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ORIGINAL ARTICLE

Safety concerns reported by coroners following fentanyl patch fatalities in England, Wales and Northern Ireland between 1997 and 2024

Eman Mshari [1,2] | Caroline S. Copeland [1] | Georgia C. Richards [3]

[1]Centre for Pharmaceutical Medicine Research, Institute of Pharmaceutical Science, School of Cancer & Pharmaceutical Sciences, Faculty of Life Sciences & Medicine, King's College London, UK

[2]Ministry of Health, Kuwait City, Kuwait

[3]Department of Analytical, Environmental and Forensic Sciences, Institute of Pharmaceutical Sciences, School of Cancer & Pharmaceutical Sciences, Faculty of Life Sciences & Medicine, King's College London, UK

Correspondence
Georgia C. Richards, Department of Analytical, Environmental and Forensic Sciences, Institute of Pharmaceutical Sciences, School of Cancer & Pharmaceutical Sciences, Faculty of Life Sciences & Medicine, King's College London, UK.
Email: georgia.richards@kcl.ac.uk

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No funding was obtained to undertake this study.

Abstract

Aim: To identify safety concerns reported by coroners following fentanyl patch-related deaths in England, Wales and Northern Ireland, and determine differences in coronial reporting.

Methods: A systematic case series linking the National Programme on Substance Use Mortality (NPSUM) and the Preventable Deaths Tracker (PDT) (https://preventabledeathstracker.net/) to identify fentanyl patch-related deaths. Keyword searches for 'patches' were conducted, and reports were screened for eligibility in duplicate. Data were extracted and descriptively analysed, and deaths were categorized by safety events.

Results: There were 99 fentanyl patch-related deaths between 1997 and 2024, with 89 reported to NPSUM and 12 Prevention of Future Deaths reports (PFDs) from the PDT, with only two duplicates across both databases. Seventy-seven safety events were reported by coroners, with adherence and usage (34%), administration (32%) and prescribing (6%) being the most common. Compared with deaths reported to NPSUM, PFDs were more common for females (58% *vs*. 33%), older adults (median age: 53 *vs*. 45 years), occurred more in hospital (42% *vs*. 9%), were of accidental manner (83% *vs*. 22%), and were prescribed patches (100% *vs*. 54%). A live dashboard of PFDs was developed to continue surveillance https://preventabledeathstracker.net/case-study/fentanyl-patches/).

Conclusions: Safety events, including poor adherence, usage and administration errors of fentanyl patches, were repeatedly identified by coroners, which mostly occurred in males aged 35–49 years. Information from coroners should be systematically monitored to inform the safety of prescribing and use of fentanyl patches, including identifying gaps in care, education and policies.

Protocol registration: https://doi.org/10.17605/OSF.IO/GMHNW

KEYWORDS
coroners, deaths, drug safety, fentanyl, opioids, pharmacovigilance, transdermal patches

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1 | INTRODUCTION

Opioid-related deaths have increased in England and Wales in the past two decades, from 471 in 1993 to 2551 in 2023[1]. Deaths involving **fentanyl** have similarly increased in this period in England and Wales, from one in 1999 to 41 in 2023.[1] Opioid-related deaths have also increased in Northern Ireland from 71 in 2013 to 103 in 2023,[2] with fentanyl-related deaths increasing from four in 2013 to six in 2023.[2] However, national statistics do not report deaths following drug use by formulation, which has implications for drug safety.[3]

Fentanyl is a highly potent and fast-acting synthetic analgesic commonly used for analgesia and anaesthesia.[4] It is available in various forms, including solutions for injection, nasal sprays, transdermal patches, buccal and sublingual tablets and lozenges.[4] Despite the prescribing of fentanyl decreasing in England and the Republic of Ireland between 2014 and 2022,[5] the UK's Medicines and Healthcare products Regulatory Agency (MHRA) issued a drug safety alert for fentanyl patches to improve guidance on their safe disposal and to reduce harms following reports of accidental transfers of fentanyl patches.[6,7] Similarly, the US Food and Drug Administration (FDA) issued a warning in 2024 regarding safety concerns following the accidental exposure and handling of transdermal fentanyl patches by children.[8] The MHRA collects information on adverse drug reactions through its spontaneous reporting system, the Yellow Card Scheme. As of 17 July 2025, the MHRA reported 82 fatal outcomes involving transdermal fentanyl between 1996 and 2018.[9] However, a systematic analysis of the safety concerns surrounding these deaths has not yet been conducted, which could support safer prescribing and use of fentanyl patches.

Reports from coroners provide insights into the circumstances of deaths following drug use.[10,11] A retrospective observational study of coroners' and toxicology reports from the National Programme on Substance Use Mortality (NPSUM) found 298 deaths involving pharmaceutical fentanyls, including fentanyl, **alfentanil** and **remifentanil**, in England between 1998 and 2017.[12] A systematic case series of coroners' Prevention of Future Deaths reports (PFDs) published in England and Wales using the Preventable Deaths Tracker (PDT)[13,14] identified 219 deaths from opioids between 2013 and 2022, with nine involving fentanyl.[15] Despite the escalating trends in fentanyl deaths and published warnings regarding fentanyl patches, there has not yet been a data-linkage study to assess the complete picture of harm involving fentanyl patches. Therefore, this study aims to conduct the first data-linkage case series of coroners' and toxicology reports using the NPSUM and PDT to identify safety issues reported by coroners following fentanyl patch fatalities, and assess the differences in deaths reported to each database.

What is already known about this subject

- Fentanyl-related deaths have increased globally.
- The UK's Medicines and Healthcare products Regulatory Agency (MHRA) published several safety warnings regarding accidental exposure and inappropriate disposal of fentanyl patches.
- The extent of safety events and deaths involving fentanyl patches had not yet been explored.

