Professional Duty of Candour

This response has been prepared by the Ethics and Practice Committee of the Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the UK (FPM). The FPM is a professional membership organisation and standard-setting body, with 1,500 members, who are practising pharmaceutical physicians who work in the pharmaceutical industry, clinical research organisations, academia and the medicines regulatory agencies.

Pharmaceutical medicine is a medical specialty concerned with the discovery, development, evaluation, licensing and monitoring of medicines and the medical aspects of their marketing. Some pharmaceutical physicians are employed by organisations while others are self-employed and are contracted by multiple different companies. The FPM's members work in diverse areas; from front line clinical trials, to pharmacovigilance, pharmaceutical marketing and medicines regulation. In the context of a physician working within the pharmaceutical environment, direct contact with patients happens in a limited number of circumstances. Pharmaceutical physicians are often responsible for a cohort of patients rather than a single patient and their work frequently has a significant public health impact.

Questions around "duty of candour" tend to focus on communications to patients and relatives when there have been 'failings in care'. Still, the penultimate sentence of the Professional Duty of Candour makes clear:

'*They* [healthcare professionals] *must also be open and honest with their regulators, raising concerns where appropriate. They must support and encourage each other to be open and honest, and not stop someone from raising concerns.'*

Therefore, the duty of candour is very pertinent for the interaction of pharmaceutical physicians and other healthcare staff involved in medicines development and post-authorisation activities. The duty of candour for pharmaceutical physicians should consider not only clinical trials but also post-marketing safety concerns, lack of efficacy and misleading marketing. Pharmaceutical physicians differ in several aspects from clinical doctors, whose work involves direct patient care, with respect to the duty of candour and the answers below reflect these differences.

Question 1
Do you think there has been a change in professionals' attitudes to candour since 2014? If so, how?

In general terms the increased importance of candour in communication seen across the healthcare system has been reflected in the pharmaceutical industry. Physicians are aware of the importance of being honest and open with patients. One area where this is most clearly seen is in relation to data disclosure from clinical trials. The pressure for changes in this area has come from both internal and external factors distinct from the 'Hard Truths' initiative, but, in terms of ethical principles, there is much in common.

The recent changes to the Serious Breech Regulations by the MHRA (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment

data/file/705179/Guidance_for_the_Notification_of_Serious_Breaches_of_GCP_or_the_Trial_Protocol_Version_5.1_04-05-2018_.pdf) enforces the need for the duty of candour to be applied and places a responsibility on healthcare staff in the pharmaceutical industry to equivalent standards as our clinical colleagues. These changes are well publicised and hence the need for enhanced vigilance of duty of candour is evident. The MHRA document is careful in that it places no blame on why these breeches occur. The ability to work in a no-blame culture encourages a duty of candour.

There remains no accepted definition for 'something going wrong', and, in particular, the concept of the 'near miss' and the associated need for candour is vague. There is lack of clarity around the extent to which uncertainty should be conveyed to patients and communication in situations where there was potential for harm, but no harm done (e.g. where medicines in clinical trials are recalled because of manufacturing issues).

The situation is made more complicated as companies devise their own procedures for the investigation of serious breeches, which will allow them to comply with the Serious Breech Regulations. Many companies use corrective and preventative action (CAPA) procedures as the standard approach.

Questions 2-5

Is it possible to measure the extent to which professionals are complying with the professional duty of candour? If measurement is possible, do regulators have a role in these tasks

The duty of candour is difficult to measure; we need to know first what should be conveyed to patients before we can measure if this is done. Furthermore, there would need to be a way for physicians to summarise/ reflect on the issues without this being held against them (i.e. the recent high-profile GMC case relating to Dr Bara-Garba). The duty of candour has less to do with a culture of compliance and more to do with a culture of responsibility, openness, and accountability. What we should want to measure, want to know, is in cases where the duty of candour was 'not complied with' – where did the system/process fail the physician and patient?

Within the practice of pharmaceutical medicine, there are things that go wrong that we are aware of immediately and other instances that with hindsight/ retrospective review we can see went wrong. For the second type, we need a way to assess whether anything different could have been done originally or if the issue is only apparent with the benefit of hindsight. For example, should a pharmaceutical physician have identified a safety issue by review of clinical trial data or did this issue genuinely only become apparent only with accumulation of post authorisation safety data?

