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# **How well do Regulation 28 reports serve future public health and safety ?**

Short title: The Haphazard Regulation 28 Report

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## **Abstract**

H.M. Coroners issue Regulation 28 (Reg.28) reports following inquests. These reports concern hazards which, if mitigated, might prevent future deaths and have addressees who are best placed to take remedial actions. Since 2013, the reports and addressees' responses are copied to, and electronically published by, The Chief Coroner, in non-exclusive demographic, aetiological or venue categories. Three of those categories were chosen so as to minimise the replication of unique cases: child deaths, alcohol drugs and medications (ADM) and railways, with the most recent  $n = 50$  reports in each category. A further *ad hoc* sample of neonates was taken after a finding in the first of these. The principal findings are: a) H.M. Coroners generate Reg.28 reports at different rates (including 27 Coroners' Areas with none at all; random variation probability  $p \approx 10^{-6}$ ); b) there is a large deficit of addressees' responses compared with Reg.28 reports that are issued; c) addressees from large organisations are more likely to respond than small ones; d) substantive remedial actions appear in only a further subset of addressees' responses; and e) there is a gender imbalance in Reg.28 reports which is least explicable for neonates. It is concluded that the Reg.28 report system is haphazard in many ways. As the only official publication from H.M. Coroners' courts, the role of Reg. 28 reports in preventing further deaths has a large scope for improvement, which might promote support from bereaved families and the wider public for the process of inquest. Suggestions for process improvement are made.

## **Keywords**

H.M. Coroner, Regulation 28 Report, Decision making, Public health and safety

## **Introduction**

H.M. Coroners have a duty to write a Regulation 28 (Reg.28) report when, during their investigations, they identify causes for concern that, if addressed, could prevent future deaths. This duty is provided for by statute<sup>1</sup>, regulation<sup>2</sup>, and *Guidance no.5* from the Chief Coroner<sup>3</sup>. The addressee(s) of the Reg.28 report is/are whomever the Coroner believes can take desirable, remedial action(s). Addressees are instructed to reply to the report (usually within 56 days), or to inform the Coroner why no action is being taken. The Chief Coroner is copied on all Reg.28 reports, and there is a presumption of publication both of the report itself and the addressees' responses. Since 2013, publication has been web-based, with reports allocated to one or more non-exclusive categories based upon demographics, aetiology, or venue (see Table 1). Almost all Reg.28 reports issue follow an inquest, and use a template provided in the Chief Coroner's *Guidance*.<sup>3</sup> Thus, the overall purpose of the Reg.28 report is to reduce the probability of future unnatural deaths by creating a public record that identifies hazards, and can stimulate mitigation of risk.

The purpose of this study was to investigate the efficiency and effectiveness of the Reg.28 report system. The system relies on three separate activities: report generation, addressee's response, and implementation of mitigating actions. The public record is a suitable resource for this study because the system is designed to generate information in the public domain for future use. Is the Reg.28 report system efficiently contributing to the objective of improving public health and safety, and, if not, then how might this process be improved ?

## **Methods**

### *Sampling*

Cursory inspection found that unique cases might be allocated to more than one category of Reg.28 report by the Chief Coroner's office. Therefore, three categories were chosen with the aim of as little overlap as possible: these were: child death, alcohol, drug and medications (ADM) and railways. Without any basis for a power or sample size calculations, but in pursuit of current coronial practice, the most recently published (by 10 June 2020), consecutive, 50 cases in each category were chosen for study. The earliest date for each sample was 11 Feb 2019 (child deaths), 17 Sep 2019 (ADM), and 21 Oct 2013 (railways). Following an initial observation among the child deaths category, a subsequent, *post hoc* sample of all published cases involving neonates (a further 29 cases dating from 2013) were studied separately (see below). The term 'neonate' is used below to refer to all deaths up to 28 days of age, recognising that this conflates+ the UNICEF definitions of perinatal death (days 1 – 7) and neonatal death (days 8 – 28).<sup>4</sup>