What this study adds

- First data-linkage study of Prevention of Future Deaths reports (PFDs) with the National Programme on Substance Use Morality (NPSUM) database to explore coronial reporting differences.
- 99 fentanyl patch fatalities reported by coroners between 1997 and 2024.
- Safety concerns continue, which can be tracked in real-time (https://preventabledeathstracker.net/case-study/fentanyl-patches/)

2 | METHODS

A retrospective data-linkage cohort study of coroner reports was designed and pre-registered on an open repository.[16]

2.1 | Data collection

Reports were identified from the NPSUM, previously known as the National Programme on Substance Abuse Deaths (NPSAD), which collects cases voluntarily reported by coroners in England, Wales and Northern Ireland when at least one psychoactive or controlled substance is detected in the post-mortem or if the deceased had a known history of drug use.[17] This information is emailed from the coroner's office to the NPSUM team, which is manually extracted into a database using SPSS. In NPSUM, searches were conducted between 1997 and July 1, 2024, using the numerical code assigned for fentanyl, as well as searches in the cause(s) of death, verdicts, accident details and other information data fields. Fentanyl patch cases were searched by text detection using the keyword 'patch' (Table S1).

Deaths were identified from the PDT (https://preventabledeathstracker.net/),[14] which automatically collects coroners' Prevention of Future Deaths (PFD) reports from the Judiciary website using a reproducible web scraper and algorithms that standardizes the manually reported information.[14,18] PFDs are written by coroners in England and Wales when they believe that actions must be taken to prevent future deaths, which are sent to organizations to respond within 56 days.[19–21] Each PFD and any responses are processed by Amazon Web Services (AWS) to enable free text searches. The searches were conducted in the PDT from July 2013 to November 2024 (Table S1) and were manually screened to confirm whether the fentanyl patch caused or contributed to the death.

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2.2 | Eligibility and screening

Cases were included if the death involved a fentanyl transdermal patch or if the coroner raised safety concerns relating to the use of fentanyl patches by the deceased. Cases were excluded if they involved other medicinal forms of fentanyl, including solutions for injection, nasal sprays, buccal or sublingual tablets and lozenges. Cases were also excluded when the coroner did not report the formulation of fentanyl.

2.3 | Data extraction

The following variables were extracted for both databases including demographics (age and sex), date of report, deceased name, coroner name, jurisdiction and coroner area, date of death, coroner conclusion (verdict), causes of death, manner of death, circumstances of death, living conditions, place of death, substances reported, drugs implicated and prescribed and the date/s of inquest. For NPSUM, post-mortem drugs were extracted from the toxicology and post-mortem reports. For the PDT, coroners' concerns and details on who were sent the reports and whether they responded were also extracted. The variables extracted were aligned with the data structure of NPSUM to allow for data linkage and comparison.

2.4 | Data analysis

Deaths were compared and linked using the deceased's name, date of death and coroner's area to determine which cases are reported in both NPSUM and PDT, assessing duplication and the reporting of deaths by coroners. Descriptive statistics were used to analyse the quantitative data, including calculating medians and interquartile ranges (IQRs) for continuous variables (e.g., age) and frequencies and percentages for categorical variables (e.g., sex). The number of deaths, using the date of death and date of report, were plotted over time and geographically by coroner area to assess trends. A choropleth map with declines was used to create a colour spectrum and visualize the data. Cases were assigned to ONS's age classification 18b groups (e.g., 0–4 years; 5–9 years; 85 years and over).[22] The years of life lost (YLL) for each death were calculated using the ONS's Life Expectancy Calculator,[23] and the total and median values were calculated. Using the YLL, we calculated the monetary value of statistical life years (VoSLY) from the HM Treasury 2020–21 guidance of £70 000 per life lost[24] and determined the total and median VoSLY.

During this process, safety events reported by coroners were identified and categorized into the following predefined categories: (i) manufacturing, (ii) prescribing, (iii) dispensing, (iv) administration, (v) adherence/usage and (vi) aftercare. The administration category included using a fentanyl patch in any method outside its intended transdermal formulation, such as by oral ingestion, heating, inhalation or injection. Adherence and usage category involved exceeding the licensed dosage (e.g., wearing multiple patches concurrently), non-adherence to prescribing and counselling instructions of the drug. The source of the fentanyl patch (i.e., illicit, online and prescribed), and indication for use were also analysed.

The organizations to whom PFDs were sent were categorized, and their response rates were calculated. Reports were categorized as 'completed' if all requested responses were published at the time of analysis, 'partial' if some but not all responses were published, or 'overdue' if no response was published as per Regulation 29 of the Coroners (Investigations) Regulations 2013.[19] We have reported the proportion of reports and organizations with and without responses.

2.5 | Software

IBM® SPSS™ version 29 was used to collect and store the database for NPSUM. WordPress and AWS were used to collect and store data for the PDT. Google Sheets was used to link, analyse and visually present the data. Datawrapper was used to create the choropleth map. The Open Science Framework (OSF) was used to register and share study materials.[16,25]

2.6 | Nomenclature of targets and ligands

Key protein targets and ligands in this article are hyperlinked to corresponding entries in http://www.guidetopharmacology.org, and are permanently archived in the Concise Guide to PHARMACOLOGY 2023/24.[26]

The authors confirm that the PI for this paper is Dr Georgia Richards and that she had direct responsibility for database management.

3 | RESULTS

There were 101 reports identified, including two duplicates across both NPSUM and PDT databases, totalling 99 unique fentanyl patch-related fatalities. There were 89 unique cases identified in NPSUM and 12 from the PDT (Figure 1). The first death involving a fentanyl patch occurred in 1999, and most deaths occurred in 2019 (Figure 2). However, due to delays in inquests and reporting, more deaths are expected to be received by both NPSUM and the PDT for 2023 and 2024.

