

# **Open Disclosure**

Guidance Document  
From the Board of the  
Faculty of Radiologists

V1.2, April 2016

## **1: Scope:**

This guidance applies to members and trainees of the Faculty of Radiologists, RCSI. This guidance document has been developed to provide further support for Radiologists when engaging in Open Disclosure and should be used in conjunction with the HSE Open Disclosure Policy 2013 and the HSE/SCA Open Disclosure National Guidelines 2013.

## **2: Introduction**

Medical council standards in professional conduct and ethics 2009 state that:

*“Patients and their families are entitled to honest, open and prompt communication about adverse events that may have caused them harm. The medical professional should acknowledge that an event happened, explain how it happened, apologise if appropriate, and give an assurance as to how lessons have been learned to minimize the chance of this event happening again in the future.”<sup>1</sup>*

Disclosure of harmful medical errors to patients has emerged as a professional standard across medical specialities.<sup>2</sup> The HIQA Standards for Safer Better Healthcare 2012 require that:

*“service providers fully and openly inform and support service users as soon as possible after an adverse event affecting them has occurred, or becomes known and continue to provide information and support as needed.”*

Positive benefits of Open Disclosure include maintenance of the patient’s confidence in the health care provider, prevention of misconceptions about what caused their adverse event and facilitation in decision making about future care.<sup>7</sup> The HSE and State claims agency in 2013 published a document on Open Disclosure (OD).<sup>3</sup> It outlines that OD should occur when a patient has experienced a mild, moderate or severe adverse event, or when the patient has been involved in a near miss incident. Harm may result from inherent risks associated with a specific procedure or treatment, systems failures within an institution or provider performance.

The Faculty recognizes the HSE document fails to address nuances of the practice of Radiology. In many areas of medicine, there is a direct cause and effect relationship leading to patient harm. Error is inherent in Radiology, with recognized error rates of 2-20%.<sup>4</sup> The diagnostic performance of many imaging examinations is commonly somewhat limited. Errors of observation and interpretation may occur, accurate diagnoses may not be arrived at due to misleading or insufficient patient data, study quality may be suboptimal due to technical factors; and interobserver variability is an unavoidable aspect of radiologic practice. A Radiologist’s performance may be subject to numerous biases.<sup>5</sup> Refinement of diagnosis is a dynamic process. For many patients, the

correct diagnosis is only arrived upon after days/weeks/months of investigations, reached after assimilation of clinical, laboratory, radiologic and histopathologic data in a multidisciplinary setting.

An abnormality may be detectable on retrospective review of a study, but not prospectively detectable. Errors of interpretation should be judged against the standard of an average competent Radiologist working under standard conditions rather than the unachievable standard of perfection.<sup>6</sup>

Nuances of radiologic practice may be difficult for a patient to appreciate. However patients are aware radiologic errors may occur and patient representative groups have made it known patients wish to be informed should an error come to light.

The Faculty supports the principals of OD. The Faculty also recognizes that limitations exist in relation to its universal implementation. Strict application of the HSE recommendations for OD in light of the known intrinsic error rate would, in busy Departments, have profound implications for service provision and productivity. The principal obstacle to OD is the absence of legal protection for participants, exposing healthcare workers to litigation. Currently there is no exemption from Freedom of Information (FOI) enquiries. The proposed Health Information Bill is promised to contain a key statutory provision that would allow medical practitioners to make an apology and provide an explanation without these being construed as an admission of liability in a medical negligence claim. In the absence of the official protection proposed in the Health Information Bill, the Faculty of Radiologists wishes to provide its Members and Fellows with guidance on how to manage requests for OD in their institutions.

Radiologists should participate in OD, because if we rely on other medical personnel to disclose our errors, we will have little input into whether and how errors are communicated to patients.<sup>7</sup>

### **3: Management of Radiological Errors:**

#### **(a) Obligations:**

- A Radiologist who identifies a radiologic error or discrepancy should, where possible, consult with the Radiologist who originally reported the examination to decide which of them will make contact with the most responsible physician (MRP). The Radiologist bringing the case forward will be termed the “index Radiologist.”
- The index Radiologist should make the MRP managing the patient aware of the finding, which must then be considered in the appropriate clinical context. This Radiologist-to-physician disclosure may take place in the multidisciplinary team meeting setting.
- The Radiologist who identifies the error should refer the case to the local Quality Improvement (QI) meeting.
- Individual Departments should have a designated OD lead to participate in high-level OD meetings, distinct from the QI coordinator. Currently

Administrative Directors of Radiology Departments are fulfilling this role and formally recognizing its increasing importance with the designation OD lead is suggested. Each OD lead should undertake training – the Faculty will work with the HSE to design and provide this training when a quorum of OD leads has been identified.

