Annex B

CONSULTATION QUESTIONNAIRE

Question 1:
Do you agree that the arrangements that should be in place to support an organisational duty of candour should be outlined in legislation?

Yes ✓ □

Comments

- ‘Patients First’ is a UK wide, network of health professionals; nurses, doctors, managers, other staff and their supporters whose purpose it is to reduce death and harm in the NHS by campaigning for Governments to create policies and laws that ensure the NHS becomes open and fully accountable.
- Peter Walsh, CEO, Action against Medical Accidents, recently wrote, “I believe that the introduction of the new duty of Candour is potentially the biggest advance on patients’ rights in the history of the NHS. It stems from the experience and priorities of patients and families, who have suffered avoidable harm and not been told the truth.”
- Doctors, nurses and midwives working in the UK are governed by GMC and NMC standards which requires ‘registrants to be candid with people harmed by their practice.’
- One of the key principles of 2013 NHS Scotland National Framework for dealing with adverse events is ‘Openness about failures - errors identified, reported and managed in a timely manner and patients/families told what went wrong in a timely manner.’
- Proposal [notes 2.1] quote international figures – only 30% of between 10%-25% adverse events are disclosed to patients.
- If we assume, figures for NHS Scotland are somewhat similar, then clearly despite GMC & NCM moral and ethical standards and NHS codes of conduct re. probity, a wide gap exists between incidents and the reporting of them.
- Peter Walsh also says, that patients/families who have suffered harm, “have been devastated almost as much by the lack of honesty as by the event itself.”
- The Scottish Government [notes1.3] recognises that a number of barriers exist to being open after adverse events have occurred, including lack of institutional support.
- The way forward, must be, for organisations to establish an ethical culture and system in which all patient safety incidents are openly and honestly reported, investigated and analysed with shared learning to follow.
- We have learned from enquires into recent NHS scandals that frontline staff did not feel safe in coming forward to report mistakes or abuse, and all too often the organisations concerned were wilfully blind and dishonestly complicit in covering up harm, suffered by patients.
- Many NHS scandals have featured whistleblowers, whose honestly held concerns have been ignored, whilst they themselves have been victimised by NHS organisations, in Scotland as well as elsewhere.
- Patients First actively supports all those who raise concerns about patient safety. All NHS healthcare professionals should be free to raise patient care and safety concerns without fear of impact upon their careers or other retribution.
- If, under the current system, NHS organisations cannot all be trusted to put patient safety first, legislative action, such as the proposed statutory duty of candour, must not just be put in place but must be enforced by the Scottish Government, to ensure that all do fully comply with patient safety regulations.
- N.B. Re.2009 study of reporting of patient safety incidents from all acute hospitals in England. [Hutchinson,Young et al]

Conclusion:
Incident reporting rates from acute hospitals increase with time, from connection to the national reporting system, and are positively correlated with independently defined measures of safety culture, higher reporting rates being associated with a more positive safety culture.

Question 2:
Do you agree that the organisational duty of candour encompass the requirement that adequate provision be in place to ensure that staff have the support, knowledge and skill required?

Yes ✓ □

Comments

NHS Scotland organisations will have to:

- Jointly review their current policies and risk management procedures, to determine where and how existing clinical governance systems need to be strengthened and/or create additional policies dealing specifically with being honest with patients or service users when things go wrong.
- NHS Boards and Management at all levels, will have to be fully committed to implementing the organisational duty of candour and to lead from the front by driving forward a NHS reporting, analysis and learning culture based on openness, honesty and transparency, which for some NHS Scotland organisations will demand revised thinking and in some cases a shift from a defensive position, where organisation reputation has at times, come before patient safety concerns.
- GMC has issued a joint statement with other regulators, setting out a professional duty of candour. In addition the GMC, is currently working, together for the first time, with the NMC on joint guidance to doctors, nurses and midwives on what a duty of candour will mean in practice – to be published March 2015.
Many front-line staff will no doubt feel apprehensive about what a contractual duty of candour exactly means in practice and how it impacts on their current ethical duties. There may be concerns about admitting medical errors and a blame culture or from the past treatment of whistleblowers, understandable concerns about raising patient safety issues and possible damage to future careers.