3.1 | Demographics

Fentanyl patch-related deaths were most common in males (66%, n = 65), with the median age at death of 45 years (IQR: 36–57 years, range: 10–93 years, n = 99). However, deaths where a coroner wrote a PFD mainly occurred (58%, n = 7) in females (Table 1). Across all deaths, the age range with the majority of deaths was between

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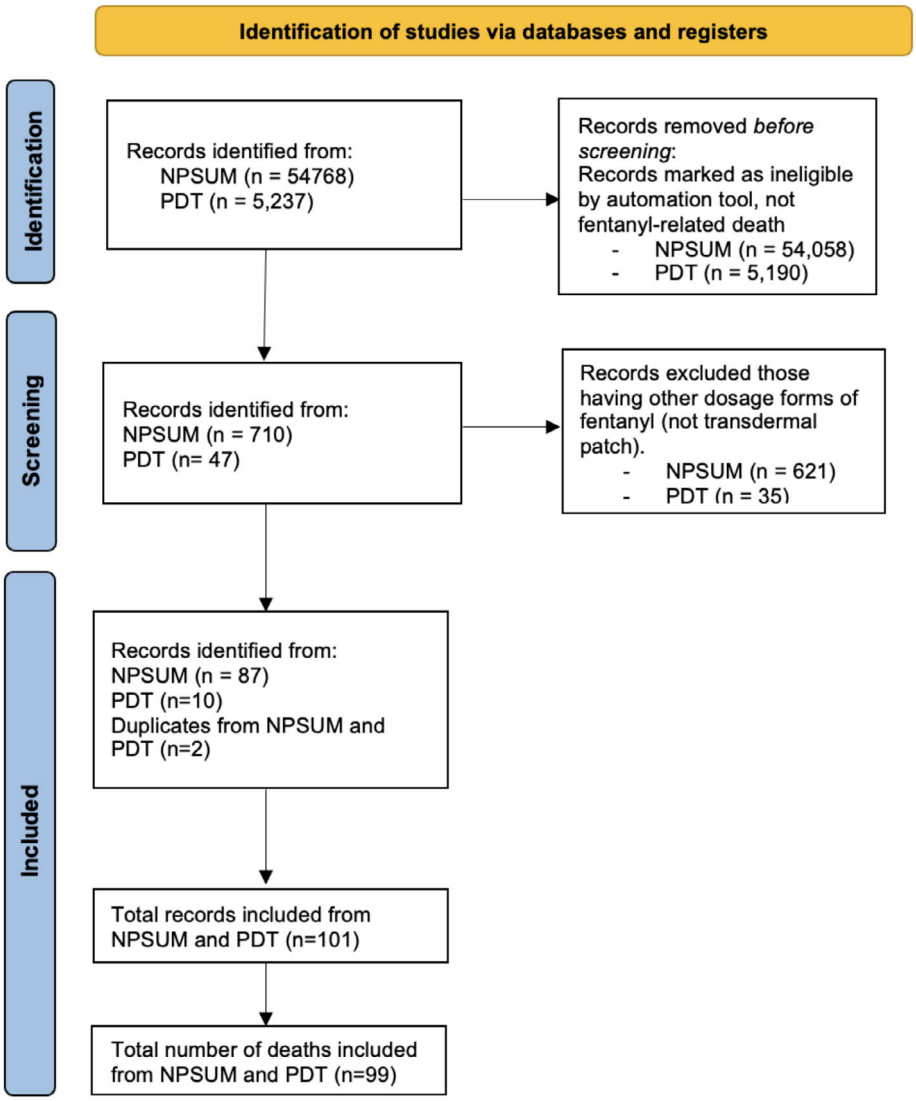


FIGURE 1 PRISMA flow diagram for case identification and selection of fentanyl patch-related deaths reported by coroners to the National Programme on substance use mortality (NPSUM) database for England, Wales, and Northern Ireland since 1997–2024 and the Preventable Deaths Tracker (PDT) database of Prevention of Future Deaths reports (PFDs) for England and Wales since 2013–2024.

35 and 49 years (40%, n = 40). However, the age range among fatalities when coroners wrote PFDs was higher, between those aged 50 and 64 years (42%, n = 5). The majority (73%, n = 72) of deaths occurred at the deceased's place of residence, which remained consistent for cases in both NPSUM and the PDT. However, a greater percentage (42%, n = 5) of PFDs were written by coroners when the death occurred in a hospital (Table 1).

The total years of life lost (YLL) were 3790 years, equating to a total value of statistical life (VSL) of £265.3 million (Table 1). This amounts to a median of 39 years (IQR: 29–49) lost for every fentanyl patch-related death, costing £2.73 million per death (IQR: £2.03–£3.395).

3.2 | Types of deaths

Coroners' conclusions following the inquest were most often (45%, n = 45) drug-related, followed by accidental or misadventure (30%, n = 30) and suicide (10%, n = 10) (Figure 3). The majority (96%, n = 95) of deaths involved multiple drugs, with only three deaths (3%) involving fentanyl alone, and the number of drugs was not reported in one death. Most of the fentanyl patch-related deaths resulted from misuse (72%, n = 71), while just over one-quarter (28%, n = 28) of deaths were accidental. However, for PFDs, most (83%, n = 10) were written for accidental deaths, with only two following fentanyl-patch misuse (Table 1).

3.3 | Fentanyl sources

Fentanyl patches were mainly (59%, n = 58) prescribed to the deceased, with 8% (n = 8) prescribed by their general practitioner (GP), followed by the hospital (4%, n = 4) and the Accident and Emergency (A&E) department (n = 1). The data on the source of prescription was not reported for the remaining fentanyl patch deaths (n = 45). All PFDs involved prescribed fentanyl (Table 1), with most (58%, n = 7) prescribed by the GP, followed by the hospital (25%, n = 3) and A&E department (8%, n = 1). The source of prescription

