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Safety, Quality and Standards Directorate

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To: Bernard Mitchell, HSC Board
Mary Hinds, PHA

Re: Revised arrangements for managing adverse incident reporting and the establishment of the Regional Adverse Incident and Learning (RAIL) system

Purpose

1. The purpose of this paper is to;
   (i) provide an update on progress towards establishing new arrangements for managing and learning from adverse incidents;
   (ii) set out proposed roles and responsibilities of the Board and Agency in this regard ;
   (iii) detail the proposed oversight arrangements for this function;
   (iv) provide an overview of the project management structures which it is proposed be established to oversee the implementation of the RAIL model.

Context

2. As you will be aware, following last year's review of the Serious Adverse Incidents (SAIs) reporting system which identified significant weaknesses, a proposed new model has been developed, in partnership with the HSC, which will strengthen the existing arrangements for identifying, disseminating and implementing regional learning arising from adverse incidents occurring in the HSC.

Progress

3. The RAIL model, and its accompanying strategic implementation plan, has subsequently been approved by both the Departmental Management Board and Minister, and work has begun to implement this. The target date for full implementation of the new RAIL model is April 2011. Initial discussions have

been held with the Chief Executives of both the HSC Board and Public Health Agency to apprise them of the direction of travel in relation to adverse incident reporting, and holding guidance on interim reporting arrangements was issued to the HSC in March.

4. Further, more detailed guidance on this subject is currently being developed, in consultation with HSC colleagues, for planned issue in June, or as soon as possible thereafter. It is important that there is clarity about how adverse incidents will be managed until the new RAIL model is fully operational, and that these interim arrangements take appropriate account of the revised roles and responsibilities of the new regional bodies post RPA.

5. The detailed guidance will set out details of interim arrangements which will be put in place to manage the transition from the existing SAI reporting arrangements to the establishment of RAIL, to include the phasing out of the SAI system and the introduction of the structures that will underpin the new RAIL system. It will also define the incident reporting roles and responsibilities of Trusts, the family practitioner services, the HSC Board and Public Health Agency, and the extended remit in this regard of the Regulation & Quality Improvement Authority (RQIA).

6. Project management arrangements which will oversee the implementation of the RAIL model will shortly be established. It will be important that these are structured in a manner which appropriately reflects the roles of the respective stakeholder organisations in the new regional arrangements for reporting and learning from adverse incidents, and the Department will be writing formally to both the Board and Agency to invite their participation in these structures.

Location of RAIL

7. The RAIL model envisaged the establishment of a dedicated small team which would assume responsibility for managing the RAIL functions and for identifying and disseminating regional learning and recommendations, either directly to the HSC or via recommendation to the Department. The Department would be advised of major learning which may be issued

regionally as guidance or standards to the HSC, or which may inform other Departmental functions such as policy development and review, legislative change or priority setting.

8. While the review considered various options for the location of RAIL, it recommended locating it within the new Public Health Agency. It was the view of the review team that the function of RAIL – to contribute to improvement in the safety and quality of services through effective dissemination of lessons learned from adverse incidents and near misses – would fit best with the preventative focus of the Agency. In addition it was understood that the Agency would have a specific role in safety and quality at Director level, and with embedded social and primary care staff it was considered that it could bring a professional identity and leadership to RAIL. The 'special relationship' with the HSC Board would facilitate a robust means of ensuring that regional learning identified and disseminated by the Agency would be taken into account through commissioning.

9. Accordingly both the Departmental Board and the Minister approved the recommendation that the RAIL team be sited within the Agency earlier this year. However, it should be borne in mind that this recommendation was made prior to the formal establishment of either the Board or Agency and was consequently based on a developing (and therefore necessarily incomplete to some extent) understanding of the respective roles of these bodies.

Role of the Agency

10. The case for locating RAIL within the Agency remains that which informed the review's recommendation – that the learning function of RAIL fits best with the preventative focus of the Agency, and that the Agency's dedicated function in respect of safety and quality will provide a focus and impetus for effective dissemination of learning. Locating RAIL within the Agency is also likely be helpful in building the perception in the HSC that a key focus of adverse incident reporting and management is on learning so as to improve quality, which is an important consideration in fostering an effective reporting and learning culture in the service.

