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Irish Inquiry Reports Relating to Perinatal Deaths and Pregnancy Loss Services

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Abstract

Aims
External inquiries are carried out following specific adverse events in healthcare, many in maternity care; to identify issues and make recommendations to improve standards of care.

Methods
Ten publically-available national inquiry reports published between 2005-2018 relating to pregnancy loss services, were reviewed by 2 clinicians, separately, examining the content and recommendations from each report.

Results
A total of 258 recommendations were made in 9 reports (90%). Five inquiries (50%) clearly stated that affected families were involved and four (40%) involved affected clinical staff. In 9 reports (90%) recommendations included: increase workforce staffing and/or training, strengthen clinical governance, enhance adverse incident management and comprehensive data collection e.g. maternity outcomes. Only two inquiry reports (20%) stated that feedback was sought from key stakeholders prior to publication.

Conclusion
A collaborative and standardised inquiry process involving and supporting all persons affected as well as key stakeholders would ensure that all relevant issues are identified, recommendations are implemented and essential lessons are learned.

Introduction

An external inquiry is established, when required, to examine issues of public concern or importance.[1] In the health services, inquiries aim to establish facts, identify modifiable factors after adverse outcome(s) and ensure essential lessons are learned, and thereby prevent a recurrence of the events.[2, 3] An inquiry should always remain inquisitorial and avoid becoming adversarial.[3] For affected families and even the public, well-executed inquiries can contribute to restoring confidence and trust in health services, as well as providing resolution/closure.[2, 3] Government and/or health service departments may commission an inquiry due to public pressure to respond to tragedy or to highlight areas of need for change.[2]

External inquiry teams or panels should be independent with no vested political or personal interest to the events under review.[1] Ideally, panels are made up of multidisciplinary teams with experts from various backgrounds (including healthcare professionals, risk or quality management personnel, support or patient representative groups and administrative support) with defined roles and access to all relevant documentation.[4] An external inquiry requires a significant commitment of time and resources; therefore it can be a costly endeavour.[2]

Many external inquiries related to maternity services in Ireland have been carried out over the last 15 years, often after negative media reporting of adverse events (e.g. maternal/perinatal deaths) that have occurred. The aim was to identify issues in the maternity care provided to pregnant women, and to make recommendations based on these findings to improve the standard of care. The Health Service Executive (HSE) Incident Management Framework – Guidance 2018 (which replaced the HSE Safety Incident Management Policy 2014) advocates for recommendations to apply the SMART (i.e. specific, measurable, achievable, realistic or time-bound) principle to facilitate the development of clear and relevant action plans.[4] However, generated inquiry recommendations assessed in previous Irish and British research have not been consistently or entirely implemented.[1, 2, 5] We aimed to examine and compare the general structure, methodology, findings and recommendations of 10 Irish inquiry reports (published between 2005 and 2018 relating to perinatal deaths and pregnancy loss services), in order to identify standardised inquiry procedures and highlight recurring recommendations in the reports.

Methods

Ten publically-available national inquiry reports, published between 2005 and 2018 relating to perinatal deaths and pregnancy loss services, were identified from national inquiries into the maternity services in Ireland.[6-15] The focus of each report is outlined in table 1. The reports were reviewed and assessed by 2 clinicians, separately, to compare and examine the content and recommendations made in each report.

Quantitative and qualitative data was collected using a standardised and specifically designed review tool (based on the HSE Systems Analysis Review Report Checklist). The review tool has 21 items divided into 6 separate sections which cover aspects such as: terms of reference, general content, review methodology and recommendations. Where applicable, the answers were scored: Yes, Partial or No. A copy of the review tool is available from the authors upon request. Descriptive analyses of the main characteristics of the reports were carried out to give an overview of the terms of reference and inquiry review process, and to identify recurring themes in the recommendations.