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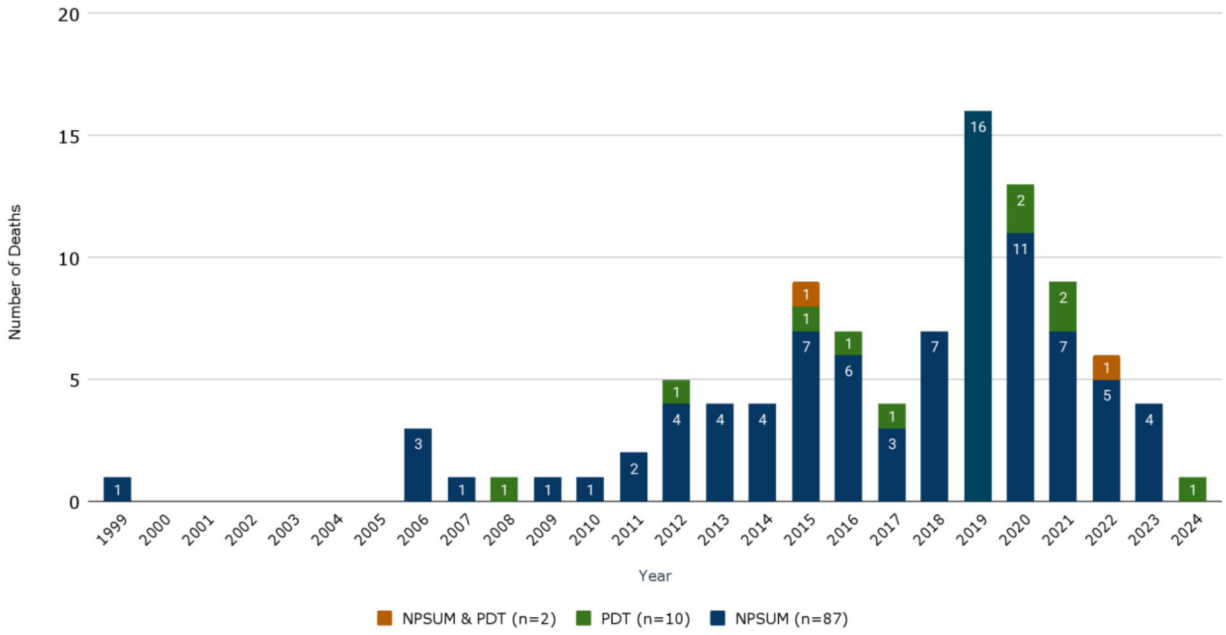


FIGURE 2 Number of fentanyl patch-related deaths reported by coroners in the National Programme on substance use mortality (NPSUM) database for England, Wales, and Northern Ireland from 1997–2024 (blue) and the Preventable Deaths Tracker (PDT) database of Prevention of Future Deaths reports (PFDs) for England and Wales from 2013–2024 (green), where there were two duplicate cases after linkage (orange).

TABLE 1 Demographics of the fentanyl patch-related deaths reported by coroners in the National Programme on substance use mortality (NPSUM) database for England, Wales, and Northern Ireland since 1997–2024 and the Preventable Deaths Tracker (PDT) database of Prevention of Future Deaths reports (PFDs) for England and Wales since 2013–2024.

		All deaths (n = 99)		NPSUM (n = 89)		PDT (n = 12)	
		n	%	n	%	n	%
Male sex		65	66	60	67	5	42
Median age, years (IQR)		45 (36–57)	-	45 (36–56)	-	53 (39–61)	-
Age range (years)	5–19	2	2	1	1	1	8
	20–34	18	18	16	18	2	17
	35–49	40	40	39	44	1	8
	50–64	26	26	22	29	5	42
	65–79	7	7	6	7	2	17
	80+	6	6	5	6	1	8
Years of life lost (YLL) (Median years, IQR)		39 (29–49)	-	40 (28–48)	-	32 (26–46)	-
Value of statistical life (VSL, Median GBP, IQR)		£2 730 000 (£2 030 000 - £3.395000)	-	£2 800 000 (£1 960 000 - £3 360 000)	-	£2 240 000 (£1 837 500 - £3 185 000)	-
Value of Prevented Fatality (VPF, Median GBP)		£258.7 million	-	£232.6 million	-	£31.4 million	-
Place of Death	Own place of residence	72	73	68	76	6	50
	Hospital	13	13	8	9	5	42
	Other residence	12	12	11	12	1	8
	Car Park/Car	2	2	2	2	0	0
Accidental deaths		28	28	20	20	10	83
Prescribed fentanyl		58	59	48	54	12	100
Reporting deaths, median (days, IQR)		240 (170–504)	-	232 (162–425)	-	524 (228–687)	-

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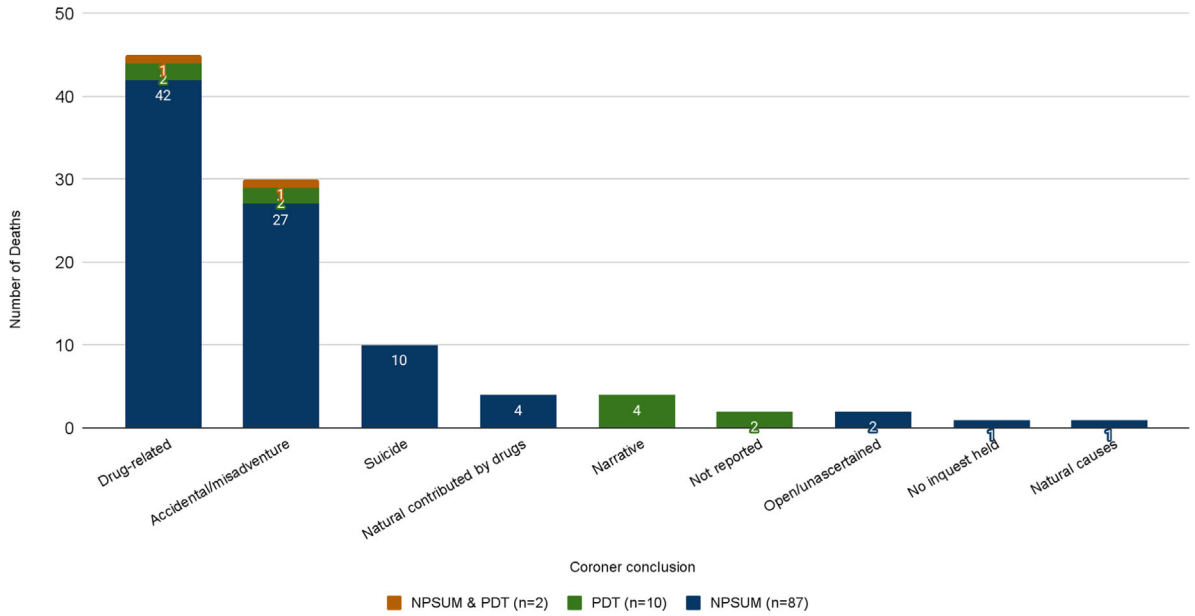


FIGURE 3 Coroners' conclusion following fentanyl patch-related deaths in the National Programme on substance use mortality (NPSUM) database for England, Wales and Northern Ireland since 1997–2024 (blue), the Preventable Deaths Tracker (PDT) database of Prevention of Future Deaths reports (PFDs) for England and Wales since 2013–2024 (green), and duplicate cases following linkage (orange).