11. The Public Health Agency will therefore assume lead responsibility for operating the RAIL system, including hosting the small team responsible for managing the RAIL functions, securing professional input as appropriate. It will ensure regional learning is identified and disseminated and will support the HSC Board in holding HSC Trusts and Family Practitioner Services to account for the discharge of their responsibilities in this regard. In addition, the Agency will have responsibility for promoting the reporting and management of, and implementing the learning from, adverse incidents/near misses occurring within the context of the services that it provides.

12. Specifically, the Public Health Agency is required to:

- Maintain a system to record and track adverse incidents that occur within the Public Health Agency;
- Alert the Department to incidents within the PHA that meet the criteria set for the Early Alert system;
- Investigate incidents using a method proportionate to the incident and complete the investigation report in a timeframe appropriate to the incident, typically no more than 12 weeks from becoming aware of the incident;
- Keep relevant parties informed at all stages of the incident, investigation and follow-up;
- Notify the Department of recommendations that are relevant regionally;
- Implement regional and local recommendations;
- Be able to provide evidence to the Department that the requirements above are being met;
- Support the HSC Board in holding Trusts to account for their responsibilities in respect of incident reporting and investigation and provide assurance to the Department that these responsibilities are being met;

- Work collaboratively with the Department and the HSC Board to develop and progress the support structures and processes which will underpin the new RAIL system;
- Be responsible for the operational management of the RAIL system, once it transfers to the Public Health Agency; and
- Participate in the Department's shadow Regional Adverse Incident and Learning Group.

13. The rationale for recommending that RAIL be sited within the Agency rests on the assumption that the primary focus of RAIL will be on the learning arising from adverse incidents, and on ensuring that safety messages and regional learning are identified and disseminated in a consistent and effective manner. The review of the existing SAI arrangements had a very clear emphasis on establishing the most effective arrangements for maximising effective learning. There are however other dimensions which must be taken account of in order to develop a fully rounded system which is capable of addressing and effectively managing the range of implications which potentially arise when adverse incidents occur, such as provision of an early warning function and associated performance management and service improvement issues.

Role of the HSC Board

14. Although the emphasis of the RAIL model remains firmly on learning, it will be important that the Board in its role as commissioner of services exercises a performance management oversight of adverse incidents occurring in those services. Adequate information on adverse incidents is likely to be an important component of the Board's assurance framework and associated risk management arrangements, enabling the Board to make a judgement on whether satisfactory assurance has been provided regarding action taken to minimise recurrence.

15. In addition to reporting SAIs to the Department, Trusts and Family Practitioner Services were also required in the past to report SAIs to their respective HSS Boards. Each of the old Boards had arrangements in place to consider and

review SAIs, and the HSC Board is currently considering how these arrangements will translate to the new structure.

16. In parallel with learning, there is also inevitably a complementary performance management dimension to adverse incident reporting. An incident or pattern of incidents may be indicative of an underlying performance or commissioning issue, either individual or systemic, and it is the responsibility of the Board to identify and address such issues in its service improvement role.

17. In line with the Board's performance management and accountability functions, it has responsibility for holding Trusts to account for the effective discharge of their responsibilities in reporting and investigating adverse incidents and near misses, and for providing assurance to the Department that these responsibilities are being met and that learning is being implemented consistently and effectively. The Board is therefore responsible for maintaining those adverse incident reporting and monitoring mechanisms it considers necessary to enable it to carry out the full range of its commissioning, performance management and service improvement functions effectively. In addition, the Board is responsible for promoting the reporting and management of, and implementing the learning from, adverse incidents/near misses occurring within the context of the services that it provides.

18. Specifically the Board is required to:

- Alert the Department to incidents in Family Practitioner Services that meet the criteria set for the Early Alert system;
- With input from the PHA, hold Trusts to account for their responsibilities in respect of incident reporting and investigation and provide assurance to the Department that these responsibilities are being met;
- Hold Family Practitioner Services to account for the responsibilities in respect of incident reporting and investigation and provide assurance to the Department that these responsibilities are being met;

- Maintain a system to record and track adverse incidents that occur within the HSC Board;
- Alert the Department to incidents within the HSC Board that meet the criteria for the Early Alert system;
- Investigate incidents using a method proportionate to the incident and complete the investigation report in a timeframe appropriate to the incident, typically no more than 12 weeks from becoming aware of the incident;
- Keep relevant parties informed at all stages of the incident, investigation and follow-up;
- Notify the Department of recommendations that are relevant regionally;
- Implement regional and local recommendations;
- Be able to provide evidence to the Department that the requirements above are being met; and
- Participate as a member of the Department's shadow Regional Adverse Incident and Learning Group.