- Should a non-Radiologist encounter a radiologic discrepancy it is desirable for that doctor to inform the reporting Radiologist and involve them in any OD process that results from the radiologic error.

### **(b) Quality Improvement (QI) Meetings**

The Faculty has been proactive in the establishment of the national Quality Improvement programme. The QI conference is an educational platform which reviews discrepant cases, highlights teaching cases, details technical problems which may have resulted in suboptimal study quality and compliments ‘good calls’ and are now routine in most Departments. These meetings have been established despite the lack of FOI protection and medico-legal indemnity for those choosing to involve themselves with the process. This has been achieved through central anonymisation of discrepancies along the chain of events. It is recognised that a radiologic discrepancy may not result in actual patient harm, and disclosure of such an event may lead to added patient distress e.g. in the setting of a terminal malignancy. The QI meeting coordinator has no direct role in the OD process as this Radiologist is merely facilitating an educational activity. Submission of a case to a QI meeting implies compliance with these OD guidelines, and the OD process should proceed separately.

### **(c) Patient Harm**

An important part of the OD process is establishing that patient harm occurred. Patient harm may be graded in terms of severity of any injury incurred, or an event that may have lead to undue patient stress. For example:

1. An overlooked adrenal adenoma on a CT abdomen for staging colon cancer will likely not lead to patient injury and therefore does not merit OD – it should however be referred to the local Quality Improvement meeting.
2. Now consider a patient with suspected Cushing’s disease: an overlooked adrenal adenoma in this context could lead to a delay in patient diagnosis and appropriate management. Such a discrepancy should be communicated to the patients’ most responsible physician. The index Radiologist and the MRP should consult to determine if any patient harm is directly attributable to the discrepancy.
  - a. If it is determined that patient harm has resulted, the MRP may undertake a “physician disclosure” to the patient, with the agreement of the Radiologist. This low-level physician disclosure should be recorded in the clinical notes by the clinician and as an addendum to the report of the examination by the Radiologist. The case should be referred to the local QI meeting so that possible system errors can be discussed and eliminated.
  - b. In cases where there is clear patient harm attributable to the discrepancy, a high-level Open Disclosure meeting will be mandatory, involving the hospital’s Risk Management service. Open Disclosure should be recorded in the clinical notes by the

clinician and as an addendum to the report of the examination by the Radiologist. The case should be referred to the local QI meeting so that possible system errors can be discussed and eliminated.

The entire process is summarized in Figure 1.

### **(c) The Open Disclosure Team**

It is desirable for individual institutions to have OD teams in place, to provide local support and advice, to facilitate any meetings that may occur, to liaise with patients and their families and to make records. Representatives from patient advocacy and risk management will typically be present. The Radiology Department should be represented by the lead OD Radiologist when a radiological error is being disclosed. The patient and/or their family will be advised of the members of the team they will be meeting with. The team should meet in advance of the patient meeting to plan the meeting outline.

### **(d) The Open Disclosure Discussion:**

The cornerstone of an OD conversation should include a factual description of what occurred, an acknowledgement of any harm that resulted, an apology and reassurance in relation to ongoing care and the steps being taken to minimize a recurrence of the same event. The style of language used should be descriptive, factual and patient-friendly. Open Disclosure discussions should not be based on speculation or conjecture.

