



5TH ANNUAL CONGRESS Bridging the gap for a safer care

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The communication of care-associated harm: An essential component of the quality system

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HAUTE AUTORITÉ DE SANTÉ



The objectives

- Identifying situations needing a disclosure
- Position of the disclosure within the quality improvement system
- Sharing practices
- Realizing what « what not to do » after a care-associated harm event
- Improving communication
- Reminder of the rules of good communication



The program

- What are we talking about?
- Why define the disclosure rules?
- Why is it important and difficult to communicate in case of a care-associated harm?
- Presentation of a clinical situation
- How to communicate in case of a care-associated harm?
- Presentation of a satisfactory disclosure
- Special cases
- Tools



01

What are we talking about?



The French context

1. Prevalence of serious adverse events (leading to the extension of hospitalization, to a handicap or to the patient's death)
 - Between 275 000 et 395 000 SAE/year during an hospitalization, among which 95 000 to 180 000 are considered as avoidable ($\approx 40\%$) (ENEIS, 2010)
 - or 753 to 1 082 SAE/day
 - or 1 SAE every 5 days in a 30 beds unit
2. A significant proportion of patients' complaints are related to a communication problem
3. A high expectation of patients :
 - To know
 - To understand
 - To be informed



The French context

4. An regulatory and ethical obligation

- L'article L.1142-4 du CSP: «Any person who is victimized or who is the victim of an injury ... shall be informed by the professional, healthcare establishment, health service or organization concerned of the circumstances and causes of the damage. This information shall be delivered to him no later than 15 days after the discovery of the damage or his express request ... ‘
- Article 35 of the Medical Code of Ethics stipulates that: "The physician shall give the person to whom he examines, he cares for, or provides advice on fair, clear and appropriate information about his condition, investigations and care, he suggests. Throughout the illness, it takes into account the personality of the patient in his explanations and ensures their understanding. “

5. A HAS Certification Criterion that demonstrates some difficulties:

- Criterion 11c "Patient information in case of care-related harm" is the 3rd criterion most affected by decisions (37 decisions). It falls under the criterion "Quality management of the patient's medication management" and "Management of the patient's file"

→ A gap to be corrected



02

Why define the disclosure rules?



Which adverse events?

- Every adverse event which leads to a physical or psychological harm
- It does not concern only medical malpractice, but also:
 - complication linked to the pathology of the patient,
 - therapeutic hazard

→ The seriousness of the harm should always be considered from the patient's point of view and not from the professional's who could be tempted to minimize the consequences



The objectives

- Meeting the legitimate expectations of the patients with a care-associated adverse event
- To calm relations between caregivers and patient
- To reassure and accompany ALL care caregivers (medical and para-medical) to express the « difficult to say »
- To develop a safety culture:
 - Approach risk management not only in terms of prevention, but also in terms of recovery
 - Culture of transparency
 - Culture of learning by mistakes



Disclosure of a care-associated harm and risk management

- Communication and transparency, an approach within a policy in healthcare risk management

- Reporting adverse events
- To analyse adverse events in a systemic way (taking into account all aspects of the health system)
- To learn from mistakes
- To implement a collective approach
- To improve the professional practices (action planning)



Example

- JF is about to deliver her second child / No problem during pregnancy
 - In the delivery room: suspicion of fetal distress → the staff informs that a C-section will be performed and asks the husband to come back the day after
 - Suddenly, before initiating the C-section: hemorrhage,
 - The day after, the patient, crying, says to her husband : « I don't know what happened. I've been taken to the OR. I've heard a scientific word which I didn't understand »
 - The husband asks a nurse: « Well, she had an hysterectomy! »
 - When the doctor comes, the couple wants to understand what hysterectomy is: « that's what we had to do, there was a hemorrhage, it's the good practice in such a case. »
 - Back home, the patient finds out on internet what an hysterectomy is.
 - The patient asks the doctor for more explanations: the answer is the same but with an irritated tone
- **The couple initiates proceedings**
- The medical expert, designed by the institution takes some time to explain that the hemorrhage was so severe that without the hysterectomy, the patient would have died and there was no alternative for the medical team.
- **Termination of proceedings but the couple didn't understand why it had been necessary to go this far...**



03

Why is it important and difficult to communicate
about a care-associated harm?



