

Alcohol use and misuse, self-harm and subsequent mortality: an epidemiological and longitudinal study from the multicentre study of self-harm in England

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ABSTRACT

Objectives Alcohol use and misuse are strongly associated with self-harm and increased risk of future self-harm and suicide. The UK general population prevalence of alcohol use, misuse and alcohol-attributable harm has been rising. We have investigated the prevalence of and trends in alcohol use and misuse in self-harm patients and their associations with repeat self-harm and subsequent death.

Methods We used patient data from the Multicentre Study of Self-Harm in England for 2000–2009 and UK mortality data for patients presenting from 2000 to 2007 who were followed up to the end of 2009.

Results Alcohol involvement in acts of self-harm (58.4%) and alcohol misuse (36.1%) were somewhat higher than found previously in self-harm patients. Alcohol involvement and misuse were most frequent in men, those aged 35–54 years and those from white ethnicities. The frequency of alcohol misuse increased between 2000 and 2009, especially in women. Repetition of self-harm was associated with alcohol involvement in self-harm and particularly with alcohol misuse. Risk of suicide was increased significantly in women misusing alcohol.

Conclusions Alcohol use and misuse in self-harm patients appears to have increased in recent years, particularly in women. The association of alcohol with greater risk of self-harm repetition and mortality highlights the need for clinicians to investigate alcohol use in self-harm patients. Ready availability of alcohol treatment staff in general hospitals could facilitate appropriate aftercare and the prevention of adverse outcomes.

INTRODUCTION

Alcohol is frequently used around the time of a self-harm act,¹ especially in men, although there are indications that the proportion among women is increasing.^{2–3} Alcohol misuse is also particularly common within the self-harm population. Alcohol dependency has previously been found in up to 23% of self-harm patients in the UK.⁴ Its prevalence appeared to increase during the 1990s, especially in women.² This is of particular concern as alcohol misuse is also associated with increased risk of suicide,⁵ with the risk of suicide having been shown to increase by up to 17 times in patients dependent on alcohol.⁶

In 2007, approximately 24% (33% of men, 16% of women) of the general adult population in England consumed alcohol in a hazardous way, with

Key messages

What is already known on this subject

- ▶ Research has consistently shown alcohol use and misuse to be associated with self-harm and suicide but evidence from large-scale longitudinal studies has been lacking.
- ▶ Alcohol misuse within the general UK population has increased in recent years but up until now it was not known whether this was also the case within the self-harm population.

What this study adds

- ▶ This longitudinal study of the UK's self-harm database between 2000 and 2009 showed alcohol use and misuse in self-harm patients to be more prevalent than has been previously reported and alcohol misuse to have increased significantly in this population between 2000 and 2009, particularly in women.
- ▶ The findings highlight the need for clinicians to investigate alcohol use in self-harm patients and for ready availability of alcohol treatment specialists within hospitals to facilitate prevention of adverse alcohol-related outcomes.

the number of adults dependent on alcohol having risen from 1.1 million in 2000 to 1.6 million in 2007.^{7–8} Alcohol-related hospital admissions increased by 85% in England (from 510 780 to 945 470 admissions) between 2002/2003 and 2008/2009.⁹ It is currently estimated that around 15 000 deaths (~3% of all deaths) in England per year are attributable to alcohol.¹⁰ The 2003 Licensing Act became fully effective in the UK on 23 November 2005. Although the new licensing laws were intended to reduce rates of drinking-related harm and crime, claims were made that some of the specific changes (eg, 24 h licensing) may actually have the opposite effect. Findings on the impact of the Act have been mixed with some authors reporting a rise in alcohol-related emergency department (ED) attendances and ambulance callouts.¹¹

It is not known whether current UK trends in alcohol use and misuse within the self-harm population are mirroring those in the general population. Previous research in the UK has suggested an ongoing increase over a 30-year period.^{2–4 12} It is also not known whether the Licensing Act (2003) has had any impact on these trends within the self-harm population. In this study we have used data



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from the Multicentre Study of Self-Harm in England³ to investigate the prevalence of and trends in alcohol involvement and alcohol misuse in self-harm patients, including the possible impact of the Licensing Act (2003). We have also examined the association of alcohol involvement and misuse with repeat self-harm and mortality, particularly suicide.