Addressees were classified into: Government (Westminster, Cardiff or local), NHS entities (Trusts, hospital health boards, clinical commissioning groups), Professional bodies (Royal Colleges, General Medical / Nursing Councils), independent safety institutes (Health Safety Investigation Branch, National Institute for Health and Clinical Excellence, Clinical Care Quality Commission, British Standards Institute), law enforcement (police services, H.M. Prison and Probation Service, National Offender Management Service), railway companies and Authorities (H.M Inspector of Railways, Rail Safety and Standards Board), and other (a wide variety of low-frequency reports e.g., GP surgeries, a martial arts school, Safeguarding Children Boards, CAfCASS, and the Scout Association). Addressees' actions were classified as: actual or identified change to physical equipment or facility, actual or identified change to process specifically related to the unnatural death, actual or identified change to a system

process that contributed to the unnatural death, no identified change in any physical equipment or process, but acknowledging report.

The choice of three discrete categories of Reg.28 report was successful in that only one child death also appeared in railways, and another child death appeared in the ADM category. Thus, the 150 sampled cases represented 148 unique fatalities; these two cases were left in both of their categories for analysis (i.e., N = 50 for each category). Three Reg.28 reports each concerned two deceased, and these became six unique cases in the database.

### *Data management*

The sampled Reg.28 reports were abstracted into a database using Microsoft© Excel©. Case identifiers were the (non-consecutive) reference numbers assigned by the Chief Coroner's office, and a further serial number within each report category for the database. The items of information relevant collected from each Reg.28 report were surname, forename(s), gender and age of the deceased, date of the report, Coroner's area generating the report, addressee(s), medical causes of death, conclusions (formerly verdict), summary narrative of circumstances, Coroner's concerns, whether specific action was recommended, date(s) of response(s) (if any), actions taken by respondents (if any).

Although a data sufficiency of 66% ([items recorded / total possible number of items] x 100%) had been prospectively decided, in the event, the Reg. 28 report template had been completed fully in more than 95% of cases. Forename(s) were used to confirm gender in seven cases. The age of the deceased was unavailable in four child deaths, 17 ADM cases, and 19 railway fatalities (although the latter were not children). In one case, the deceased was in her 'GCSE school year', and an age of 15 years was allocated. In some cases, the age was determined to the nearest day from the narrative of circumstances (e.g., deceased neonates following adverse obstetrical events). Addressees were those specifically identified; those

merely receiving copies of the report as interested parties were not included. There was one (railways) report whose 56-day response interval had not expired.

The geographical location of each Coroner's office was found from current internet information, and plotted using a publicly available road map of England and Wales.<sup>5</sup> Multiple Coroners' Areas within the same city (London and Manchester) were analysed separately. Due to the merging of some Coroners' areas during the reporting intervals (e.g., four areas merging at Maidstone (co.Kent), and three at Winchester (co.Hants.), some adjustment to the number of Coroners' areas was required, with a total of 80 being used for analysis. The relative size of the Coroners' areas was estimated using the total number of reported deaths for the year 2017 (merged when appropriate), which was the most recent data available;<sup>6</sup> these ranged from 255 (City of London) to 6709 (Nottinghamshire) cases per year.

All data used was already published and in the public domain. There were no new human data collected. Research Ethics Committee approval was therefore not required.

## **Results**

### *Regulation 28 report generation and addressees*

Figure 1 shows the standardised report rates among the 53 Coroners' Areas that generated at least one report. Twenty-seven of 80 Coroners' Areas had no published reports in any of the three selected categories. The finite, *post hoc* probability of 150 reports distributing at random into any combination of 53 out of 80 Coroners' areas (without adjustment for area size) was calculated as:

$$p = (53/80)^{150} \times [80! / (53! \times (80 - 53)!)] \approx 10^{-6}.$$

The geographical distribution of Reg.28 report origins, did not match that of Coroners' offices, in that central England was under-represented. For railways, there were report clusters

in Manchester and London, corresponding with the densest railway networks in England and Wales, plus Hertford (co.Herts.) and Bedford (co. Beds.) corresponding with the roots of the East and West Coast mainline services (which branch further north), respectively.