Why is it important?

- The consequences of the harm increase the patient's vulnerability
 - The expected improvement of their health condition is not effective
 - The consequences can be physical but also psychological, social or material
 - The patient will express complex and various emotions: loss of confidence, anxiety, anger, frustration...
 - The patient expresses expectations
 - To obtain a recognition of the harm they have experienced
 - To understand what happened and what will be the consequences
 - To understand why the event happened
 - To be sure that corrective actions will be implemented to avoid the recurrence
- ➔ To allow the patient to repair
➔ 3 key words: transparency, empathy, listening



Why is it difficult?

- The caregiver-patient relationship is complex
- Health professionals are not trained in how to give patients information after injury
- Particularly following a mistake, health professionals will manifest inhibitory emotions:
 - Guilt, shame, frustration, feeling of failure, fear of the "look" of others
 - ...
...
- Healthcare professionals fear being taken to court



The benefits

- To inform the patient allows to:
 - Calm the relation between caregivers and patient: the patient's needs are considered and professionals feel relieved
 - Project a positive attitude: professionals are involved in a continuous improvement process
 - Reduce the need to court proceedings (experience of Michigan Health System)

(Source: Rodham Clinton I, Obama O. Making patient safety the centerpiece of medical liability reform. *N Engl J Med* 2006; 354(21):2205-8.)



04

Presentation of a clinical situation



Presentation of clinical situation - Discussion (10')

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→ Expose any experience of harm and/or disclosure



05

Presentation of a disclosure



Presentation of a disclosure

- Buzz group (20')

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- Organise sub-groups
- Identify a rapporteur for each sub-group
- Interactive discussions on what was problematic
- Interactive discussions on how to improve



06

How to communicate?



Upstream (1)

- Implement a disclosure policy:
 - Formalized and distributed in coordination with all actors
 - Supported by the policy of care quality and safety improvement
 - Organises the system and the structures to be created
 - Informs the professionals about the objectives and the steps to follow
 - Identifies available resources
 - Organises support for professionals

➔ Transparency and climate of trust to promote the reporting of adverse events, their analysis and implementation of corrective actions.

➔ Charter of non-punishment / of commitment of reporting
- Communicate this policy
 - ➔ To professionals
 - ➔ To patients (welcome booklet)



Upstream (2)

- Training (initial and continual skills) → communication skills
 - Active listening
 - Empathy
 - Communication in difficult situations
 - Recognition and management of one's emotions
 - Anger management
 - Behaviour towards a colleague involved in a care-associated harm and needing support
- Theoretical and practical training
 - Training and simulation sessions
 - Peer analysis groups



After the occurrence of a care associated harm

- The 3 phases of disclosure:
 - Before
 - During
 - After



Before disclosure (1)

- Clinically manage the patient to mitigate the consequences of the event and ensure continuity of care
- Gather all available information (the entire multi-professional team)
- Inform the administrative and medical management and risk management coordinator of the establishment

→ Internal meeting to prepare the disclosure as soon as possible after adverse event

→ Taking into account the level of emergency



Before disclosure (2)

- Prepare the interview with the patient:
 - What facts are we sure of?
 - Who will lead the interview?
 - Who will attend the meeting?
 - When and where will be the interview?
 - What are the foreseeable needs of the patient?
 - Inform the patient that a meeting will be organised about his care without disclosing the content

→ The patient must be informed before the meeting about the people who are expected to attend give his / her agreement



The disclosure (1)

- Why?
 - To inform
 - To support
 - To heal
 - To consolidate the relationship



The disclosure (2)

