Pharmaceutical Medicine (2023) 37:357–363
https://doi.org/10.1007/s40290-023-00486-8

SYSTEMATIC REVIEW

Recognition of Coroners' Concerns to Prevent Future Deaths from Medicines: A Systematic Review

Robin E. Ferner[1,2] · Richard Brittain[3] · Anthony R. Cox[1] · Carl Heneghan[4] · Georgia C. Richards[4] · Jeffrey K. Aronson[4]

Accepted: 28 May 2023 / Published online: 8 July 2023

Abstract

Background Coroners, who hold inquests to determine the causes of unnatural deaths in England and Wales, having recognised factors that could cause other deaths, are legally obliged to signal concerns by sending 'Reports to Prevent Future Deaths' (PFDs) to interested persons. We aimed to establish whether Coroners' concerns about medications are widely recognised.

Methods We searched MEDLINE, Embase and Web of Science up to 30 November, 2022 for publications linking PFDs and medications using a combination of search terms "coroner*", "inquest*", "medicine*", "medication*" and "prevent*". We also searched the *BMJ*, a UK journal that carries news items; and the databases Nexis Advance and News On the Web for reports in national newspapers between 2013 and 2022, using the search terms ("regulation 28" OR "prevent future deaths" OR "prevention of future deaths") AND "coroner". We recorded the number of publications, as well as their citations in Google Scholar at 23 May, 2023.

Results Only 11 published papers on medicines referenced UK PFDs, nine of which were from our group. The *BMJ* carried 23 articles mentioning PFDs, five related to medicines. Of 139 PFDs (out of over 4000) mentioned in national newspapers, only nine related to medicines.

Conclusions The PFDs related to medicines are not widely referred to in medical journals or UK national newspapers. By contrast, the Australian and New Zealand National Coronial Information System has contributed cases to 206 publications cited in PubMed, of which 139 are related to medicines. Our search suggests that information from English and Welsh Coroners' PFDs is under-recognised, even though it should inform public health. The results of inquiries by Coroners and medical examiners worldwide into potentially preventable deaths involving medicines should be used to strengthen the safety of medicines.

Digital Features for this article are available as supplementary material.

Key Points

Coroners write Reports to Prevent Future Deaths.

Reports to Prevent Future Deaths can identify important concerns related to medicines.

However, those related to deaths from medicines are rarely the subject of articles in the medical or lay press.

✉ Robin E. Ferner
r.e.ferner@bham.ac.uk

1 Institute of Clinical Sciences, University of Birmingham, Birmingham B15 2TT, UK

2 West Midlands Centre for Adverse Drug Reactions, City Hospital, Birmingham B18 7QH, UK

3 St Pancras Coroner's Court, London N1C 4PP, UK

4 Centre for Evidence-Based Medicine, Nuffield Department of Primary Care Health Sciences, University of Oxford, Radcliffe Observatory Quarter, Woodstock Road, Oxford OX2 6GG, UK

1 Introduction

Adverse drug reactions, medication errors and non-therapeutic uses of drugs lead to potentially avoidable harms that sometimes have fatal outcomes. Responsibility for determining the causes of unnatural deaths in England and Wales rests with Coroners, independent judicial officers who must identify who died and determine how the person came to die, when, and where [1]

The Coroner's Office in England probably dates back to the end of the twelfth century [2]. Current legislation in England and Wales is contained in the Coroners and Justice Act 2009 and subsequent amendments [3]. The Coroners and Justice Act 2009 (Commencement No. 15, Consequential and Transitory Provisions) Order 2013 brought into force on 25 July, 2013 a provision contained in Schedule 5 paragraph 7 of the 2009 Act regarding 'action to prevent other deaths' [4]. When facts that come to light during an inquest 'give rise to a concern that circumstances creating a risk of other deaths will occur or will continue to exist, in the future, and … in the Coroner's opinion, action should be taken to prevent the occurrence or continuation of such circumstances, or to eliminate or reduce the risk of death created by such circumstances, the Coroner must report the matter to a person who the Coroner believes may have the power to take such action.' Reports to Prevent Future Deaths (PFDs) are published on the website of the Ministry of Justice [5].