19. It will be crucial to the success of the new reporting arrangements that there is a clear delineation between the respective roles and functions of the Board and Agency in the new arrangements – very broadly that the Agency is concerned primarily with the analysis of reported incidents to ensure consistent identification and dissemination of any learning emerging, while the focus of the Board will be on addressing any performance management and service improvement issues arising.

20. Failure to achieve clarity on this distinction risks a perception in the HSC that RAIL is concerned only with identifying performance management issues, which may in turn inhibit reporting of incidents (hence the reason for not locating RAIL in the HSC Board). This is a significant risk, particularly in light of the perceived under-reporting which already exists in a number of specialities. The review was clear that a central aim of the RAIL model should be to facilitate a change in culture in the service away from a reluctance to report for fear of sanction, to one of a willingness to report to ensure learning

and improved services while still retaining appropriate governance arrangements in respect of identified performance issues.

Oversight arrangements

21. In addition to managing the early alert system, the Department will retain responsibility for oversight of reporting arrangements, seeking assurance from both the Board and the Agency that Trusts are meeting their responsibilities in relation to reporting and investigating incidents and that any local or regional learning emerging is being consistently identified and effectively disseminated.

22. The existing Departmental SAI Review Group will play an important role in the interim transition arrangements. It will retain responsibility for considering regional learning implications from those incidents received by the Department up to the date of issue of the detailed guidance circular referred to in paragraph 4 above, and consequently the Department will continue to request appropriate follow-up information from reporting organisations in relation to these cases. With regard to incidents occurring subsequent to the issue of the guidance, the Group will consider incidents where the HSC Board, Public Health Agency or Trusts have identified regional learning as a result of their investigations. It will also consider any learning on interface issues with mental health services and ensure that this is shared with RQIA.

23. To reflect its revised remit, the Review Group will be reconstituted as a shadow Regional Adverse Incident and Learning Group. New terms of reference will be agreed to define the Group's role through the transitional period until the Public Health Agency assumes full responsibility for the operation of the RAIL network. The membership of the Group will be reviewed to ensure that it adequately reflects this revised agenda, with the reconstituted group continuing to be chaired by the Department. Representation will be drawn as appropriate from the key stakeholders in the RAIL system, to include the HSC Board, the Public Health Agency, HSC Trusts, the Regulation and Quality Improvement Authority and Departmental policy and professional representatives.

Overview of RAIL implementation project

24. The project management structures which will shortly be put in place to oversee implementation of the RAIL model will include the establishment of a Project Board, chaired by the Department, with membership to include representation from the Agency, HSC Board, RQIA, Trusts, BSO and PCC as appropriate. A small time-bound project team, reporting to the Project Board, will be responsible for developing a plan to ensure that the project aims and objectives are delivered within timescale and budget. The project team will be chaired by a representative of the **Public Health Agency**, and will include representation from the Department, HSC Board, PHA, BSO, RQIA and the PCC.

25. The objectives of the project are as follows;

    a. The establishment of a Regional Adverse Incident Learning Group, whose role is to review learning arising from adverse incidents and disseminate that learning across HSC;
    b. The Development of IT systems to support incident reporting, investigation and the analysis of individual and groups of incidents;
    c. The establishment of a Regional Adverse Incident Learning Network which will include the appointment of specialty leads to provide leadership, encourage reporting and review incidents; and
    d. To develop a plan for the evaluation of the RAIL network 2 years after establishment.

26. The new reporting model will be introduced on a phased basis, initially in a number of pilot schemes if this is judged appropriate, to be followed by a broader rollout which will be informed by learning from the pilot schemes The project team will oversee and evaluate the development and pilot process, and will explore appropriate supporting structures, including IT systems (in partnership with the RBSO), reporting forms and transitional protocols. Evaluation of the pilot schemes will inform refinements to the new model prior to any decision to introduce it regionally. The establishment of an effective accountability chain between the lead regional organisation(s) and

the Department will also be an important milestone in this stage of the implementation process. The target date for the full implementation of the RAIL model is April 2011.