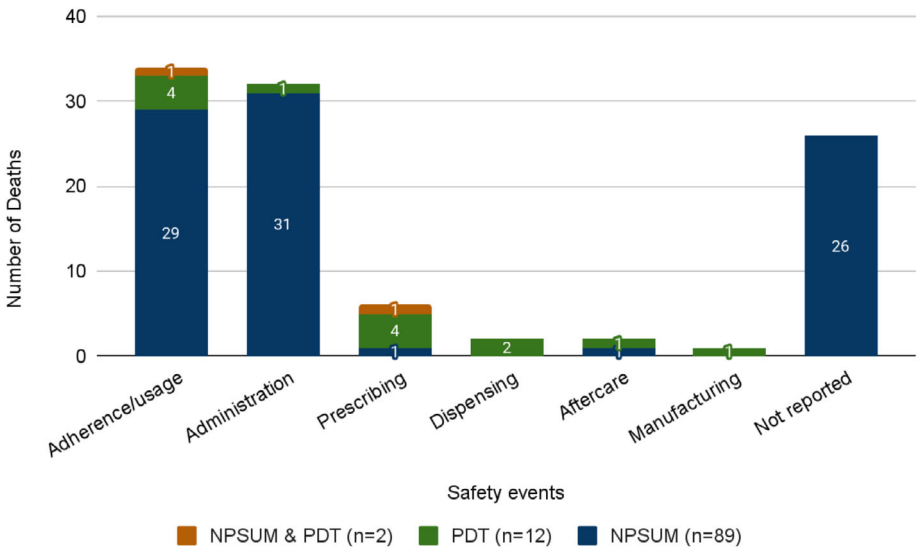


FIGURE 4 Safety events reported following fentanyl patch-related deaths by coroners in the National Programme on substance use mortality (NPSUM) database for England, Wales, and Northern Ireland since 1997–2024 and the Preventable Deaths Tracker (PDT) database of Prevention of Future Deaths reports (PFDs) for England and Wales since 2013–2024.

was not reported in one PFD. Patches were sourced from third parties in 7% of deaths, including from mothers (4%, n = 4), fathers (1%, n = 1), brothers (1%, n = 1) and partners (1%, n = 1), all of which were reported to NPSUM. In three deaths, fentanyl patches were purchased illicitly, with one using the black market. The source of the fentanyl patch was not reported in 31 deaths.

3.4 | Fentanyl indications

For those prescribed patches, chronic pain was the most common indication for use (16%, n = 16), followed by cancer (3%, n = 3). One death involved the prescription of a fentanyl patch for an ankle injury, and one involved a 10-year-old opioid naive child who received a fentanyl patch for the off-label use of pain associated with cerebral palsy while in the A&E department. The indication for the remaining cases was not known (n = 37).

3.5 | Safety events

Seventy-seven safety events were reported by coroners across the 99 deaths, with one quarter (26%, n = 26) not reporting any events. The most common safety event occurred in the adherence

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and use of fentanyl patches (34%, n = 34), followed by the administration of the patch (32%, n = 32), and the prescribing (6%, n = 6) (Figure 4). In deaths where there were adherence and usage safety events, 31 used multiple patches, and three wore patches during a hot bath or shower, which led to a rapid release of fentanyl. In deaths where there were administration errors, 20 individuals used the fentanyl patch orally (e.g., ingestion, chewing or found in the mouth at the time of death); seven individuals heated, inhaled or smoked fentanyl from the patch; and five individuals injected the fentanyl.

Prescribing safety events included the lack of medication reviews (n = 1), concomitant prescription with other drugs, resulting in drug–drug interactions (n = 2), the prescription of an incorrect dose (n = 1), inappropriate prescribing (n = 1) and the off-label prescribing to a 10-year-old opioid naive child (n = 1). For dispensing safety events, one death reported a missed opportunity for the hospital pharmacy to review the dispensing of the fentanyl patch, which may have resulted in the supply being discontinued. In another death, the excessive dose of the fentanyl patch was not identified by the hospital pharmacy before dispensing.

Aftercare safety concerns involved the use of an outdated fentanyl patch in one death and the failure to return the unused fentanyl patches to nursing staff in another. One death involved the excessive release of fentanyl from a compromised patch due to a manufacturing defect.

3.6 | Geographical variations

Fentanyl patch-related deaths were reported in 32 coroner areas, representing only 40% of the jurisdictions across England, Wales and Northern Ireland (Figure 5). One-fifth of deaths (n = 21) were reported by coroners in Northern Ireland, followed by Greater Manchester South (n = 11) and Staffordshire and Stoke-on-Trent (n = 7) (Table S2).

3.7 | Coronial investigations

The median time from death to coroner report was 240 days (IQR:170–540, range: 33–3756 days, Table 1). Among coroners' areas with multiple deaths (n ≥ 2), Jersey had the shortest reporting period (median: 92 days), followed by Northern Ireland (119 days) and Berkshire (128 days). Greater Manchester South had the longest reporting period (median: 468 days), followed by North Yorkshire and York (446 days), and London West (407 days) (Table S2).

In areas that reported one death, Liverpool and the Wirral area had the fastest median reporting time of 74 days, followed by Manchester West with a median of 82 days, and South Wales Central with 89 days. The areas with the longest median reporting intervals with one report were North West Wales (805 days), followed by Cambridgeshire and Peterborough (503 days).