We have previously examined PFDs to find those relevant to harm from medicines. For example, a manual survey of 500 PFDs found 99 related to medication [6], and an automated search using a web-scraper compiled a list of over 4000 PFDs, more than 250 of which are related to alcohol, drugs, or some aspect of medication, for example, drug delivery or administration [7, 8].

Based on findings at a formal judicial inquiry, Coroners' concerns are set out in PFDs that require responses from those to whom they are addressed. These are usually organisations that are directly involved in the event, but they can include organisations (such as regulatory bodies) with national responsibilities. They should also help to inform national and international strategies for reducing harms from medicines, but are only likely to do so if they are noticed in medical journals or by the wider public. We have previously suggested that addressees, including Government organisations, may not respond adequately to PFDs [9]. We hypothesised that the concerns of Coroners relating to medicines expressed in PFDs are not widely disseminated, either to the public or in medical journals. We aimed to establish whether such concerns are widely recognised.

2 Methods

We searched MEDLINE, Embase and Web of Science from inception to November 2022, using a combination of search terms "coroner*", "inquest*", "medicine*", "medication*", and "prevent*", and selected papers in the medical literature referring to Coroners' PFDs. We retrieved full-text versions of each relevant paper and also established how often it had been cited using Google Scholar. We analysed the full-text papers to determine the subject of the paper.

We also searched the *BMJ*, which is a UK general medical journal that carries news reports, and the databases Nexis Advance and News On the Web for reports mentioning PFDs in British newspapers, *The Guardian*, *Times*, *Daily Telegraph* and *Independent*, and the *Daily Mail, Daily Record, Daily Star, Mirror* and *Sun,* 2013–22, using the search terms ("regulation 28" OR "prevent future deaths" OR "prevention of future deaths") AND "coroner". In Nexis Advance, we then chose the option 'Duplicates of high similarity grouped' to amalgamate articles with (near-) identical titles from, for example, different editions of the same newspaper. From these, we selected articles mentioning PFDs related to medication, according to a previously published algorithm [6]. When articles relating to medicines referred to inquests on specified individuals, we established that a PFD on the individual could be found on the Judiciary website [5].

The number of publications was recorded, as well as their citations in Google Scholar at 23 May, 2023.

3 Results

3.1 Medical Journals

Our searches in Embase, MEDLINE and World of Science identified 92 non-duplicate entries for published papers, of which 16 appeared to be relevant by title and abstract (see Preferred Reporting Items for Systematic Reviews and Meta-Analyses [PRISMA] diagram, Fig. 1). The 16 full papers were retrieved; of these, ten referred to PFDs issued after inquests in which medication was determined to have caused or contributed to the death. One additional paper was identified from reference lists. One or more authors from our research group contributed to nine of the 11 full papers identified, and one was an editorial comment on a paper from the group. Two further papers from our group are in press [10, 26]. The subjects of the papers are shown in Table 1.