In addition to guidance on duty of candour thresholds, procedures and training in skills needed to deal with patients/families, structures must be in place to support clinical and other staff in all aspects of managing patient safety issues, confident in the knowledge that from now on there will organisational support, which is absolutely essential if lessons are to be learned from mistakes.

Clearly frontline staff will be distressed when incidents of harm occur to patients in their care.

In an article, Dr. Stephanie Brown, director of policy at MPS, says that in a survey of members, 70% said they received no or limited support when a mistake was made.

Duty of candour legislation, must ensure that staff can depend on full organisational support at all stages.

- **Summary:**
  - Codes Employee Conduct [ including Board, Non-executive & Executive, & senior management ] - Deliberate non-adherence to duty of candour regulations added to list of gross misconduct.
  - Training throughout the organisation with patient involvement.
  - Board & senior management – leading implementation from the front and by example of high standards expected, developing a more open culture where incidents are reported, investigated, analysed and openly discussed locally and nationally.
  - Review relevant clinical governance procedures – additional policies if required to be in line with other NHS organisations.
  - Nationally agreed standard systems and monitoring processes put in place.
  - Named ‘duty of candour ’ leads [accountable internally to named non-executive lead Board member] - to plan, inform & monitor throughout the organisation, feedback internally and share lessons learned externally with other organisations and report to relevant external regulator.
  - Staff advice & training – knowledge and interpretation of duty of candour regulations, training in skills on managing and investigation of patient safety incidents, including skills in communicating with patients/families, information on advocacy support systems provided for staff.
  - Organisations accountable to Scottish Government.

**Question 3a:**
Do you agree with the requirement for organisations to publicly report on disclosures that have taken place?

- **Yes ✓**

**Comments**
- NHS Scotland can only gain and maintain public trust if organisations and services are fully open, honest and transparent when things go wrong.
- As proposal [note 8] : NHS organisations should each:
  - Report publicly on duty of candour training and support systems, which they have put in place.
  - Mindful of patient confidentiality, disclose according to the agreed frequency, the number and level of disclosable incidents which have triggered a duty of candour response,
  - Share locally and nationally, learning outcomes and steps put in place to prevent similar incidents in the future.
  - Patients/families should be notified when their case has been publicly disclosed.

**Question 3b:**
Do you agree with the proposed requirements to ensure that people harmed are informed?

- **Yes ✓**

**Comments**
- If a statutory duty of candour is introduced, the public must be fully informed about what changes mean and what patients/families can expect from the NHS should a disclosable incident occur. There must be two-way communication in which patients/families are listened to and opinions respected.
- The Patients Rights [Scotland] Act 2011/2012 summaries a patient’s rights and responsibilities. Amongst many other things, patients have the right to expect care and treatment carried out according to recognised clinical guidelines and standards, to expect prescribed medicines to be appropriate, the right to be given clear communication about care and treatment and to be treated with dignity and respect.
- The Act states that patients have the right to be told the outcome of any investigation into concerns or complaints.
- **NB.** However, there is no direct mention in the Act of a patient’s right to be told when harm has occurred during their care.
- If information about harmful care or treatment has been withheld from patients, the above rights have been contravened. Having a right to be told the outcome of an investigation is worthless if patients are unaware that mistakes have been made or are deprived of full facts, affecting possible courses of action.
- If a statutory duty of candour is passed, patients’ rights to be told about harm, would need to be added to the list in the Patients’ Rights Act.
• Even if it is not possible to remedy the harm, being told the whole truth would give patients/families a degree of satisfaction and generally increase public confidence in a more honest and transparent NHS Scotland and end speculation about cover ups.
• Some advocates of a statutory duty of candour are of the opinion that if patients/families are told the truth, it will lead to a reduction in compensation claims against the NHS but in some cases the information given, may prompt others to do so.
• NB. A criticism of a report, commissioned by the UK secretary of State for Health, Jeremy Hunt, is, what is in the small print ie. the March 2014, report suggests that the Government looks at ways, to minimise the possibility that explanations given to harmed patients by medical staff can subsequently be used as evidence to support a negligence claim. Put in another way, the report is saying, that statutory duty of candour, should not help harmed patients in getting compensation for the harm suffered, which is complete antithesis to open, honest and transparent communication with patients/families.
• Any attempt by NHS organisations to somehow frame what patients/.families are told in a way that it would limit or hamper compensation claims, would be morally and ethically wrong. If patients/families have suffered harm, they are entitled, if they wish, to seek fair damages and use given explanations to substantiate claims.
• NHS Scotland must ensure that legislation protects patients’/families’ rights before anything else, regardless of the consequences, because it is the right thing to do.