Table 1. Report focus and year of publication

Report	Focus of report	Year of publication
1	National paediatric post-mortem practice and procedures [6]	2005
2	Inquiry into the case of a maternal and perinatal death at a regional hospital [7]	2008
3	Identification of trends about the causes of miscarriage misdiagnoses [8]	2011
4	Inquiry into the case of a maternal death at a regional hospital [9]	2013
5	The safety and quality provided to pregnant women at risk of deterioration (based on findings in one regional hospital) [10]	2013
6	Perinatal deaths and related matters in one regional hospital (over 8 years) [11]	2014
7	The safety and quality provided to patients at one regional hospital, including maternity care [12]	2015
8	Governance of maternity services at one peripheral hospital [13]	2015
9	Evaluation of 203 maternity related complaints received by the HSE [14]	2017
10	Maternity services and 18 perinatal deaths at one peripheral hospital (over 6 years) [15]	2018

Results

Structure of the inquiry reports

The layout and length of the 10 analysed inquiry reports varied significantly. All but one had clearly defined sections. The make-up of the inquiry teams, the report commissioner and the manner the affected clinical staff and patient and/or family were involved in the review process is outlined in table 2. Half of the reports (n=5) clearly explained the inquiry methodology used (including reference to review tools). International, as well as national guidelines, were used as reference standards in 6 reports (60%). Three reports (30%) used national guidelines as reference standards; one report (10%) does not mention any guidelines. Four of the inquiry reports (40%) describe clearly how the relevant clinical staff were involved in the review, one further inquiry held interviews with staff representatives and in one inquiry interviews were carried out, but it is unclear from the report with whom. All affected families were involved in 4 inquiries (40%) and one further inquiry involved some of the affected families (table 2). Three reports (30%) outlined how the outcome of the inquiry was communicated to the families directly. Four reports (40%) commented on good aspects of care provided; however, the reports focussed mostly on unfavourable issues.

Table 2. Report structure

Report	Length (pages)	Inquiry team	Commissioned by	Timeframe of review	Clinical staff involvement	Patient/family involvement
1	143	Only the author of the report named	Government	8 months	Submissions from hospitals	Written accounts by families submitted
2	15	Multidisciplinary team (4 people)	HSE NE	Not stated	Interviews with 31 staff members	Interviews with 2 family members
3	57	Multidisciplinary team (14 people making up 2 teams)	HSE	10 months	No, anonymous case reviews	No, anonymous case reviews but cases identified through patient helpline
4	108	Multidisciplinary team (8 people)	Hospital, HSE	7 months	26 interviews with key staff	Offered and declined
5	31	Multidisciplinary team (published in separate document)	HSE (Director General)	11 months	No	No
6	86	Not stated	Minister for Health	Not stated	Meetings with staff representatives	Meetings with some families
7	210	Multidisciplinary team (6 people)	Minister for Health	13 months	Interviews, group meetings, observations	Meetings with 15 families
8	11	Only the author of the report named	HSE	Not stated	Interviews (number not stated)	No
9	66	3 phases to the review, 3 teams	HSE	3 years	No	Telephone, mail and email correspondence; Meetings with external clinical experts in phase 2
10	136	Multidisciplinary team (8 people)	Chief Clinical Director, Hospital Group	3 years	Interviews with senior clinicians and managers; 201 separate staff interviews relating to specific cases	Open forum meeting, followed by private meetings with 9 families; 16 families interviewed regarding 18 specific cases

Recommendations made in the reports

All reports made recommendations; these were in clear sections in 9 (90%) reports (table 3). A total of 258 recommendations were made in 9 (90%) reports (table 3). Nine reports (90%) made nationally applicable recommendations. The SMART principle (1. Specific, 2. Measurable, 3. Achievable, 4. Realistic, 5. Time-bound) for developing recommendations as advocated by the HSE Incident Management Framework was fulfilled in only one report (table 3).[4] The SMART principle describes elements that recommendations should have to promote

implementation.[4] The recommendations were scored 1 for each element, to give a score out of 5 (table 3). Recommendations were either discussed with key stakeholders or the organisation named responsible for implementation of recommendations in three reports (30%). A clear timeline for implementation of all recommendations was set out in only one report (10%).