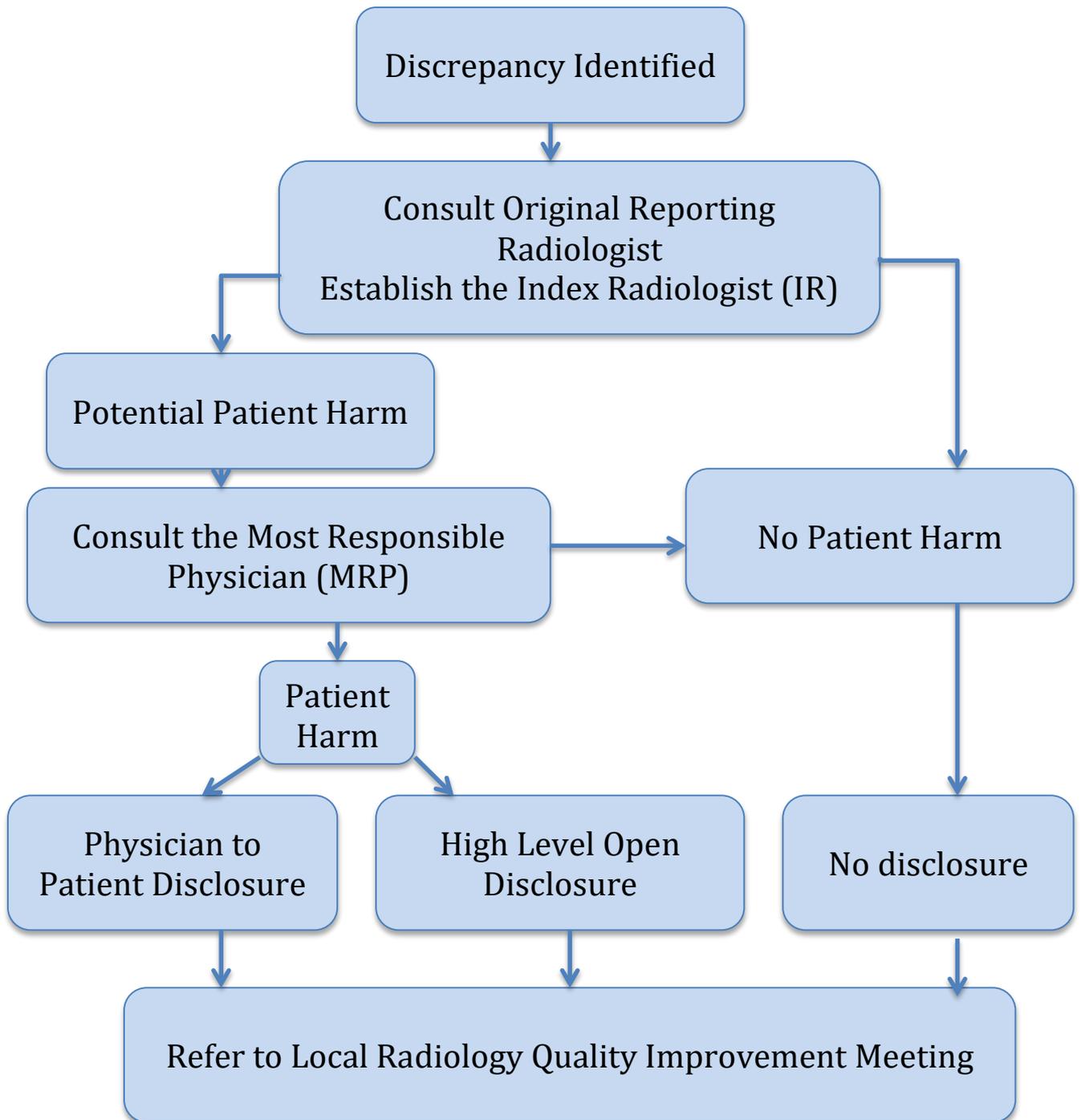
Empathy is especially important and must be embraced during Open Disclosure discussions with patients and their families. Expressing regret or saying sorry to the patient for what happened and demonstrating an understanding of the impact the event has had or is having on the patient demonstrates that you care and that you are trying to stay connected with them. The absence of empathy following adverse events is one of the chief drivers of medical malpractice claims.

### **(e) Training & Support**

Participating Radiologists should receive training in OD, and the Faculty is committed to supporting its members in the form of education sessions, workshops and web-based resources. Online Radiology reporting sessions simulators can be designed, which could reproduce standard reporting sessions that could be used to demonstrate the prospective detectability of a lesion by a group of peer Radiologists.<sup>8</sup>

The Faculty plans to provide PCS Internal Credits (up to 3 per case) for Radiologists involved in OD. One credit will be awarded to the index Radiologist who uploads the report of an OD case to Medhub in the format 'Description of error/ category of error (technical, perceptive, procedural, or interpretative)/ lesson(s) learned/ changes made/ submission to QI meeting confirmed.' Two additional credits may be awarded based on hours spent on OD meeting and preparation.

The Faculty may be contacted for help with regard to specific clinical scenarios or further clarification - users should take care to anonymize any patient identifying data.



**Figure 1.** Recommended pathway a Radiologist should pursue when a suspected discrepancy is found.

## References:

1. Guide to professional conduct and ethics for registered medical practitioners. Medical Council 7<sup>th</sup> edition 2009.
2. Safer Better Healthcare Standards. Health Information and Quality Authority 2012.
3. Open Disclosure: Communicating with service users and their families following adverse events in healthcare. HSE October 2013.
4. Discrepancy and Error in Radiology: Concepts, Causes and Consequences. Brady A et al. Ulster Medical Journal 2012; 81(1):3-9.
5. Biases in radiologic reasoning. Gunderman RB. AJR Am J Roentgenol. 2009 Mar;192(3):561-4.
6. Perceptual error and the culture of Open Disclosure in Australian radiology. Pitman AG. Aust Radiology (2006)50;206-11.
7. Stepping out further from the shadows: disclosure of harmful radiologic errors to patients. Radiology. 2012 Feb;262(2):381-6. Brown SD et al.
8. Ziltron. Cloud-based Simulators and Apps for medical professionals. [www.ziltron.com](http://www.ziltron.com) (Accessed April 8, 2016).

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