There was also substantial variation for the multiple Coroners' areas within London and Manchester. Excluding the smallest service (the City of London), the standardised reporting rates were (Reg.28 reports / 1000 total reported cases in 2017): 0.42 – 3.99 in London, and 1.15 – 4.87 in Manchester.

A gender imbalance, with a female minority, was observed for all three Reg.28 report categories (n = 50 each): child deaths 19 (38%), ADM 20 (40%), and railways 11 (22%). Neonatal deaths were all either obstetrical fatality or post partum sepsis (there were no examples of primary foetal pathology), and, as discussed below, the gender imbalance extended to this subset (n = 14) of whom only five (36%) were female. An *ad hoc* further sample of all published Reg.28 reports involving neonates was then undertaken, regardless of date. The proportion of female deceased did not differ greatly between the original sample and the *ad hoc* sample: the latter (n = 29) contained only nine (31%) female fatalities, and the aggregate was 14 female deceased of 43 (32.6%) neonates, among the total of 166 child deaths.

A qualitative finding was that almost all Coroners relied on the stereotypical wording in Box 6 of the template (see below) when requesting actions (see Table 2). However, in outlining their concerns in Box 5, some sort of specific action was often alluded to. For example, in a case of Sudden Infant Death Syndrome the Coroner's concerns included that the deceased's mother never saw the same midwife twice, that there were communication problems among midwives, and no advice against co-sleeping had been given (the addressee, an NHS Trust responded with some concrete organisational changes). However, other Coroners' concerns were less specific, e.g., one ADM case where the Coroner simply noted the additive or supra-additive pharmacodynamic effects (respiratory depression) of a particular drug

combination (with an addressee's response noting this was already in standard textbooks and other publications).

### *Addressees and Responses*

All Reg. 28 reports had  $\geq 1$  addressee, and there was a mean of 1.57 addressees for each report (Table 3). Overall, among  $n = 236$  addressees, the response rate was 37.4%. Reg.28 reports without any response were (% of unique cases,  $n = 50$  each category): child deaths (48%), ADM (36%) and railways (36%).

The probability of a response also depended on the type of addressee (Table 4). NHS entities and railway companies / authorities led the response rates, while Network Rail ( $n =$  addressed 26 times) had the highest individual published response rate (73% of all addressed reports). The single unexpired 56-day response interval for a Railways report would have added 0.47% to that category, had a response been received.

### *Addressees' actions*

Published responses to Reg.28 reports often contained multiple elements. The proportion of responses that represented more than mere acknowledgment, and indicated remedial action(s) of any type, were termed 'Substantial responses', and were sparse compared with the other two categories (Table 5). An effective response rate, being the proportion of addressees submitting published substantial responses was 25.2% for child deaths, 11.0% for ADM and 47.8% for railways; the latter value was dependent on the relative responsiveness of Network Rail as a single addressee.

## **Discussion**

The study sampled the 50 most recent published reports in three categories child deaths, ADM, and railways. Publication rates varied in non-random fashion when standardised for size of Coroner's Area. A gender imbalance was identified that extended to neonates. Published response rates varied among types of addressee, and category of report, but with a general, substantial deficit to the numbers of Reg.28 reports issued. Substantial published responses (with identifiable remedial actions specified) demonstrated an additional deficit.

The railways category differed from the other two. Firstly, for actions taken, there was a greater proportion of physical equipment changes, and fewer process changes, than among child deaths and ADM. This was associated with a larger proportion of substantial responses; this might suggest that process changes are harder to accomplish than changes to physical equipment. Secondly, as shown in Table 3, there were relatively fewer multiple addressees in railways category reports, consistent with longstanding railway law, and its few competent authorities.<sup>7</sup> Coroners might have found it easier to identify the appropriate addressee for a railways report than for child deaths and ADM.