Question 3c: Do you agree with the proposed requirements to ensure that people are appropriately supported?

Yes ✓ □

Comments
• Communication between healthcare professionals and patients/families should be completely open and honest from the outset of any clinical relationship and should be equally so if something goes wrong.
• If patients/families have suffered medical harm, as per nationally agreed definitions, through no fault of their own, they should automatically be entitled to support, emotional and/or practical, being available and timely offered, by relevant, trained persons [note 6.6] from the disclosure stage and ongoing support, dependent on the nature and severity of the physical or psychological harm and in consultation with patients/families, including whether or not they wish to be involved with the review process.
• In each instance, there should be both internal and external monitoring of support provided and with reference to patients’/families’ satisfaction with that process.
• Patients/families must feel confident that necessary changes have been put into practice nationally, to avoid as far as possible, similar incidents of harm happening again.

Question 4:
What do you think is an appropriate frequency for such reporting?

Quarterly □  Bi-Annually □  Annually ✓ □  Other □ (outline below)

Comments
At least annually, as proposed [note 7.3]

Question 5:
What staffing and resources that would be required to support effective arrangements for the disclose of instances of harm?

Comments
• The introduction of a statutory duty of candour has both financial and staffing implications for Health Boards and care services, which are already stretched to the limit.
• In order to implement measures to ensure that staff have the required knowledge and skills as indicated in answer to question 2, extra financial help towards staffing and practical implementation will have to be provided by Scottish Government.
• External monitoring will have to be factored into overall costs.
• N.B. Additional comment:
  o According to published figures, NHS Scotland has spent more than £ 200 million pounds during the past six years on negligence claims. However, much of that huge sum is spent on defence fees, by NHS organisations, fighting claims and only a small amount accounted for by compensation awarded to victims.
  o NHS organisations seem to have limitless access to tax payers money to employ top defence lawyers, while patients/families, on an uneven playing field, risk financial hardship if they pursue a case.
  o Duty of candour legislation will be successful if NHS organisations start to acknowledge that mistakes will be made, admit liability and compensate patients/families accordingly.
  o Based on breakdown of past NHS Scotland costs on claims, there should be a huge saving if many of the defence lawyer fees are removed from the equation.
Do you agree with the disclosable events that are proposed?

Yes ☑

Comments
- The 2013 HIS review, [notes 4.6] re. national programme, supporting learning following adverse events, revealed wide and inconsistent approach across NHS Scotland.
- Critical to effectiveness of duty of candour legislation, is not only the importance of nationally agreed definitions of harm being agreed in reference to different health or social contexts but measures put in place to monitor and ensure that all organisations are interpreting them in a consistent and fair manner.
- Agreed definitions re. what defines a duty of candour disclosable event, should not preclude incidents of low harm being disclosed to patients or near misses being recorded, analysed and lessons learned.

Question 6b:
Will the disclosable events that are proposed be clearly applicable and identifiable in all care settings?

Yes ☑

Comments
- Healthcare is provided by healthcare workers in a variety of settings from NHS hospitals to people being cared for in their own homes. If poor standards of care/treatment result in patients/families suffering harm, then duty of candour legislation should apply equally, in whatever context the care is being carried out.
- Extending duty of candour to include providers of child and social care services [note 1.4] to be open and transparent about care is right and of the highest priority.

Question 6c:
What definition should be used for ‘disclosable events’ in the context of children’s social care?

Comments
- Definitions should be drawn up in consultation with professional experts from that field.

Question 7
What are the main issues that need to be addressed to support effective mechanisms to determine if an instance of disclosable harm has occurred?

Comments
- See response Question 6a

Question 8:
How do you think the organisational duty of candour should be monitored?