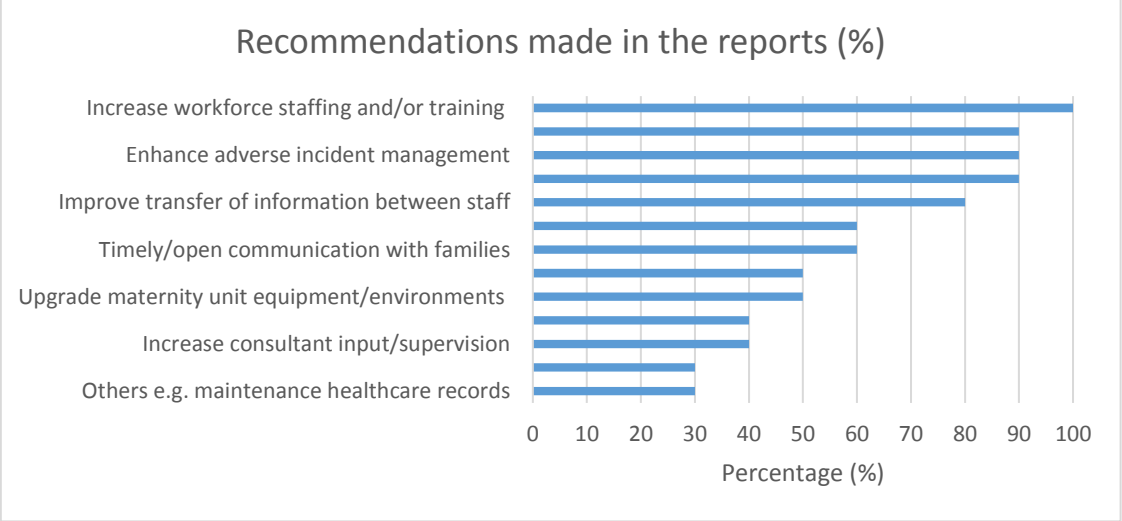
Table 3. Report recommendations

Report	Specific section for recommendations	Number of recommendations	Linked to findings	SMART *	Actions necessary to reduce recurrence risks highlighted
1	Yes	50 within 7 themes	Yes	3/5 (not time-bound, not consistently specific)	Yes
2	Yes	27 divided into 3 categories based on priority	Yes	4/5 (not time-bound)	Yes
3	Yes	20 within 6 themes	Yes	3/5 (not time-bound, not consistently realistic)	Partial
4	Yes	9 divided into 2 groups	Yes	4/5 (not consistently time-bound)	Yes
5	Yes	34 divided into local and national	Partial	2/5 (not consistently specific, measurable, time-bound)	No
6	Yes	53 (11 of these labelled overall recommendations)	Partial	5/5	Partial
7	Yes	8	Yes	2/5 (not consistently specific, measurable, time-bound)	Yes
8	No	Embedded into main text not highlighted as recommendations	No	Not possible to assess as recommendations embedded into main text	No
9	Yes	22 divided into 2 phases	Partial	4/5 (not time-bound)	No
10	Yes	35 within 5 theme	Yes	4/5 (not time-bound)	Yes

*Specific, Measurable, Achievable, Realistic, Time-bound

Themes generated from the recommendations and the frequency (%) with which these were made in the reports are illustrated in figure 1. Other recommendation themes included: maintenance of professional competence (30%), reviewing legislation (e.g. Coroners Act, Civil Registration Act, Termination of pregnancy) (30%) and perinatal post-mortem consent and procedure (20%).

Figure 1. Themes and frequency of recommendations



Discussion

We examined and compared the general structure, methodology, findings and recommendations of ten inquiry reports in detail. The inquiries were commissioned by the HSE or the Department of Health. Only 5 reports (50%) explained the inquiry methodology used clearly. It is not clear in the other 5 reports (50%) whether the method used is simply not outlined or no formalised method was used. The focus of the 10 inquiry reports varied significantly, but they were all related to the maternity services and adverse pregnancy outcomes. Generally, pregnancies are seen as having only positive outcomes and therefore adverse outcomes can generate significant public interest.[16, 17] Inquiries take a significant time to be completed (7 months to 3 years in this cohort), this delay in report publication means that public opinion is often formed by immediate media coverage of events rather than inquiry findings.[1, 16]

The reports under review varied from 11 to 210 pages in length. Lengthy reports are unlikely to be read in full, therefore having a comprehensive executive summary and recommendations section is essential to present the key learning points.[2] Seven of the inquiries (70%) were carried out by an appropriate multidisciplinary team, however, the selection process of the experts/professionals in the team is not clearly outlined. Ireland is a small country with a limited number of experts/specialists in its maternity service; appointing experts to lengthy inquiry processes reduces their time commitment to a service already under pressure.