H.M. Coroners have individual jurisdictions with geographical boundaries, and are appointed by Local Authorities. Analysis by location of origin therefore reflects the practice of a Senior Coroner and/or any associated Area or Assistant Coroners (who, when investigating, all act with similar powers). The generation of Reg.28 reports among the 80 Coroners' areas was bimodal. The probability that, by chance, 27 Coroner's areas should have had no published reports in any of these three categories, with this sample size, was infinitesimal. The only interpretation is that Coroners have varied practices regarding whether to generate a Reg.28 report.

The types of addressee were also not random, but were rational given the categories of Reg.28 report that had been selected. Obvious examples included NHS entities predominating among obstetrical fatalities, and railway authorities and companies among railways cases.

The circumstances of death, conclusions (formerly verdicts), and Coroners' concerns (Boxes 3 – 5 of the Reg.28 report template) have not been analysed in detail, beyond the observation that there were substantive entries in all 150 cases. These are qualitative data and some sort of mixed methods analytical approach could have been used. However, that approach would commence an investigation into the public health and safety problems being reported, rather than the intention here, which is to study the Reg.28 report process itself.

The fact that almost all Reg.28 reports contained only the stereotypical wording in Box 6 of the template is consistent with both the Chief Coroner's *Guidance*<sup>3</sup> and obiter in *Clegg* [1996].<sup>8</sup> Coroners cannot be expected to be experts in matters such as railway engineering or NHS logistics, nor to be able to recommend what might be optimal among alternative, feasible, remedial actions in order to mitigate a particular risk. Placing the onus on the addressee for design of precise actions would appear to be a rational delegation of role to the best-qualified party.

The gender imbalance found in this study extends previous findings. Maclean found a male predominance both among cases reported to Coroners and the proportion of cases proceeding to inquest.<sup>9</sup> It can be hypothesised that female patients are more likely to be known to their general practitioner (and thus have a higher probability for straightforward death certification and registration), and that males are more likely to engage in suicide and other behaviours leading to death by misadventure.<sup>10</sup> However, these medical explanations are largely related to post-pubertal circumstances, and do not explain the gender imbalance among child deaths, and neonates, in particular. The large majority of the latter were obstetrical

fatalities , and the rest were occasional cases of sepsis: neither has an epidemiological gender bias.

This study has limitations. First, only three categories of Reg.28 reports were sampled, and 50 from each were chosen as a compromise between focussing on reasonably current practice and small sample bias. However, increasing the sample size for neonates *ad hoc* did not substantially change the estimates for gender imbalance among those in the initial fifty cases. Nonetheless, the study could be extended, at the risk of greater numbers of unique cases appearing in more than one Reg.28 report category.

Secondly, there is the issue of publication bias. This seems unlikely for the Reg.28 reports themselves because: i) there are reasonably even intervals for publication dates in each of the three categories (data not shown), ii) the gender imbalance matches that for inquests (see above), and iii) there would seem to be little motive for selective publication because the Chief Coroner's *Guidance* specifically indicates a '*presumption of publication*'.<sup>15</sup> For responses, the publication policy is the same.

Thirdly, the interpretation of addressees' responses (Table 5) are probably the most liable to subjective error. The 56-day requirement is for a response to the report, not for remedial action itself. A compliant response might be simply the addressee stating no action will be taken with some justification(s). Alternatively, the response might describe planning for some sort of change that will require more than 56 days to implement.

No similar studies for comparison have been found. The absence of easy comparisons between Coroners' practices is discussed further below.

The legal framework (see Introduction) is insufficient if it is assessed by the implementation of the Reg.28 report process. Here, some 27 Coroners' Areas were without a single published report, which is clearly not random given the sample size. Moreover, the large deficits in supposedly mandated responses, and the further deficit in specific remedial actions

being taken, all show that the Coroners' and Addressees' statutory duties are, in many cases, not being fulfilled. For Coroners, the Chief Coroner's *Guidance* reads (para 8)<sup>3</sup>: '*It is for each Coroner to decide on a case by case basis whether he or she has a statutory duty to make a report*' thus diluting the statutory duty<sup>1,2</sup> to a discretionary one. For addressees, there are no sanctions for failing to respond to a Reg.28 report. Coroners are under no obligation to follow up with addressees that fail to respond, and the Chief Coroner's database makes no provision to record any.