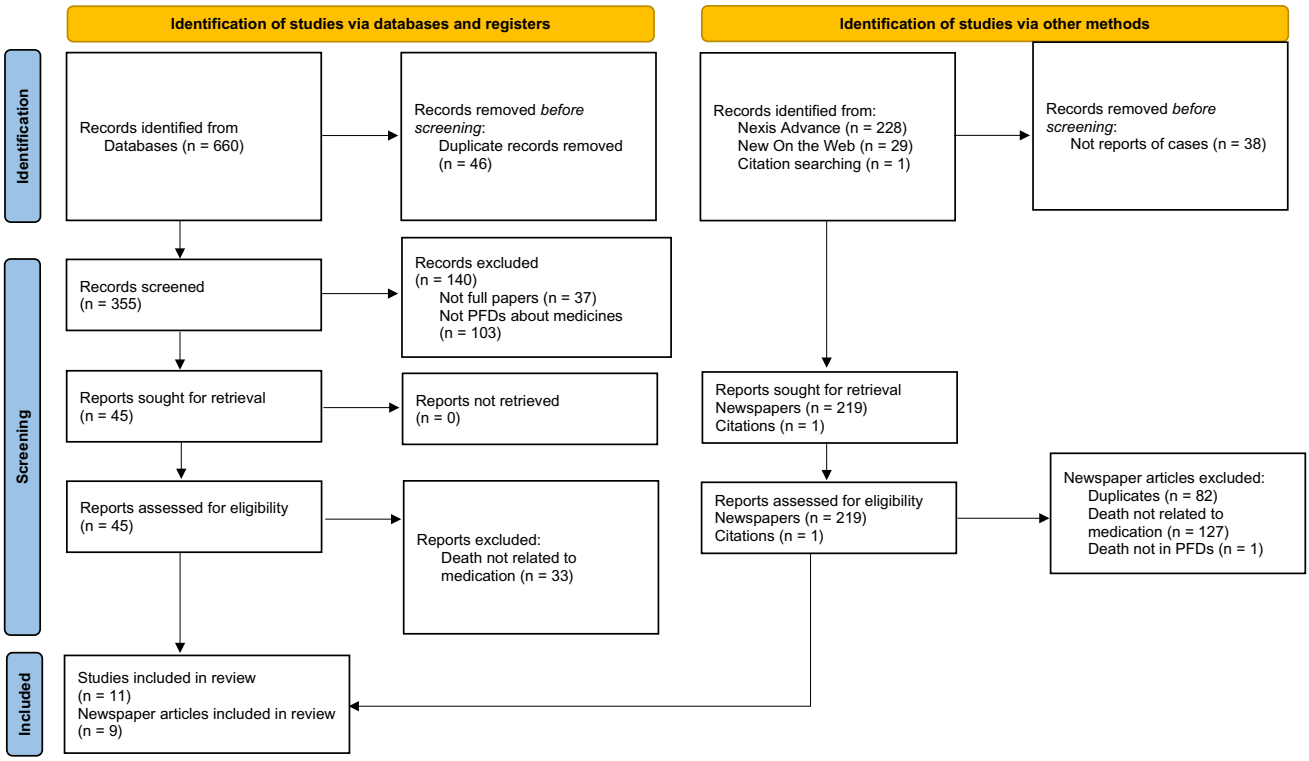

Fig. 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flowchart. *PFD* Coroner's Regulation 28 Letter for the Prevention of Future Deaths

Table 1 Full papers indexed in Embase, MEDLINE or Web of Science concerning Coroners in PFDs (Regulation 28 letters) related to medicines

First author	Subject	Reference number	Citations[a]
Anis A	Anticoagulants	[17]	7
Aronson JK	Medications purchased on-line	[18]	7
Bilip MK	Emollients and smoking	[19]	6
Cox AR	Tramadol	[20]	5
Dyer C	Editorial comment	[21]	4
Ferner RE	Deaths from medication	[6]	34
Ferner RE	Deaths from medication, responses to PFDs	[9]	16
Fox AW	Critique of Regulation 28 letters	[22]	8
Richards GC	Alcohol-based hand gels	[23]	18
Richards GC	Coroners' concerns to prevent harms	[24]	13
Thomas ET	Diclofenac-induced adverse effects	[25]	7

Since our search, two further paper from our group have been accepted for publication [10, 26]

PFDs Letters to Prevent Future Deaths

[a]From Google Scholar on 23 May, 2023

3.2 Newspapers

We identified 341 articles in national British daily newspapers, of which 84 were automatically removed because they were of 'high similarity' (see the PRISMA diagram, Fig. 1). Removing further duplicates reduced the number of relevant articles to 139, of which 11 referred to one or more unique PFDs related to medicines (Table 2).

