The duty of candour: submission by the Foundation Trust Network

About the Foundation Trust Network
The Foundation Trust Network (FTN) is the membership organisation and trade association for the NHS acute hospitals and community, mental health and ambulance services that treat patients and service users in the NHS. The FTN helps those NHS trusts deliver high quality, patient focussed, care by enabling them to learn from each other, acting as their public voice and helping shape the system in which they operate.

The FTN has over 225 members – more than 90% of all NHS foundation trusts and aspirant trusts – who collectively account for £65 billion of annual expenditure and employ more than 630,000 staff.

Introduction
A legal duty of candour is included in the current Care Bill as part of the government's response to the recommendations of the 2nd Francis Inquiry. The Bill proposes to make it an offence for trusts and individuals to provide false or misleading information in circumstances where the trust has caused a patient harm. A contractual duty of candour has been in operation for some time and the proposed introduction of a legal duty has led to debate about what might constitute good or best practice.

The FTN was pleased to contribute to the debate on thresholds at the meeting on Thursday 9 January at the Royal College of Surgeons. This is an important issue for patients and service users, for their families and for those who provide services to them and we share the view that it should be addressed promptly. However we should not underestimate the challenges involved and we wondered if we might make a written contribution to follow up on the oral evidence we submitted on the day?

Summary
As a matter of policy and principle, the FTN supports openness and transparency in public services and believes that confidentiality should be used only to protect the privacy of individuals or in circumstances where there is an overriding commercial reason for material to be held back for a period of time. However we believe that it would be inappropriate and would muddy the water if regulations to bring the legal duty into force sought also to tackle good practice and contractual issues.

Where a breach can lead to prosecution and possible criminal sanctions the matter in question needs to be sufficiently serious as to justify a criminal justice approach. The nature of the offence needs to be specific so that conscientious individuals know how to avoid committing it and are easily able to do so. Contractual and best practice issues do not require the same rigour in definition and in the case of good practice this might go down to the level of 'good to have' rather than 'must do'. We would be delighted to contribute to any future debate on a contractual approach to candour and on good practice in promoting openness and transparency in the NHS provider sector. However we do not believe that justice would be done to defining a legal duty of candour by seeking to conflate it with contractual and good practice issues.

The Issues in Detail

The Care Bill as it stands proposes an offence of providing false or misleading information in the event of a patient being caused harm by the healthcare provider. It is our common experience that when something untoward occurs, the amount of information that is available increases over time as data is gathered, analysed and interpreted. At the point of the incident what might appear to be accurate may well turn out not to be the case. So an organisation could issue information in good faith that subsequently turned out not to be true. The incentive therefore would be to say nothing pending a thorough investigation.

What does and does not constitute 'misleading' information is likely to be the source of creative and profitable activity for the legal profession unless it is closely and precisely defined. Much of what is published that turns out to be misleading in the NHS is accidental and is often attributable to inadvertently ambiguous terminology or plain poor writing. We think that it is the intent to mislead that is important here. If an organisation provides information that deliberately sets out to lead a false conclusion, that is qualitatively and morally different from a situation where the recipient of information forms a different conclusion from the one intended. The regulations need to take account of this important distinction.

It must also be accepted that not all harm to patients in a healthcare setting is attributable to the healthcare provider. While incidents such as 'never events' might almost invariably be the fault of the provider, incidents such as falls for example, could be caused by the patient, or even negligence on the part of a member of their family. Where there is disagreement about fault there is also likely to be a dispute about whether information provided is true and accurate. So once again this is a matter that requires quite careful consideration.

Attention needs to be given to whom the duty applies. Is it to boards and top managers? If so, would it be a defence that they have put in place robust systems and process to deliver the fair and honest provision of information, have trained their staff and collectively seek assurance that what they have put in place is largely effective? Would the duty apply to informal information given by staff during the course of discussions with patients and their families? If so this is something over which boards would have little control other than through policy and training. Or would the duty only apply in the case of definitive statements issued at a senior level on behalf of the provider organisation?

Finally consideration needs to be given to who the recipient of the duty is. Clearly it will be the patient if the patient is alive and is in a position to understand what has happened and what the consequences are. But there will be cases of harm where the recipient will be a family member or carer, raising the question of under what circumstances this may be appropriate. This might be something to be dealt with at the stage where a patient is giving consent in an acute setting, but as we point out below, care is provided in a variety of settings across mental health, community and ambulance services including within the community and indeed the privacy of people's own homes.

Setting

While healthcare may be provided to patients or service users in a facility completely under the control of a single provider, in community, emergency response and mental health settings healthcare is often already provided away from a location under the control of the provider. This is likely to make it much more difficult to identify the proximate cause of harm and whose responsibility it is. In community and mental health settings harm may occur when the staff of the healthcare provider are not present. Attributing responsibility under such circumstance is at best debatable and will often prove to be impossible. Yet when individuals or their family are distressed because of an instance of harm disputed ground is likely to be relatively common and

boil down to opinion. It is difficult to fully understand the role of a legal duty of candour in circumstances where one may be dealing with opinion rather than fact. It is equally difficult to understand how legal sanctions could be effectively and fairly applied .

Thresholds

The provision of healthcare involves uncertainty and outcomes are not always those that were intended. The NHS carries out more than 1.3 million procedures a week and if harm accrues in even of fraction of 1% of cases that still means several thousand cases of harm a week ranging from the relatively trivial to the catastrophic. As we stated earlier in a legal duty of candour needs to deal with matters that are serious. The difficulty here lies in defining the threshold. The clearest and simplest way in which to apply the duty would be to limit it to cases of death since this is unambiguous and not open to misinterpretation. It has been suggested however that this is too high a threshold and that the duty should apply to cases of serious harm. This may not seem wrong in principle, but in practice what constitutes serious harm can be difficult to define, particularly in the early stages after an incident. A fall which appeared to cause moderate and temporary harm may subsequently be seen to result in permanent serious harm or even death. Thresholds between serious and moderate harm are likely to be open to interpretation. There are likely to be grey areas and honest differences of opinion. However if organisations err on the side of caution how far should they go? Without comprehensive guidance resources are likely to be misdirected.

Sanctions

Foundation trust boards can be removed by Monitor if they preside over a serious breach of the licence. Foundation trusts are obliged to comply with the law, so monitor could already intervene were the situation to warrant it. Contractual sanctions also apply in the event of a breach of the contractual duty of candour. An additional legal sanction, a fine perhaps, would be simply to remove scarce resources from the provider to no positive effect. Furthermore boards could, in theory, be punished several times for the same offence. The primary purpose of setting out a duty in statute is to secure compliance. We believe that the necessary levers are already in place to achieve compliance.

Openness, transparency and culture

It is perhaps worth remarking that organisations that are open and transparent behave that way because of their leadership and the culture that those leaders promote. They look to embed such cultures in their organisations because it is good for business, not because they fear prosecution. Openness and transparency are necessary and good business practices for the NHS and we should expect over time to see NHS culture move progressively in that direction for good business reasons.

However there are risks if we attempt to use the wrong tools to safeguard the types of culture that we would like to see. The increasingly legalistic nature of the NHS (taking the proposed statutory duty of candour alongside provisions for false and misleading information and the 'fit and proper persons' test) risk unintended consequences. These may well include discouraging the talented, high calibre leaders we need to drive an open culture from joining, or staying with, the NHS. It should not be forgotten that secrecy is a direct consequence of the command and control culture and the culture of blame that was at the heart of the NHS for many years. It will take leadership and determination rather than legislation to achieve and embed lasting change cultural change.

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