Ongoing reliable internal adverse incident reviews may reduce the need for external inquiries, reserving their use for exceptional adverse events of public concern. Ninety percent of reports (n=9) advised enhancing adverse incident management in the maternity services. Of note the HSE Incident Management Framework 2018 has been published since the most recent inquiry was completed.[4] This Framework recommends that all persons affected by an incident (i.e. service users, families and staff) should be aware of any review undertaken and ideally be involved in the process.[4] We suggest the same principle be applied to inquiries. Timely and open communication with families after an adverse event was recommended in 60% (n=6) of reports. Families value transparent, kind and compassionate interaction with hospital staff after adverse outcome, especially a perinatal death, whereas lack of information or explanation may exacerbate feelings of anger and frustration.[18]

Every inquiry or incident review report should include recommendations directly linked to the key findings. Clear and relevant recommendations are more likely to be implemented than non-specific and impractical recommendations. [5, 19] Furthermore, appropriate and well-defined recommendations encourage the development of action plans. The HSE Incident Management Framework advocates the generation of SMART recommendations.[4] Out of the 10 reports only one (10%) fulfilled all 5 criteria, however in this report not all recommendations were directly linked to the key findings. The average score for the 9 reports was 3/5. Nine reports (90%) did not give a defined timeline for implementation of all the recommendations. It was not clearly described who had responsibility for implementation in 90% of reports (n=9). To support implementation of recommendations, the development of a standardised, systematic approach to inquiry recommendations would be beneficial.

Involving key stakeholders in the making of recommendations increases the chances of successful implementation.[1] This is especially important for hospital-specific recommendations. One possible method is to request feedback on draft recommendations over a defined period of time, before publishing the appropriately revised final report recommendations. Two of the 10 Irish inquiry reports (20%) stated that feedback was sought prior to publication of the report.

In Ireland, as in the UK there are no formal systems in place for following up recommendations made in inquiries.[2] Three of the reports (30%) highlighted a concern regarding the incomplete implementation of previous inquiry recommendations. This raises the following questions: what responsibilities does the commissioning agency have in following-up on the implementation of recommendations made by the inquiry team they have put in place? And who is accountable if recommendations are not implemented? The inquiry report is just the first step in managing adverse incidents, as highlighted by Macrae (2016): “The search for safety starts, rather than ends, with incident reports”.[20]

It is difficult to assess fully what impacts these inquiry reports have had on maternity services directly, as some changes may have occurred with policy improvements anyway. Of note, all 10 reports (100%) made recommendations in relation to workforce staffing and/or training. A service that is chronically under-staffed will not be able to facilitate protected time for important training and education of its workforce. However, in the time since the first report publication in 2005, pregnancy loss/perinatal bereavement care has improved nationally as recommended in 40% of reports. In 2016, the HSE National Standards for Bereavement Care Following Pregnancy Loss and Perinatal Death were published.[21]

Since publication of reports 4 and 5 (table 1) awareness of the deteriorating pregnant patient has increased. Early warning systems (recommended in 30% of reports) have been introduced and multidisciplinary sepsis training implemented. National maternity outcome reporting (Irish Maternity Indicator System) commenced in 2014 and reports 30 common indicators (e.g. miscarriage misdiagnosis) across the 19 maternity units annually.[22] Ongoing maternal and perinatal outcome data collection has been recommended by numerous National Perinatal Epidemiology Centre (NPEC) reports (including Perinatal Mortality Report 2016, Neonatal Therapeutic Hypothermia in Ireland 2016-2017 and Severe Maternal Morbidity Report 2014).[23-25]

In this cohort of reports, ninety percent (n=9) recommended comprehensive data collection in the maternity units to identify areas in need of improvement. However, it is important to also provide resources for addressing these shortcomings and ensure duplication of data collection/reporting does not occur. Nine reports (90%) advocated for stronger clinical governance in the maternity service. Steps taken to date to strengthen the maternity service governance include: the publication of National Maternity Strategy (2016-2026), the establishment of the National Women & Infants Health Programme (NWIHP) and the evolving formation of maternity networks.

In conclusion, inquiries are important to investigate rare, exceptional incidents of public concern, however they entail lengthy and sometimes complex processes; thus, a timely and robust internal inquiry might instead address local concerns in a more timely manner. Reliable, beneficial internal incident reviews require staff training in-and availability for incident management.

A collaborative inquiry process involving and supporting all persons affected, as well as key stakeholders would ensure that all relevant issues are identified, recommendations that can be implemented will be generated and essentials lessons are learned. The approach to recommendations and the process for implementation of these recommendations should be clearly documented, including who has responsibility to oversee implementation. Developing a standardised and systematic structure for inquiry methodologies and reports would be beneficial to this process, and encourage completion of the investigation cycle.

Declaration of Conflicts of Interest:
There authors have not conflicts of interest to declare.

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