In addition to the articles referring to specific PFDs, *The Guardian* published three analyses of PFDs and *The Times* published one, with titles including 'High number of prison deaths are preventable, says a damning new report' [11] and 'Ten women murdered after violent partners allowed gun'

Table 2 Articles from UK newspapers that mentioned specific inquests referred to PFDs, 2013–22; duplicates of three relevant articles in the *Daily Telegraph* are not included; one PFD relating to a drug-associated death reported in the *Mirror* could not be identified in the judiciary website)

Newspaper and date	Brief details	Judiciary PFD reference
Guardian 2016-04-29	An A-level student developed a drug-induced psychosis after taking MDMA at a music festival	2016-0176
Guardian 2016-12-18	A prisoner overdosed on a cocktail of drugs while on the detox wing of the jail	2015-0468
Guardian 2018-06-03	A person with a long history of mental health problems was sectioned after taking novel psychoactive substances and became aggressive and suicidal	2018-0126
Guardian 2019-05-24	A person was issued with a prescription for antidepressants, but no arrangements were made for a seven-day follow-up as per NICE guidance	2019-0504
Guardian 2021-05-10	A woman died from an insulin overdose after being told that her benefit payment would be withdrawn	2021-0043
Guardian 2021-12-06	Before the pandemic, a drug-dependent man taking prescribed methadone had been given it in daily dosage bottles three times a week; this was altered to collection once every 14 days and in larger doses; he had no measuring implement or instructions on how to use the medication	2020-0275
Times 2017-08-09	A man became addicted to loperamide and was taking 150 tablets a day	2017-0195
Times 2020-11-07	A student became psychotic after taking the drug doxycycline	2020-0151
Times 2021-02-11	A cocaine death led to criticism of an Oxford college's drug use policy	2021-0027

MDMA methylenedioxymethamphetamine, *NICE* National Institute for Health and Care Excellence, *PFDs* Reports to Prevent Future Deaths

[12]. In 2018, *The Guardian* published an account of the methods used to investigate deaths of mental health patients after National Health Service (NHS) care failures [13]. The *Guardian* researchers relied on PFDs stored as publicly available .pdf documents on the Chief Coroner's website between 1 January, 2012 and 8 February, 2018, converting almost 2000 documents to machine searchable text using optical character recognition software and searching for relevant terms. Failings were assigned to one of 15 categories. *The BMJ* published 23 articles by the legal correspondent Clare Dyer that referred to PFDs, not all of which were indexed; five referred specifically to medicines (Table 3).

4 Discussion

This study shows that medical journals have published very little based on PFDs related to medicines, and that the UK's national newspapers largely ignore Coroners' concerns. In 2019 (the last year before the coronavirus disease 2019 pandemic), 530,841 deaths were registered in England and Wales [14]; 210,900 deaths were referred to Coroners, who ordered 82,100 post-mortem examinations and opened 30,000 inquests [15]. Coroners wrote approximately 520 PFDs that year, some of which were written to multiple addressees. However, many Coroners did not write a single PFD. Responses are published on the Judiciary.gov.uk website at the discretion of the Chief Coroner. We have noted previously that the website publishes only a minority of responses; even after Freedom of Information requests to the addressees of PFDs, only two-thirds of responses were available [9].

Our study is limited by the use of only one source to establish the number of citations of published papers. However, the source we used, Google Scholar, includes citations to electronic media, reference books and other citing works, and thus is expected to overestimate the number of citations relative to other sources. A further limitation is that more thorough searches may have uncovered further relevant publications, but failure to find articles about PFDs with simple searches suggests that they are less likely to be found or cited by those who may be able to prevent deaths more widely. We cannot eliminate the possibility that PFDs are accessed directly and used in local policy and training initiatives—and future work could include examining the extent to which Medication Safety Officers and Chief Medical Officers of NHS trusts use available PFDs. The paucity of studies based on PFDs contrasts with the substantial number of studies that have used the Australian and New Zealand National Coronial Information System [16], which has contributed to 206 publications cited in PubMed, of which 139 relate to medicines. That database contains information on every death reported by a Coroner in Australia from 2001 and New Zealand from 2007, with the express intention of helping Coroners fulfil their mandate to improve public health and safety. It contains details of the deceased