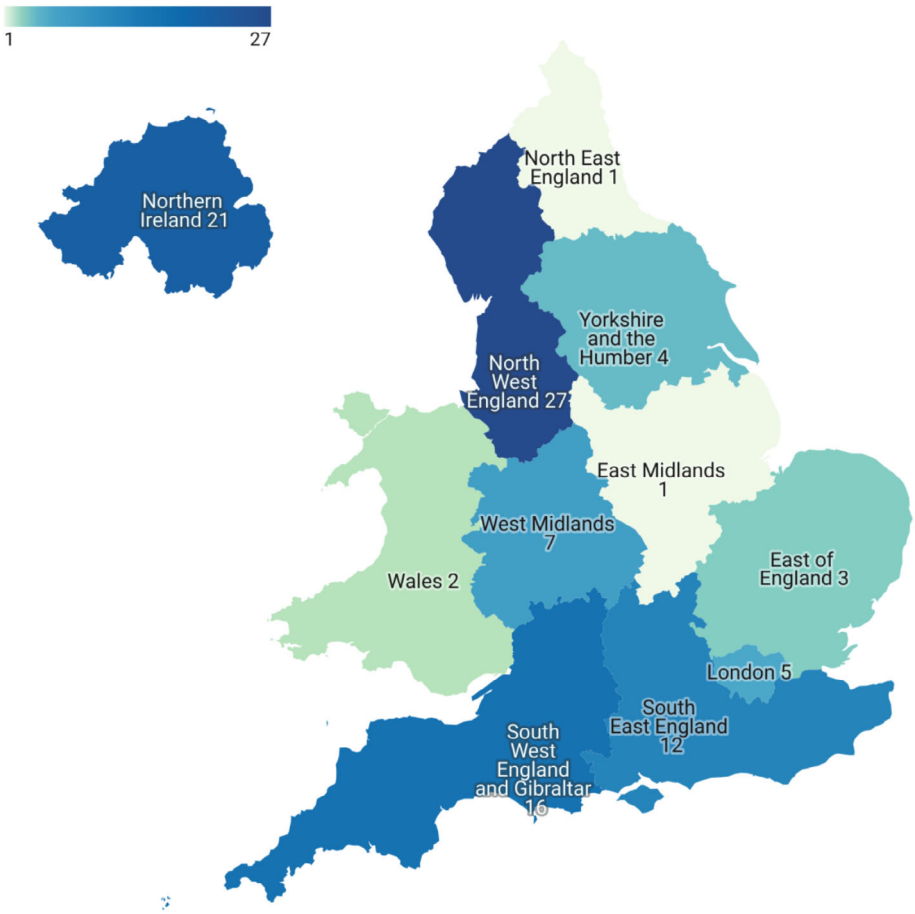


FIGURE 5 Choropleth map of fentanyl patch-related deaths reported by coroners in England, Wales, and Northern Ireland from the National Programme on substance use mortality (NPSUM) database for England, Wales, and Northern Ireland from 1997–2024 and the Preventable Deaths Tracker (PDT) database of Prevention of Future Deaths reports (PFDs) for England and Wales since 2013–2024. Data for Jersey is included in the South West England and Gibraltar region.

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Deaths were reported to NPSUM at a median of 232 days (IQR: 162–425 days) after death, compared to a median of 524 days (IQR: 228–687 days) after death for the writing of PFDs (Table 1).

3.8 | Coroners' concerns and responses to PFDs

Twelve coroners raised 52 concerns across 15 domains (Figure 6). Most concerns were regarding poor communication (n = 6), information (n = 6) and systems and processes (n = 6).

Nineteen organizations received the 12 PFDs, of which 58% responded to the coroner. Most (59%) reports were sent to local organizations (Figure 7), including NHS Trusts (40%) and general practices (40%). Responses were outstanding from six organizations, including NHS England, the General Medical Council, the Royal College of General Practitioners, Churchill Surgery, NHS Bedfordshire, Luton and Milton Keynes Integrated Care Board and Manchester University NHS Foundation Trust.

A live reporting dashboard was developed to continue the tracking of fentanyl patch-related PFDs (https://preventabledeathstracker.net/case-study/fentanyl-patches/).[27]

4 | DISCUSSION

There were 99 deaths reported by coroners in England, Wales and Northern Ireland following the use of fentanyl patches between 1997 and 2024. Most of these deaths were from prescribed patches, involving multiple drugs, and among middle-aged males, resulting in 39 years of life lost for every death, costing over £265 million. Seventy-seven safety events were identified, with coroners writing 12 PFDs to 19 organizations that raised a further 52 concerns. A live dashboard of PFDs was developed to continue monitoring coroners' concerns following fentanyl patch fatalities (https://preventabledeathstracker.net/case-study/fentanyl-patches/).

In 1994, fentanyl patches were first licensed in the UK[28] and made available for prescription in 1995.[29] The UK's MHRA's Yellow Card Scheme first reported a death from fentanyl patches in 1996,[9] while the first report by a coroner in our study was in 1999. Since then, the MHRA has reported 82 fatalities involving transdermal fentanyl up until 2018.[9] Our analysis provides an up-to-date record of such deaths that combines prescribed and illicit use of fentanyl patches, drawing insights from coronial death investigations and toxicology reports. This enabled us to identify unique safety events, which we found were more common during the use, adherence, administration and prescribing of fentanyl, with concerns being raised regarding poor communication, information and systems and processes. Our research builds on previous studies in England and Wales,[12,15] but focuses on one formulation to provide a complete assessment of the harms of fentanyl patches.