External evidence suggests that Coroners indeed have idiosyncracies with regard to writing Reg.28 reports, and vary in their indifference to future public health. In 2010-2011, McGowan interviewed 32 H.M. Coroners in England and Wales (about a third of the then total). When asked about Coroner's purposes, only six of these 32 made any reference to the prevention of future deaths, with a different subset of six seeing improvement of public health as a primary purpose.<sup>11</sup> Of these few, only one Coroner mentioned the Reg.28 report (then the 'Rule 43 report') as having an active role in public health, although a few others saw a passive role in contributing data for statistical analysis by the Office of National Statistics.<sup>11</sup>

The *de facto* discretionary nature of Reg.28 report generation is perhaps consistent with individualism among other Coroners' powers. The Coroner, in his or her local domain, is subject to very little audit, and has no real resource to make comparison with the practices of others. Coroners are appointed by local authorities as the latter see fit, and can only be removed after consultation between the Lord Chancellor and Lord Chief Justice '*for incapacity or misbehaviour*'; there is no lesser disciplinary responsibility for the Chief Coroner. Roberts et al used a test set of 16 reasonably common clinical scenarios, and demonstrated that even the fundamental decision between natural and unnatural death (which governs all further investigation) varied amongst n = 64 Coroners;<sup>12</sup> that fundamental decision is further complicated because Harris has shown that there is a discrepancy between what is assessed

legally and medically as ‘natural’.<sup>13</sup> Procedural guidance at the national level is often vague beyond the Chief Coroner’s Reg.28 report template. All this allows wide variation in the criteria used in individual Coroners’ decision-making.

It is to be remembered that the grieving family and the general public often hold improvement of the public health as their motive for supporting the process of inquest. This is often couched in terms of not wanting the same tragedy to befall somebody else’s relative(s). The Chief Coroner has confirmed this: ‘*A bereaved family wants to be able to say: His death was tragic and terrible, but at least it shouldn’t happen to somebody else*’.<sup>3</sup> Part of that process must be the publication of Reg.28 reports, because, in the absence of any law reports or other publicly accessible archive, these are the only vehicle for publication of inquest findings and identification of hazards that can be mitigated by remedial actions. If, in fact, the Reg.28 report system has considerable scope for improvement (as these data suggest), then a public perception of the inadequacy of any system to help prevent ‘*..it happening to somebody else*’ will undermine support for the coronial system in general, and forego the ‘*chance for education*’.<sup>14</sup>

The Reg.28 report system could obviously benefit from some sort of nationally consistent rule on when a report should be written; if that was to prove impossible, then perhaps some variant, not necessarily demanding remedial action by a named addressee, should issue after every inquest. A national archive, open to the public could then form a useful basis for the mitigation of risk (ironically, this was the case from the 13<sup>th</sup> to mid-17<sup>th</sup> century, until abolished by law).<sup>16</sup> Such an archive could also help drive increased consistency across a wider range of Coroners’ practices because audit-worthy norms could be tested (see above). If addressees will ignore Reg.28 reports with impunity, and if they cannot be encouraged to fulfil

their duty voluntarily, then it would be easy enough to revise the Regulations to introduce sanctions, and to empower Coroners to enforce these statutory duties.

## **Conclusions**

Reg.28 reports are not operating in the manner envisaged by the Act<sup>1</sup>, Regulation<sup>2</sup> or Chief Coroner's *Guidance*<sup>3</sup>, and are haphazard in many respects. Reg.28 report generation has geographical biases, probably attributable to non-uniform attitudes of H.M. Coroners. The published *corpus* of reports has a gender imbalance, and this is least explicable for neonates. Addressees appear to be commonly ignoring their duty to respond to Reg.28 reports. Publication bias seems unlikely. The current practice is not compatible with the motivations of bereaved families or the broader public, in the interests of improving health and safety. There is ample scope for process improvement, and this could be accomplished by further Regulation, to include, if necessary, sanctions for addressees and enforcement powers for Coroners.