Table 3 Articles in the *BMJ* that mentioned PFDs related to medicines, including unindexed articles

Title	Summary of case	*BMJ* reference	PFD reference
Hospital errors led to patient's death, finds coroner	Susan Warby, 57, was mistakenly given a glucose rather than a saline drip at West Suffolk Hospital after an operation for a perforated bowel in July 2018. The Suffolk senior coroner Nigel Parsley wrote, "Susan Warby died as a result of the progression of a naturally occurring illness, contributed to by unnecessary insulin treatment, caused by erroneous blood test results."	*BMJ* 2020; 370: m3507 (published 9 September, 2020)	2020-0188
London trust given warning notice after death of mother during stillbirth	Malyun Karama, 34, died last February from a uterine rupture caused by the administration of misoprostol prescribed to induce labour after the fetus died in the womb. In a report to prevent future deaths sent last August to the hospital's medical director, Inner North London senior coroner Mary Hassell said, "The misoprostol was administered at doses in excess of the Royal College of Obstetricians and Gynaecologists national guidelines. Abnormal observations were relayed by a midwife to a senior registrar, but the doctor failed to attend Ms Karama and instead ordered fluids."	*BMJ* 2021; 372: n38 (published 6 January, 2021)	2020-0162
Doxycycline: Coroner calls for MHRA to review side effects after student jumped from plane	Tom Osborne, senior coroner for Milton Keynes, wrote in his inquest report, "The deceased was prescribed doxycycline as an antimalarial medication for use whilst in Madagascar. It was quite apparent from the evidence that she had a psychotic reaction as a result of taking the drug and yet there is nothing on the drug information leaflet that either highlights or mentions this possibility."	*BMJ* 2020; 371: m4102 (published 22 October, 2020)	2020-0151
Coroner warns about poor drug reviews after patient dies from tramadol overdose	Peter Cole, who was found collapsed at his home in Welwyn in Hertfordshire by a neighbour, had amassed a large quantity of unused prescription drugs at his house. He had numerous drugs on repeat prescription, said Geoffrey Sullivan, chief coroner for Hertfordshire	BMJ 2020; 370: m3101 (published 5 August, 2020)	2020-0123
Coroners warn health secretary of clozapine deaths	Two coroners have sent "regulation 28" letters to Matt Hancock and two NHS trusts after the deaths of Julia MacPherson and Tom Jackson, amid concerns that healthcare staff may not be sufficiently aware of [clozapine]'s serious side effects."	*BMJ* 2018; 363: k5421 (published 27 December 2018)	2018-0298 2018-0352

MHRA Medicines and Healthcare Products Regulatory Agency, *NHS* National Health Service, *PFDs* Reports to Prevent Future Deaths

and the circumstances of death, together with complete text reports relevant to the investigation. The data have informed decisions made by the Therapeutic Goods Administration in Australia and Medsafe in New Zealand on several matters related to harms from medicines. However, the National Coronial Information System is a secure database and is not publicly available.

The public interest would be served by using data from Coroners' inquests to improve public safety. While inquests in England and Wales are judicial hearings, held (with rare exceptions) in public, their findings are not easily accessible. The only official and readily available record may be the PFD, if one is issued to express a Coroner's concerns. If Coroners' concerns are to be considered, and the adequacy of responses to them properly assessed, PFDs and responses must be widely disseminated (Fig. 2).

We have found little evidence that the concerns expressed by Coroners in PFDs are widely appreciated or used to improve medication safety. There are several possible reasons: many Coroners issue PFDs infrequently or not at all. There is no effective follow-up of requests, and addressees may not reply, despite a legal obligation to do so, or may provide inadequate responses. Furthermore, the current system of publishing PFDs does not classify findings by standard International Classification of Diseases, Tenth Revision codes, does not allow them to be easily machine searched and does not provide access to the coronial determination that led to the PFD.

