms part of the State's sovereign missions. The programme's ambitious goals and their practical implementation should have required strong regional representation, with organisation of actions better shared between ARS and in collaboration with leaders and champions identified at the local level. There was certainly not enough time to further develop this implementation phase in collaboration with regional support committees or institutes.

There are significant disparities between regions as regards levels of implementation, organisation and maturity of integrated patient-safety policies. This finding might have been avoided by a close coordination at national level by the Ministry of Social Affairs' General Secretariat, which is in charge of coordinating ARS actions, and the organisation of regular exchanges devoted to sharing experiences and pooling of promising initiatives between ARS teams.

Finally, we do regret the lack of monitoring of process and of result indicators, either nationally or regionally. Such monitoring would have enabled objectification of the programme's impact on patients

and their treatments in a period marked by far-reaching organisational changes in the healthcare system, major budgetary constraints and drafting of the Health System Transformation Strategy (STSS).

Taking account of territorial and social inequalities

The 2013-2017 NPSP did not include any specific goals or actions designed to reduce unidentified social and territorial inequalities. Such inequalities remain largely undocumented in France's health system. A fortiori, assessment of the programme could not include the implementation or impact of such actions.

Recommendations for a future patient safety policy

These recommendations are based on the assessment of the 2013-2017 NPSP and also take the present context into account. The current STSS priorities emphasise the concepts of quality and appropriateness of care and do not set goals for reduction of care-related risks, at the risk of being perceived as step backwards in healthcare safety.

Epidemiological data (20,000 to 30,000 deaths potentially related to adverse events associated with care (EIASs) every year in France) show that patient safety is still a major public health issue.

The assessment of the 2013-2017 NPSP indicates that France is "in midstream": it has developed a robust framework (regulatory texts, tools and methods) that remain little known and largely unintegrated into the practices of most health professionals.

The HCSP has issued three types of recommendations:

• Promoting new goals to develop patient safety

• Implementing a robust public policy on patient safety

• Determining methods for future governance of the patient safety policy

Promoting new goals to develop patient safety

Reinforcing focused approaches in order to reduce incidence of AEs

Continuing and assessing existing focused safety programmes, in particular the programme on prevention of infections associated with care (PROPIAS 2015) and actions with regard to radioprotection

Further securing drug-related safety program proposed by the ministerial order of 8 April 2011, extending it to the patient's global pathway (see below recommendation on pathways), prioritising risky medicines and therapeutic classes that appear most involved in avoidable AEs, developing patient communication, information and education that take full account of degrees of health literacy, improving interprofessional organisation and collaboration, in particular at the level of pathway interfaces).

Developing a new focused policy on the safety of invasive procedures (the prevention of risks associated with invasive procedures should be taken into account from the point of view of the global patient's

pathway as there is considerable room for improvement in treatment prior to and following such procedures ("accompanying the ambulatory shift"), developing the appropriateness assessment with invasive procedures (respect of indications, stages and treatment deadlines, etc.) and the outcome measurements of such treatments (mortality, rehospitalisation, patient experience indicators, adverse events, etc.), implementing an overall approach to risks related to invasive procedures, rather than the current main focus on risks of infection.

Systematising a safety component in the preparation (biomedical research and authorisation of activity) and implementation of technological and organisational innovations, including digitisation of care, telemedicine and new mechanisms for coordination of care that generate new risks.

Incorporating safety questions into patients' pathways

Systematically including a care safety component in definition of the organisation and operation of pathways: HAS and Health Insurance recommendations production, regulation of healthcare organisation activities by the ARS, and experiments (Article 51 of the 2018 Social Security Funding Law provides for innovative forms of funding, overriding current pricing rules, for "innovative organisational experiments in the health system", such as coordination of health pathways, appropriateness and quality of healthcare, social and medicosocial treatment, etc.).

Fostering patients' involvement (stepping up patient education using flexible simplified methods, medical training in active listening and in, shared medical decision-making, co-construction, etc.)

Building on drug safety in order to promote patient safety along the health pathways (drug safety is deemed to be a relevant model, combining a complex process, numerous actors, fragile interfaces and the need for an efficient information system).

Consolidating the system for collection and processing of data on adverse events

Developing experience feedback (in all sectors, not only for AEs, by adapting methods for private healthcare and medicosocial settings, including patients' stories, and ensuring conditions for better AE identification and recovery).

Improving channels for declaring AEs to ARS (reviewing the scope of AEs, prioritising "short channels" for AE management, and ensuring coherence between declaration channels and health surveillance programmes.