## **Competing interests statement**

The authors declare they have no potential conflicting interests. This study forms part of a dissertation (by AWF) submitted for the degree of LLM (Birkbeck, University of London), as well as evidence submitted to the parliamentary Justice Committee's Inquiry on The Coroner Service.

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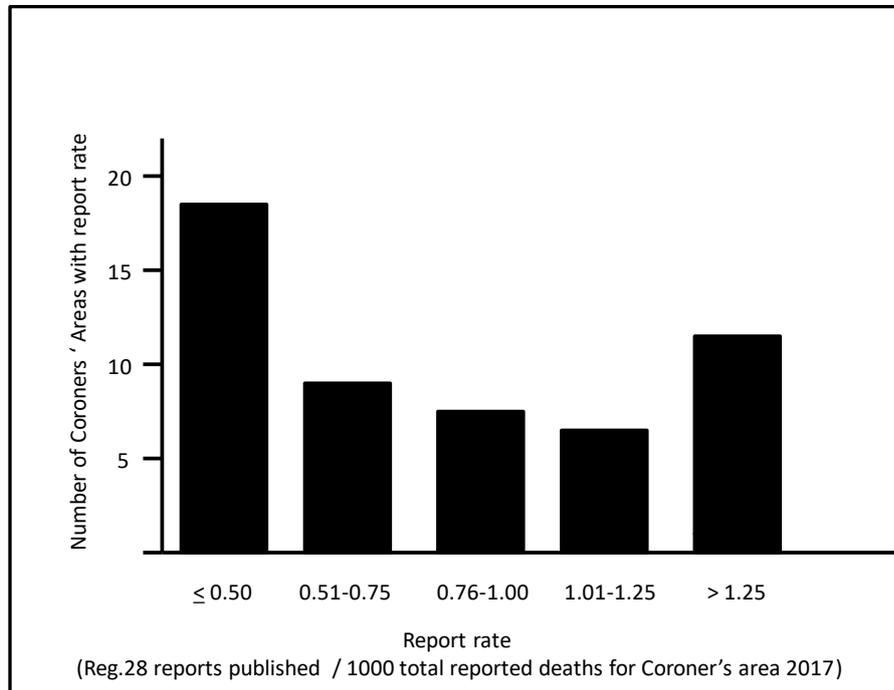
**Study guarantor:** Anthony W. Fox

**Contributorship statement:** Dr.Fox conceived the project, collected the data, constructed the database, did the quantitative analyses, and wrote the manuscript. Professor.Jacobson brought the context of the wider literature on Coroners' courts, the perspective of the families of the deceased and the general public, and numerous cogent questions that improved this study.

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**Figure 1.** Regulation 28 (Reg.28) report rates for the categories child death, AD&M, and railways among n = 53 Coroner's Areas in England and Wales. The report rate is standardised per thousand total cases reported in 2017 for each Coroner's Area as the denominator. In addition, there were 27 Coroners' Areas with no published Reg.28 reports in these three categories.

**Table 1.** Categories used by the Chief Coroner for publication of Regulation 28 reports.

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Work / Health and safety	Alcohol, drug and medications
Care home related	Child death
Community health care and Emergency services	Emergency services
Hospital death	Mental health related deaths
Other related deaths	Police related deaths
Product related deaths	Railways
Road / highway Safety	State custody deaths
Suicide	Wales

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**Table 2.** An extract from a Regulation 28 Report using the template per the Chief Coroner's *Guidance*.<sup>3</sup> Box 5: Example 'Coroner's concerns' are the first four taken from a Reg 28 report in the railways category (the name and date of the deceased are redacted here, but do appear in the database). Box 6 'Action should be taken' shows the stereotypical wording which is amended only very rarely.