The value of PFDs would be significantly increased by (i) classifying deaths according to the International Classification of Diseases codes, (ii) storing PFDs in a machine-readable form, (iii) giving access to detailed information on coronial findings that lead to PFDs and (iv) distributing notices of PFDs nationally. The results of inquiries by Coroners and medical examiners worldwide into potentially preventable deaths involving medicines should be used to strengthen the safety of medicines.

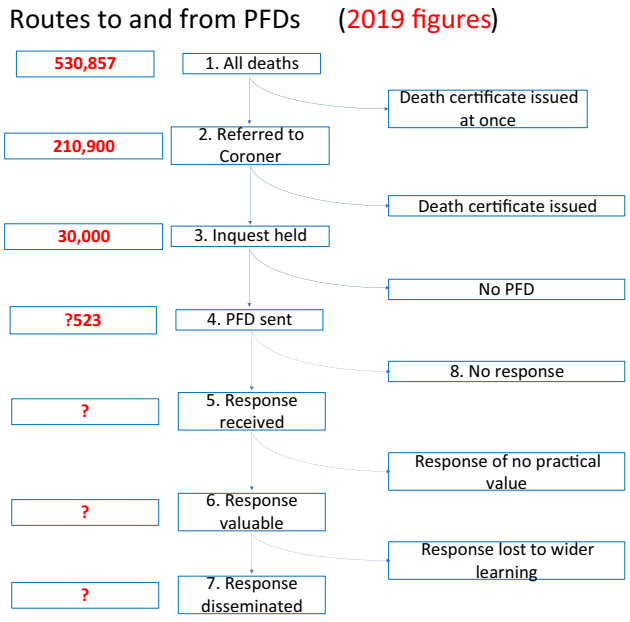

Fig. 2 Routes to and from Regulation 28 Letters for the Prevention of Future Deaths (PFDs); numerical data are from 2019

5 Conclusions

Our search suggests that, in contrast to data from the National Coronial Information System, information from UK Coroners' PFDs is underused, even though it informs public health.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s40290-023-00486-8.

Declarations

Funding No outside funding was received for the conduct of this study or the preparation of this article.

Conflict of Interest Richard Brittain is a Coroner, and Robin E. Ferner and Jeffrey K. Aronson have been remunerated for giving advice to Coroners on medicines. Anthony R. Cox, Carl Heneghan and Georgia C. Richards have no conflicts of interest that are directly relevant to the content of this article.

Ethics Approval This study used only published data and ethics approval was not required.

Consent to Participate Not applicable.

Consent for Publication Not applicable.

Data Availability More data are available at https://preventabledeathstracker.net/.

Code Availability Code for the Preventable Deaths Tracker is available at https://github.com/georgiarichards/georgiarichards.github.io.

Author Contributions REF, RB, ARC, CH, GCR and JKA all contributed to the design of the study. JKA and REF undertook the searches. REF and JKA wrote the first draft and all authors contributed to the final draft.

References

1. Coroners. https://www.cps.gov.uk/legal-guidance/coroners [Accessed 28 Jan 2023].
2. Hunnisett RF. The origins of the office of coroner. Trans R Hist Soc. 1958;8:85–104.
3. The Coroners and Justice Act 2009. https://www.legislation.gov.uk/ukpga/2009/25/contents [Accessed 28 Jan 2023].
4. The Coroners and Justice Act 2009 (Commencement No. 15, Consequential and Transitory Provisions) Order 2013. https://www.