- Who?
 - It depends on the type of the adverse event (medical error, complication related to the pathology of the patient,...), on the health facility policy, on the degree of upheaval of professional involved, the severity of the harm...
 - Usually, the doctor in charge of the patient is the most likely to make the announcement and conduct the interview
 - According to the type of adverse event and to the procedure, other professionals can attend the meeting:
 - Nurse or other paramedical professional
 - Resident or student involved
 - Manager, patient rights Ombudsman, member of the medical committee, risk manager, member of patient rights committee, ...
- In all cases, the meeting should be conducted by a medical doctor
 - 2 to 3 people + the patient + possibly the patient's next of kin



The disclosure (3)

- Where?
 - In a quiet, comfortable, protecting confidentiality and if possible dedicated place
 - With no phone
- People should not be interrupted



The disclosure (4)

- When?
 - As soon as possible, preferably within 24 hours after the detection of the adverse event,
 - At latest, 15 days after in accordance with Article L.1142-4 du Code de la santé publique
 - Immediately with the next of kin in case of death
- As soon as the physical and psychological condition of the patient allows
- Allow sufficient time



The disclosure (5)

- Behavioral skills:
 - Understandable language (\neq medical jargon)
 - Empathy,
 - Listening,
 - Body language (gestures, attitude, facial expressions, tone of the voice, rythmn of speech, dress, ...)
- Sincerity and predisposition to listening
- Balanced dialogue: exchange, listening
- Allow the patient to express his/her emotions



The disclosure (6)

- Introduction of attending professionals
 - Identity
 - Function
 - Why they are here



Disclosure (7)

- Recognition of the harm
 - Synthesis of the medical history (reason of the admission, objectives, care provided)
 - Make the patient feel he/she is the object of attention and interest on both physical and psychological levels
- **Sincerity et empathy « We regret you had such a difficult experience »**
- Description of known and certain facts → « Here is what happened and what that means for your health... »
 - **The patient must understand what happened to him/her and what are the implications**



The disclosure (8)

- Expression of regret
 - Key element of the disclosure process which confirms the recognition of the harm and contributes to building a relation of confidence →
« We wish to tell you how much we're sorry, we didn't expect this »
- Apology in case of medical or care malpractice
 - Ethically responsible, respectful and human behaviour
 - ≠ medico-legal responsibility
 - Avoid « I apologise, it's my fault »
 - Prefer « I apologise for what happened »



The disclosure (9)

- Organise the continuity of care in coordination with the patient
 - Which professional ?
 - Where ?



The finalization of disclosure

- Propose ways of supporting according to the needs and the expectations of the patient
 - Medical
 - Psychological
 - Social
 - Spiritual
 - Material ?
 - Organise the following meeting
 - Identify a focal point and provide contact information
 - Follow-up of the file
 - Information of the patient
 - Response to patient
 - Indicate remedies
- Check that the patient has no more questions



After disclosure

- Document the meeting in the medical records
- Inform the staff → organise a meeting
 - Propose a support group
 - Facilitate the expression of emotions
 - Organise the continuity of care
 - Identify corrective actions
- Ensure the follow-up of the file (focal point)
- Monitor corrective actions



After disclosure (2)

- Organise the follow-up meetings if necessary (focal point)
 - Give the information which was missing at the first meeting
 - Give the investigation results
 - Describe the corrective action plan
- Document every meeting in the patient medical record
- Organise the link with the General Practitioner
- Give feedback to the staff
- Evaluate the approach
 - Has the patient been well informed?
 - What could have we done better?
 - What is the impact for the patient? For professionals?
 - Indicators ? (to be discussed)



06

A satisfactory disclosure



Presentation of the disclosure - Discussion (10')

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- What is essential ?
- What is missing ?
- ...



06

Special cases



Immediate disclosure

- In case of an adverse event leading to emergency actions (error of surgical site, medication error, perforation during endoscopy,...) → immediate disclosure by professionals present and plan a second interview to reiterate the information in a quiet environment
- Risk : using inappropriate language

→ Identify risk situations and use simulations to train



Disclosure of a harm caused by a third part

- In case of harm caused by other professionals, in other health facilities or by a product prescribed by another medical doctor
- Same approach without criticising the involved professional and without speculating on possible responsibilities
- Involve, if possible, the professional previously in charge of the patient
- In any case, inform the professional previously in charge of the patient



Disclosure in case of serial events

- Adverse events with impacts on several persons (radiotherapy overdosage, inappropriate endoscope disinfection, ...)