Distinguishing technical support from health inspection as regards patient safety at regional level (independence of regional support structures (SRA) from ARS, better explanation of the use of inspection/monitoring missions).

Involving academic groups, national professional colleges and patients' and users' associations more closely in analysis of national data

Continuing development of a common culture of patient safety

Reviewing the pertinence of the fault-based medical liability system. Other countries (Denmark, Sweden, Norway, Finland and New Zealand) have opted for a fault-free liability system in order to encourage declaration and analysis of EIAS (in France, this latter system only covers compensation for

fault-free medical accidents managed by the National Office for Compensation of Medical Accidents: ONIAM). A development of a fault-free liability system in French law would encourage medico legal expert assessment less focused on health professionals' personal responsibility and, as in management of care-related risks, would take account during their investigations the contributory factors, human and organisational, related to the occurrence of AEs, the use of scientific data.

Homogenising and "multi-professionalising" training courses: homogeneous content – terminology, tools, non-technical skills – in addition to the WHO guide – included in training reference frameworks for all health professionals, creation of a "reference" remote training programme, multi-professionalism and joint training between patients, care providers and decision-makers, and better integration of the health simulation offer between university hospital centres (CHU) and universities.

Carrying out a nationwide survey on safety culture in the three health sectors (hospital, social healthcare institutions and private medicine) and developing/stepping up actions in the wake of its results.

*Complying with the non-punishment agreement ("*charte de non-sanction"*) following the reception of a report, in particular in healthcare organisations*

Co-developing mechanisms and assessments with patients (design of mechanisms and experiments concerning appropriateness/quality/patient safety, and pilot projects for involving users' representatives in risk management).

Developing research on patient safety

Implementing a strategy for development and support to research on patient safety, in the context of research on health services, and identifying priority themes (e.g. patients' and users' involvement in research, measurement of territorial and social inequalities with regard to patient safety, study of connections between risks and the "ambulatory shift" in medicine and surgery, development of indicators based on the National Health Data System (SNDS), and new tools for professionals adapted for the primary care and the medicosocial sector).

Implementing a robust public policy on patient safety

The choice of framework for implementation of the goals and actions recommended above, whether to define a strategy specifically devoted to patient safety or include it as part of the STSS, is a matter for political decision.

The first approach would assert the coherent, overall nature of patient safety, with its own governance, at the risk of dissociation with the current STSS focuses (quality and appropriateness of care, funding and remuneration, digital technology, human resources and training, and territorial organisation); the second approach would have the advantage of staying in coherence with current policy frameworks, the STSS in particular along with regional health programs (PRS), but would risk watering down the theme of patient safety (spread thin in the STSS, and very much in the background compared with appropriate care goals; no risk reduction goals are included in the strategy).

Determining methods for future governance of the patient-safety policy

Involving all stakeholders but ensuring tight management at national level

In order to gain in effectiveness and responsiveness, all decision-makers involved should be brought together on a single select steering committee (central administration directorates, HAS and Health Insurance) to develop dialogue mainly based on opinions and problems encountered by all stakeholders (identifying venues for dialogue before, during and after implementation of measures), and, lastly, draw on pluralist and multiple expertise.

Organising more fully devolved project management

In order to ensure greater local ownership: national management based on strategic guidelines, definition of goals and action programmes adapted at ARS (regional) level, and national coordination of ARS.

Defining methods for monitoring and the necessary information system beforehand

In order to monitor and assess: definition of quantified risk reduction goals, measurement methods (use of the SNDS), including indicators covering patients and users, useful measures at national and regional/territorial level, and methods for monitoring actions and budgets.

Improving communication on patient safety

In order to ensure wider knowledge: definition of a multiannual communication plan (drawing on the results of the 2019 National Survey on adverse Events during Hospitalisation (ENEIS)), promotion of actions, major initiatives and lessons learned from declarations of adverse events related to care, and communication of results on achievement of goals and implementation of actions.

Conclusion

These recommendations, some of which go beyond the traditional scope of patient safety, show the evolution of knowledge on scope and conditions of patient safety. The same vision is shared at international level. The stakes at play in public health suggest that there should be a rapidly implemented follow-up to the 2013-2017 NPSP.

Implementing a robust public policy on patient safety, as cited in one of the recommendations. This could take one of two forms: defining a strategy specifically devoted to patient safety or including it as a component of the STSS, a choice to be made via national political decision. The choice should be guided by a determination to maintain high visibility on patient safety while ensuring its continued inclusion in all initiatives for transformation of the healthcare system.