Comments
- As noted in response to question 1, doctors and nurses are governed by professional standards which means they already have a clear ethical duty to tell patients when things go wrong. If this was routinely happening in NHS organisations, such as hospitals, the introduction of a statutory duty of candour might never have been considered.
- However, as we know from recent NHS scandals, this is not happening, despite, as it has emerged from enquiries, doctors and nurses being fully aware of their professional duties.
- For various reasons these professionals felt disempowered and as individuals with no control, even when they spoke up, over what was happening around them.
- Organisations should put in place robust internal reporting and monitoring systems.
- Organisations should work closely with and be fully accountable to independent regulators and in turn to the Scottish Government.
- Establishing a working liaison with patients and patient support groups would be advisable, if not essential.
- Independent, external, close monitoring is essential to gauge organisational commitment to duty of candour and to ensure that procedures are being put into practice and that organisational support is there for both patients and staff.
- Regulators need to alert to any NHS organisations still being economic with the truth, for fear of litigation. If patients/families have suffered a disclosable incident, they are entitled to compensation which reflects the harm suffered.
- External regulators should report back to the Scottish Government on the progress of all organisations. The Scottish Government, should in turn, make public these findings.
- Part of the monitoring system, should include an external, independent named adjudicator, to whom dissatisfied patients/families could refer concerns about incidents of harm which have not been disclosed or concerns about an organisation’s handling of a disclosed event.
- Whistleblowers should also have access to an independent adjudicator if their patient safety concerns have not been listened to by an organisation or they have been victimised for speaking up.
What should the consequences be if it is discovered that a disclosable event has not been disclosed to the relevant person?

Comments

- A statutory duty of candour, will be meaningless if organisational requirements for a duty of candour are not being met.
- Organisations should ensure that all employees, without exception, are fully aware of the internal or external consequences to any individual or group of individuals who fail to follow duty of candour regulations.
- Scottish Government must draw up and issue guidance to organisations on sanctions which can be taken, if regulators find that they are failing to implement statutory duty of candour regulations.
- Warnings must be issued and if necessary, strong actions taken against identified individuals within an organisation who deliberately set out to breach their legal duty.
- Organisations must be left in no doubt that the Scottish Government will if necessary use legal enforcement powers to protect patients/families – with no one, at any level, above the law.
- **N.B.** The word organisation is a collective noun, used in the singular form. Each NHS Scotland organisation consists of hundreds or thousands of individuals working together. When things go wrong, it would be illogical to collectively blame the whole organisation.
- Financial sanctions against organisations, which would disadvantage patients and impinge on patient safety is illogical for the above reason and **should never be considered**
- Accountability must rest at individual, Non- executive and Executive level whose responsibility it is to ensure that all policies and codes of conduct are being strictly adhered to by managers and other professionals.
- The need for strong, ethical NHS leadership can never be over emphasised.
- There must be an end to obscuring and diffusing of responsibilities by shielding of individuals with the excuse of “a system’s failure” for personal culpabilities, in order to misguidedy defend organisational reputation.
- As a deterrent, strong action, backed by legislation, should be taken against any individual or a group of individuals within NHS organisations who are proven in to have deliberately lied or dishonestly provided disinformation, on any matter, which perverts justice and is detrimental to patients or staff – on the same lines as perjury is unacceptable in a court of law.

**Additional comments :**

- NB Few NHS Scotland frontline staff are even aware of this duty of candour consultation – admit may have come in global email but too busy because of gross understaffing to pay attention to the plethora of emails which comes through.
- Why have NHS organisations not taken steps to ensure that all staff aware of the proposed legislation and engaging them in the consultation process at local level ?

**Reading sources :**

- Patients First - www.patientsfirst.org.uk
- Being Open Framework - www.nrls.npsa.nhs.uk
- NHS Scotland National Framework 2013, for dealing with adverse events
- GMC – ‘Good Medical Practice’
- NCM – ‘The Core Standards performance & ethics for nurses and midwives.’
- Royal College of Surgeons – duty of candour consultation response.
- BMA – published articles.
- Care Quality Commission – guidance for healthcare providers.
- Action Against Medical Accidents- www.avma.org.uk
- Scottish Medical Negligence Journal
- Health Services Journal
- NAO – A Safer Place for Patients : Learning to Improve Patient Safety 2005
- MPS - Survey of medical professionals 2008
- Hutchinson A, Young T A et al, study of incident reporting and relationship to safety and quality data in acute hospitals.
- Robbie’s law - www.robbieslawtrust.co.uk