In 2008, data were aggregated on fentanyl transdermal systems in Canada, Ireland, the UK and the US, which found 281 incidents reported involving prescribing errors, of which 12 resulted in harm or death.[30] Our study of 99 deaths found six instances of prescribing errors, including the lack of medication reviews, concomitant prescribing, dosage errors and the off-label use in a 10-year-old opioid naive child. Despite the UK's MHRA issuing safety alerts in 2014, 2018 and 2020,[7,31,32] our study demonstrates that deaths from fentanyl patches

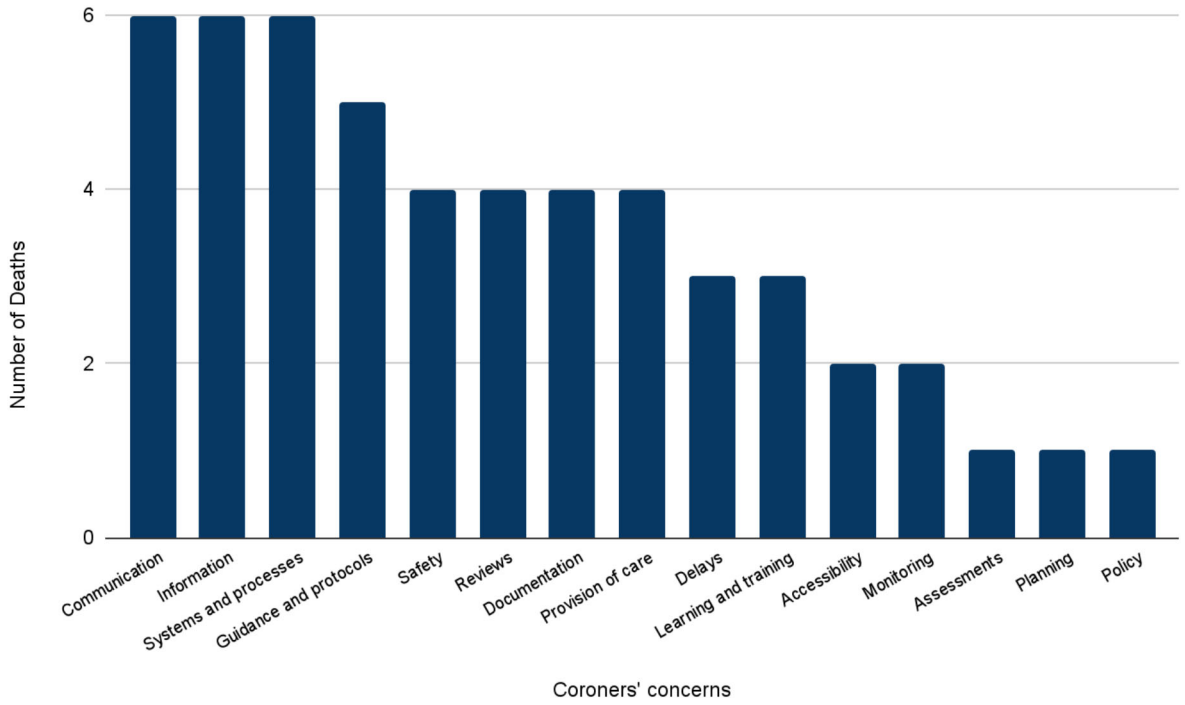


FIGURE 6 Concerns raised by coroners in 12 Prevention of Future Deaths reports (PFDs) in England and Wales for fentanyl patch-related deaths reported by coroners between July 2013 and 2024 in the Preventable Deaths Tracker (PDT) database.

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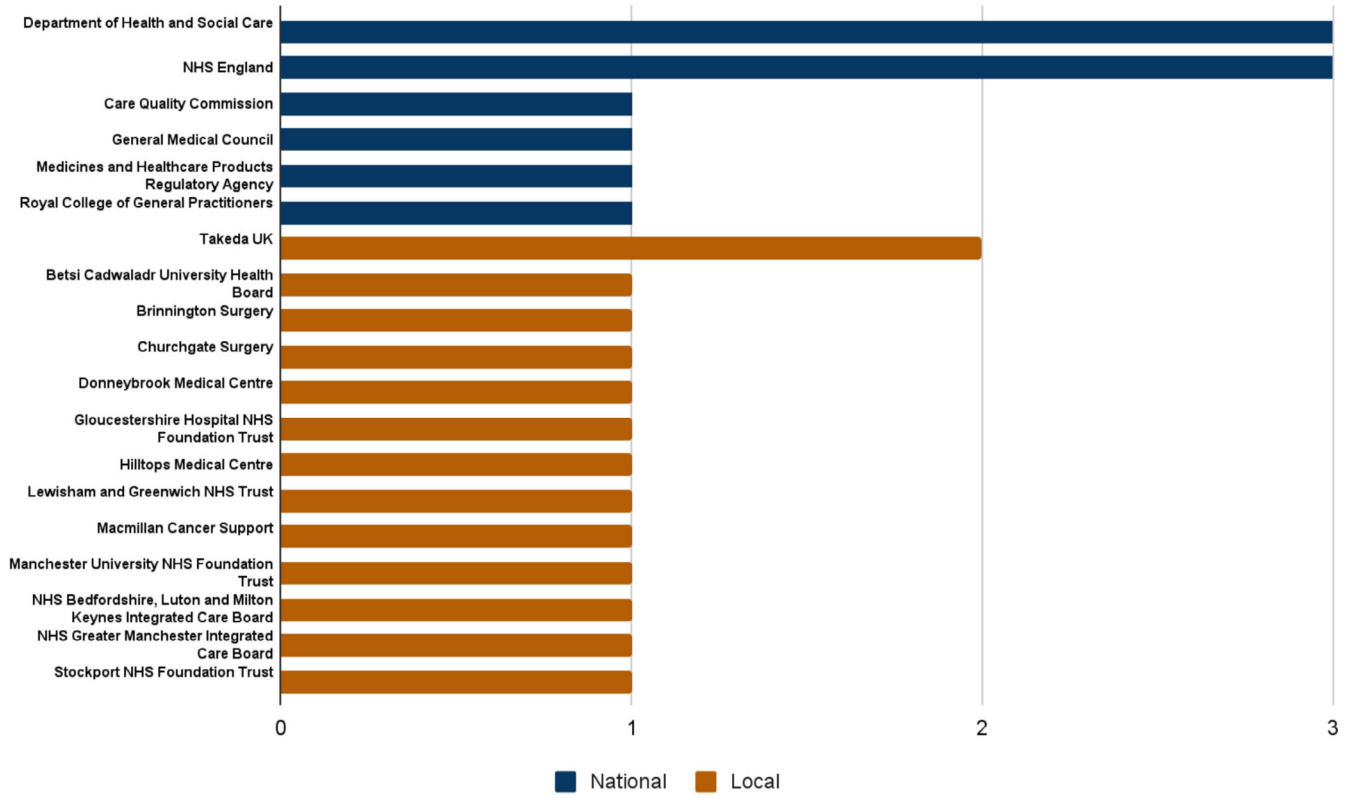


FIGURE 7 National and local organizations that received 12 Prevention of Future Deaths reports (PFDs) in England and Wales for fentanyl patch-related deaths reported by coroners between July 2013 and 2024 in the Preventable Deaths Tracker (PDT) database.

have continued. Although we found a slight decrease in deaths since the 2019 peak, this may be due to widespread delays in the coronial system.