legislation.gov.uk/uksi/2013/1869/contents/made [Accessed 28 Jan 2023].
5. Courts and Tribunals Judiciary. Reports to Prevent Future Deaths. https://www.judiciary.uk/courts-and-tribunals/coroners-courts/reports-to-prevent-future-deaths/ [Accessed 28 Jan 2023].
6. Ferner RE, Easton C, Cox AR. Deaths from medicines: a systematic analysis of coroners' reports to prevent future deaths. Drug Saf. 2018;41(1):103–10.
7. DeVito NJ, Richards GC, Inglesby P. How we learnt to stop worrying and love web scraping. Nature. 2020;585(7826):621–2.
8. Preventable Deaths Tracker. A platform to explore concerns raised by coroners to prevent future deaths. https://preventabledeathstracker.net/ [Accessed 26 June 2023].
9. Ferner RE, Ahmad T, Babatunde Z, Cox AR. Preventing future deaths from medicines: responses to coroners' concerns in England and Wales. Drug Saf. 2019;42(3):445–51.
10. Zhang Q, Richards GC. Lessons from web scraping coroners' Prevention of Future Deaths reports. Med Leg J. 2023. https://doi.org/10.1177/00258172221141284.
11. Allison E. High number of prison deaths are preventable, says damning new report. Guardian 2020 (January 22). https://www.theguardian.com/society/2020/jan/22/high-number-prison-deaths-preventable-damning-new-report [Accessed 11 June 2023].
12. Yeomans E, Greenwood G. Ten women murdered after violent partners allowed gun. Times 2021 (August 16). https://www.thetimes.co.uk/article/ten-women-murdered-after-violent-partner-allowed-gun-7v29wrhht [Accessed 28 Jan 2023].
13. Duncan P. How the Guardian investigated mental health patient deaths; methodology for researching deaths of people included analysis of almost 2,000 coroners' reports. Hundreds of mental health patients dying after NHS care failures. Guardian 2018 (March 5). https://www.theguardian.com/society/2018/mar/05/how-the-guardian-investigated-mental-health-patient-deaths [Accessed 28 Jan 2023].
14. Office for National Statistics. Deaths registered monthly in England and Wales 2019. https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/datasets/monthlyfiguresondeathsregisteredbyareaofusualresidence [Accessed 28 Jan 2023].
15. Ministry of Justice. Coroners statistics 2019: England and Wales. https://www.gov.uk/government/statistics/coroners-statistics-2019/coroners-statistics-2019-england-and-wales [Accessed 28 Jan 2023].
16. Saar E, Bugeja L, Ranson DL. National coronial information system. Acad Forensic Pathol. 2017;7(4):582–90.
17. Anis A, Heneghan C, Aronson JK, DeVito NJ, Richards GC. Deaths from cardiovascular disease involving anticoagulants: a systematic synthesis of coroners' case reports. BJGP Open. 2022;6(1):BJGPO.2021.150.
18. Aronson JK, Ferner RE, Richards GC. Deaths attributed to the use of medications purchased online. BMJ Evid Based Med. 2022;27(1):60–4.
19. Bilip MK, Richards GC. Emollients and smoking: a fire hazard that could be prevented to reduce future deaths. BMJ Evid Based Med. 2021;26(3):131–4.
20. Cox AR, Ferner R. Tramadol: repeated prescriptions and repeated warnings. BMJ Evid Based Med. 2021;26(6): e17.
21. Dyer C. Deaths from medicines: lessons from coroners' reports are too easily lost, review finds. BMJ. 2018;12(363): k4322.
22. Fox AW, Jacobson J. How well do Regulation 28 reports serve future public health and safety? Med Sci Law. 2021;61(3):186–92.
23. Richards GC. Alcohol-based hand sanitisers: a warning to mitigate future poisonings and deaths. BMJ Evid Based Med. 2021;26(2):65–8.
24. Richards GC, Aronson JK, Heneghan C. Coroners' concerns to prevent harms: a series of coroners' case reports to serve patient safety and educate the public, clinicians and policy-makers. BMJ Evid Based Med. 2021;26(2):37–8.
25. Thomas ET, Richards GC. Diclofenac in adolescents: diagnosing and treating gastrointestinal adverse drug reactions can prevent future deaths. BMJ Evid Based Med. 2021. https://doi.org/10.1136/bmjebm-2020-111640.
26. France HS, Aronson JK, Heneghan C, Ferner RE, Cox AR, Richards GC. Preventable deaths involving medicines: a systematic case series of coroners' reports 2013–22. Drug Saf. 2023;46:335–42.