→ **Special procedure depending on**

- The risk and the criticality
- The organisation set-up to identify the patients involved
- The action plan

→ **Planification**

→ **Public disclosure if necessary**



Disclosure in case of death

- Major emotional burden
- Genuine traumatic experience especially in case of unexpected death
- Denial → anger, aggressiveness, blame

- Call the relatives
- Deal with the body with respect
- Welcome the relatives in a personalised and caring way
- Announce the death to the relatives (MD)
- Giving people a voice and letting them express themselves (anger)
Express regrets and offer condolences (team)
- Inform about required formalities
- Inform the GP (personalised letter)



07

Tools



Guide

AMÉLIORATION DES PRATIQUES ET SÉCURITÉ DES PATIENTS

Annonce d'un dommage associé aux soins

Guide destiné aux professionnels de santé exerçant en établissement de santé ou en ville

Mars 2011

4 pages

AMÉLIORATION DES PRATIQUES ET SÉCURITÉ DES PATIENTS

Annonce d'un dommage associé aux soins

L'annonce d'un dommage associé aux soins consiste avant tout à établir un espace de dialogue entre soignant et patient visant à maintenir ou restaurer une véritable relation de confiance. Elle s'inscrit également plus largement et durablement dans une démarche d'amélioration des pratiques professionnelles, contribuant ainsi au développement d'une culture de sécurité des soins.

Pour en savoir plus, le guide est disponible sur www.has-sante.fr

The tools (2)

Comment annoncer un dommage associé aux soins

Les 3 temps de l'annonce

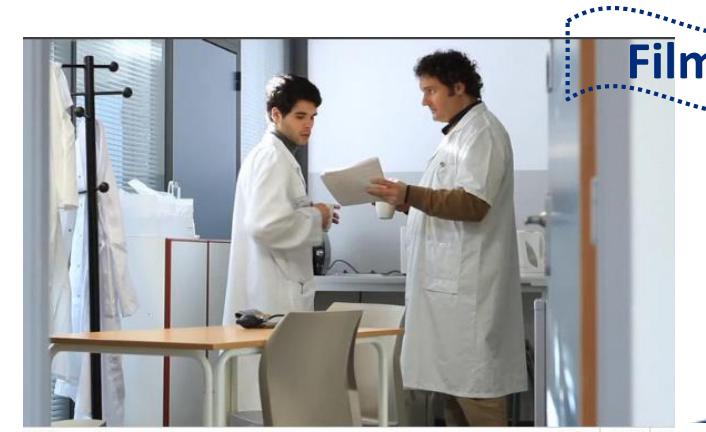
- 1 Préparer le rendez-vous d'annonce**
 - Quels sont les faits dont on est sûr ?
 - Qui assistera au RDV ?
 - Quand et où se tiendra le RDV ?
 - Quels sont les besoins prévisibles du patient ?
- 2 Réaliser l'annonce**
 - Répondre aux attentes et aux besoins légitimes des patients
 - Communication avec empathie, sincérité et honnêteté
 - Prendre en compte l'entourage du patient
 - Réassurer et accompagner les professionnels de santé
 - Respecter la confidentialité
 - Respecter l'individualité du patient
- 3 Suivre l'annonce**
 - Informer le patient des nouveaux éléments connus
 - Expliquer de nouveau des regrets voire des excuses en cas d'erreur avérée
 - Mettre en œuvre les offres de soins et de soutien proposées
 - Organiser avec le patient les soins d'aval
 - Tracer les rendez-vous de suivi dans le dossier médical

La relation avec le patient

- Quelques repères
- Représenter les patients
- Respecter la confidentialité
- Respecter l'individualité du patient

Maintenir confiance et dialogue

Pour en savoir plus, [Guide Annonce d'un dommage associé aux soins](#) sur www.has-sante.fr



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