Our study identified concerns regarding the use of fentanyl patches. For example, there were 31 individuals who used multiple fentanyl patches, with the highest numbers being between 11 and 23 patches, and three accidental deaths where fentanyl patches were worn during a hot bath or shower, which occurred in 2015, 2022 and 2023. Other countries have found occurrences; a case report published insights on a fentanyl patch death due to a hot bath in Sweden[33] and another report on the application of more than 67 fentanyl patches in the Netherlands.[34] Thus, information from coroners should be systematically and routinely used to inform drug safety and pharmacovigilance.

4.1 | Strengths and limitations

To the best of our knowledge, this is the first published study to link coroner reports from two national datasets, including toxicology reports and coroners' PFDs. The NPSUM contains over 56 000 substance-related deaths since 1997 in England, Wales and Northern Ireland, while the PDT contains over 6000 deaths from all causes since July 2013 in England and Wales. After linking the datasets, only two duplicates were found, demonstrating the value of the linkage in identifying fentanyl patch-related harms and facilitating a more comprehensive monitoring approach than previous studies and efforts.[9,12,15,31] Despite this strength, the number of fentanyl patch-related fatalities may be an underestimation due to delays in inquests, reporting and coronial variation. The NPSUM receives reports voluntarily from coroners, with variations over time in compliance by coroners' areas and geographical coverage. Similarly, despite PFDs being a statutory requirement for coroners in England and Wales, studies have demonstrated the variation in writing of reports, with most published by coroners in London and Manchester.[35,36] Thus, this study may not represent all fentanyl patch-related deaths in England, Wales and Northern Ireland, and the findings may not be generalizable to trends found in Scotland. We also identified incomplete reporting for some variables, including 31 deaths that did not report the source of the patch, and where no information on the formulation of fentanyl was available, the cases were excluded from this study. Nevertheless, this study provides the largest case series of fentanyl patch-related deaths in the UK, and provides the first evidence base for deaths referred to the coroner in England and Wales that do and do not result in a PFD.

4.2 | Implications

Our research demonstrates that healthcare professionals should remain vigilant when prescribing and dispensing fentanyl patches due to their risk of accidental deaths and potential for misuse. Fentanyl patches need a high level of strict control by healthcare providers.

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However, better patient care is needed to minimize drug-related harms, such as establishing a dual review system for fentanyl transdermal patch prescriptions in medical institutions, developing personalized medication guidance manuals for patients, implementing frequent medication reconciliation for patients, considering alternative non-opioid initial management for chronic conditions and delivering comprehensive counselling. More evidence is needed to determine the right patient, indication, and dosage regimen to enhance the safe prescribing of fentanyl patches. Our live dashboard can support decision-makers and provide evidence for any further policy and public health measures.

Due to data limitations, no research has investigated deaths referred to coroners that have and have not resulted in the writing of a PFD. Our study found that one in eight fentanyl patch-related deaths investigated by a coroner resulted in a PFD, which were more common for older females, deaths in hospital, accidental manners of deaths, and following prescribed patches. However, no statistical comparisons were conducted due to the small sample size. Thus, future research should assess whether these patterns remain when comparing all substance-related deaths investigated by coroners in England and Wales.

5 | CONCLUSIONS

Our study systematically compiles coroners' reports from multiple sources, providing the first data-linkage case series and a real-time reporting tool. The safety events and concerns raised by coroners following the 99 deaths should be harnessed by regulators, policy makers and healthcare professionals for surveillance and pharmacovigilance to improve the safety of fentanyl patch prescribing and use.

AUTHOR CONTRIBUTIONS

EM identified the research gap and led the writing of the study protocol, searches in NPSUM, data management, analysis, produced all figures and tables, and wrote the first draft of the manuscript. CSC provided supervisory support, and contributed to manuscript drafts. GCR led the design, conducted keyword searches in the Preventable Deaths Tracker, cross-checked extracted data, provided supervisory support and guidance on analyses, and edited all drafts of the manuscript.

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CONFLICT OF INTEREST STATEMENT

EM is a PhD student at King's College London funded by the Kuwait Cultural Office, London (2023–27). CSC is employed by King's College London as a Senior Lecturer and is a member of the Advisory Council on the Misuse of Drugs (ACMD) and is a novel psychoactive substance (NPS) expert for the European Union Drug Agency (EUDA). GCR is employed by King's College London as a AI+ Academic Senior Fellows and has a contract with the University of Oxford as a Senior Associate Tutor. GCR has had travel expenses reimbursed for attending and presenting at conferences, and received fees for speaking at events, teaching and delivering training. GCR is the director of a limited company and a community interest company (CIC) that funds the Preventable Deaths Tracker's infrastructure, and receives subscriptions to a personal Substack newsletter.

DATA AVAILABILITY STATEMENT

The study protocol was pre-registered (https://doi.org/10.17605/OSF.IO/GMHNW), and the study materials are available in the supplement and via an open repository (https://osf.io/mvq5b/). The raw data for NPSUM is available on request from the corresponding author, and PFDs are openly available on the judiciary website (https://www.judiciary.uk/prevention-of-future-death-reports/).

ORCID

Eman Mshari https://orcid.org/0009-0007-2953-243X
Caroline S. Copeland https://orcid.org/0000-0002-4462-1402
Georgia C. Richards https://orcid.org/0000-0003-0244-5620

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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