The new revision of the *International Conference on Harmonisation Guideline for Good Clinical Practice E6(R1)* places a greater emphasis on quality management systems and root cause analysis, so this does therefore cover the duty of candour for pharmaceutical physicians.

However, recent cases have eroded trust between professional regulatory bodies and physicians. Professional bodies need to spend time rebuilding trust and explaining in an open and transparent way the basis for decisions.

What role do professional regulators have in encouraging candour among their registrants?

By writing documents that encourage open dialogue in relation to the work that healthcare professionals undertake. For pharmaceutical physicians one example could be over the conduct and review of clinical trials and preventing a blame culture from emerging.

There needs to be an acceptance that we all make mistakes sometimes. We need a culture of everyone checking everyone else's work, and all staff, irrespective of seniority, should be encouraged and free to question anyone else. Learning from mistakes needs to be seen as best practice.

If regulators have a role in encouraging candour, have professional regulators been successful in carrying out this task?

Yes, but more can be done.

Can professional regulators do more to encourage candour? If so what?

Regulators need to offer support, guidance and reassurance to practitioners that there will be no culture of blame. There needs to be an open review of issues reported to patients and systems set in place to avert similar problems in future.

However, the duty of candour goes beyond interactions with the regulators. As part of the revalidation process pharmaceutical physicians are assessed against the domains of the GMC's Good Medical Practice. An important aspect of Communication, partnership and teamwork (Domain 3) is to 'Establish and maintain partnerships with patients'.

The FPM guidance document '*Good Pharmaceutical Medical Practice'* (GPMP https://www.fpm.org.uk/policypublications/GPMP) provides additional guidance for some of the special situations that pharmaceutical physicians may face particularly in relation to the development of new medicines.

Discussing potential involvement in a clinical trial is an area where the professional 'duty of candour', as it applies to information disclosure, is particularly relevant. Prior to obtaining the patient's (or health volunteer's) consent, respect for autonomy requires that the subject understands fully the risks and burdens of their involvement and what benefits they should or should not expect from their involvement. As part of GPMP it is "important to express the uncertainty before treatment and not give unfounded reassurance".

Pharmaceutical physicians may have direct individual patient contact only in connection with clinical trials, but their behaviour has indirect effects on patients via information made available to prescribers or included in patient support materials. The duty of candour should apply to the information provided that influences prescribing decisions. This information

needs to be complete, balanced and accurate and made available in a timely manner. The *Association of the British Pharmaceutical Industry (ABPI) Code of Practice* (http://www.pmcpa.org.uk/thecode/Pages/default.aspx) provides some guidance in this area. GPMP provides additional guidance in situations where the pharmaceutical physician has particular responsibilities, when patient safety may be compromised.

The duty of candour also applies to ethics committee interactions, particularly in circumstances where amendments to protocols are needed. The reasons for protocol amendments are not often explained to ethics committees.

Question 6-7
What barriers are there to professionals behaving candidly? How do professionals perceive the professional duty of candour?

As many pharmaceutical physicians work within a commercial organisation it is possible that actions taken, which are necessary to protect patients' autonomy and safety, may have the potential to have a negative financial impact on the company. The pharmaceutical physician's duty of candour should extend to discussions within the company and pharmaceutical physicians should always remember their role as advocate for patients. Physicians in this position should be supported by their regulatory bodies.

Where commercial decisions lead to the discontinuation of the development of a medicine a duty of candour applies, but the extent of this duty remains unclear.

Some physicians who work within the pharmaceutical industry are concerned about an evolution of a blame culture. Many physicians find it hard to get professional indemnity and fear of legal proceedings acts as a barrier to duty of candour.

Candour also has its limitations. Healthcare providers need to respect patient privacy as well as respect what patients may not want to know. Thus, the codes of practices for promoting candour need to be aware of the boundaries

Question 8-10
What materials or guidance relating to candour do professionals refer to? What do you recommend could be done in your sector and/or others to better encourage candour? How does your organisation encourage professionals to behave candidly?

Currently, GPMP document is being updated. The updated version will have the advantage of referencing the Government's Hard Truths (2014) document and will look to provide appropriate context within the practice of pharmaceutical medicine. The duty of candour should be continually borne in mind during the revising of this document and its influence should be evident in many of the guidelines provided.