### **5 CORONER'S CONCERNS**

During the course of the inquest the evidence revealed matters giving rise to concern. In my opinion there is a risk that future deaths will occur unless action is taken. In the circumstances, it is my statutory duty to report to you.

The MATTERS OF CONCERN are:

[Redacted name of deceased] died on [redacted date of death]. The last time the broken fence was checked was 27 October 2016. In the intervening two and a half years, reasonable endeavours had not been made to inspect (and repair) the fence.

1. The fence was marked down for annual inspections because there was no history of problems in that area. However, the inspectors conducting the inspections on 27 October 2017 and 27 October 2018 (a different inspector on each occasion) did not consider the relevant part of the fence because dense vegetation blocked their view from trackside. Neither inspector attempted to view the fence from the other (public) side, which they could easily have done. This represents a failure of the two individuals and/or a failure of their training and/or both. There are only four inspectors at Tottenham, so two inspectors represents half the inspections workforce.
2. Both inspectors inputted their inspection onto a computer system, but neither submitted a paper form as they were meant so to do. This represents a failure of the two individuals and/or a failure of their training and/or both. In any event, such a system of dual submission was inherently flawed.
3. As a consequence of no paper forms being submitted, the track engineer did not see the evidence of the failure to inspect the fence, and so was not in a position to challenge this. This represents a system failure.
4. As a consequence of no paper forms being submitted, the internal auditors did not see the evidence of the failure to inspect the fence or the evidence of the failure to challenge, and so were not in a position to highlight this. This represents a system failure.

### **6 ACTION SHOULD BE TAKEN**

In my opinion, action should be taken to prevent future deaths and I believe that you have the power to take such action.

**Table 3.** Addressees (n = 236) for Reg. 28 reports (n = 150) in each of the three selected Regulation 28 report categories.

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Addressee	Child deaths	AD&M	Railways	Total
<b>Government</b>	25	21	9	55
<b>NHS entities</b>	36	32	6	74
<b>Professional bodies</b>	5	1	0	6
<b>Independent safety institutes</b>	7	4	0	11
<b>Railway companies and Authorities</b>	1	1	48	50
<b>Law enforcement</b>	4	12	4	20
<b>Other</b>	9	11	0	20
<b>Totals</b>	87	82	67	236

**Table 4.** Responses published from Regulation 28 report addressees in the three selected categories. The Overall Response Rate for each type of addressee is the total number of responses divided by the total number of addressees (drawn from Table 2) x 100%.

<b>Addressee</b>	<b>Child deaths</b>	<b>AD&amp;M</b>	<b>Railways</b>	<b>Total addressees*</b>	<b>Overall Response rate (%)</b>
Government	4	9	5	55	32.7
NHS entities	20	10	6	74	48.6
Professional bodies	1	1	0	6	33.3
Independent safety institutes	1	0	0	11	9.1
Railway companies etc.	0	0	23	50	46.0
Law enforcement	2	4	1	20	35.0
Other	0	1	0	20	5.00
<b>Totals</b>	28	25	35	236	37.3

**Table 5.** Actions contained in 88 addressees’ responses to three selected categories of published Regulation 28 reports (n = 150). Some responses contained multiple elements. The substantive response rate is the number of addressees’ responses in the first three rows, divided by the total number of published responses for that report category. The effective response rate is the number of substantive responses divided by the number of addressees.

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	<b>Child deaths</b>	<b>AD&amp;M</b>	<b>Railways</b>
Actual or identified change to physical equipment or facility	3	1	19
Actual or identified change to process specifically related to the unnatural death	7	8	4
Actual or identified change to a system process that contributed to the unnatural death.	12	0	9
No identified change in any physical equipment or process, but acknowledging report.	12	16	15
<b>Substantial response rate (%)</b>	64.7	36.0	68.1
<b>Effective response rate (%)</b>	25.2	11.0	47.8