METHOD

Identification of self-harm patients

As part of the Multicentre Study of Self-harm in England³ data were collected on all individuals aged 18 years and over, who presented with self-harm to one of six general hospital EDs in Oxford (1), Manchester (3) and Derby (2), between 1 January 2000 and 31 December 2009. Self-harm was defined as any act of intentional self-poisoning or self-injury, regardless of motivation.¹³ We only used data from episodes where a full psychosocial assessment was conducted by a mental health specialist, as reliable information on alcohol use and misuse were not available in most other cases. Alcohol involvement at the time or within 6 h of the self-harm act and the presence of any ongoing alcohol misuse were recorded by the clinician as part of their assessment. For the purposes of this study, 'alcohol misuse' included any excessive alcohol use, alcohol dependency or chronic alcoholism with physical symptoms, as determined by the assessing clinician. In Oxford the assessing clinicians used a guideline to determine excessive alcohol use: drinking more than 21 units per week on a regular basis for men and 14 units for women. In Manchester and Derby, clinical judgement only was used to determine whether alcohol use was excessive.

Summary data

The summary cross-sectional data presented were based on each patient's first assessed episode between 1 January 2000 and 31 December 2009 whereas data on trends were based on each patient's first assessed episode in each year between 2000 and 2009. The impact of the 2005 change in licensing laws (Licensing Act, 2003) was investigated by comparison of first assessed episodes occurring before (1 January 2000–22 November 2005) and after (23 November 2005–31 December 2009) the introduction of the change.

Repetition of self-harm

Data on repetition of self-harm were based on patients with an assessed episode between 1 January 2000 and 31 December 2008, followed up until 31 December 2009. Repetition of self-harm was any further episode of self-harm (whether assessed or not) presenting to each study hospital within 12 months of the first assessed episode for each patient.

Deaths

All patients with an assessed episode between 1 January 2000 and 31 December 2007 were followed up until 31 December 2009. Deaths were identified through the Data Linkage Service of the NHS, which traced individuals using the Central Health Register Inquiry System for patients within England and Wales and the equivalent in Scotland. Individuals lost to follow-up were excluded from the mortality analyses. Deaths with an 'external cause' were those that received an accidental, intentional or undetermined (ie, open) coroner's verdict (ICD-10 codes V01-Y89, U509). Deaths in all major remaining diagnostic categories (ICD-10 codes A00-R99) were classified as 'natural'. As is conventional in UK suicide research and clinical practice, individuals receiving suicide and open verdicts at inquest were considered to have died by suicide.¹⁴

Ethical approval

The self-harm monitoring systems in Oxford and Derby have ethical approval from local Health Research Ethics Committees to collect data for local and multicentre projects. In Manchester the monitoring is conducted as part of a clinical audit system, ratified by the local research ethics committee. All centres have approval under section 251 of the NHS Act (2006) to collect patient-identifiable data without patient consent and to send patient details to the Data Linkage Service.

Statistical analyses

Self-harm data were analysed with the χ^2 test and χ^2 test for trend (where trends were approximately linear). Where tests included more than two categories, standardised residual scores were used to determine which category or categories contributed the most to a statistically significant association. The mortality data were analysed with multinomial logistic regression (adjusted for age). All analyses were conducted using SPSS V19.

RESULTS

Self-harm patients

During the 10-year study period 32 885 individuals aged 18 years and over attended EDs in the study centres, with a total of 57 734 episodes of self-harm. Two-thirds (63.7%) of these patients had at least one episode assessed by a mental health specialist, giving a study sample of 20 959 patients with 30 979 assessed episodes.

The majority (56.4%) of those assessed were female, with gender unknown for 10 individuals. The mean age at the first assessed episode was 34.3 years (SD 13.5, range 18–95 years). Over four-fifths (83.3%) of first assessed episodes involved self-poisoning, 12.4% self-injury and 4.3% self-poisoning and self-injury. The involvement of alcohol in the self-harm act was known for 94.4% of patients ($n=19\ 789$) and information on the presence of alcohol misuse was available for 87.8% of patients ($n=18\ 401$). Missing data were excluded from the relevant parts of the analysis.

The 12 494 individuals excluded from the study because they did not receive a psychosocial assessment within the study period were found to be similar to the assessed sample in terms of gender (54.7% female) and age at their first episode (32.6 years, SD 13.1, range 18–97 years). However, a greater proportion presented with self-injury as a method of harm (eg, cutting/stabbing, asphyxiation, traffic related, gas) at their first episode than in the assessed group (self-poisoning, 77.5%; self-injury, 20.4%; self-poisoning and self-injury, 2.1%; $\chi^2=472$, $p<0.0001$).

Alcohol involvement in self-harm

Alcohol was involved in 58.4% ($n=11\ 556$) of self-harm episodes, and this was significantly more frequent in men than women (table 1). Alcohol involvement was significantly more common for men and women aged 35–54 years than other age groups (table 1). It was also more frequent in patients of white ethnicity compared with those of non-white ethnicity. Alcohol involvement was less commonly associated with self-injury than self-poisoning or both methods combined (table 1).

There was a small increase of 4.9% in the frequency of alcohol involvement in self-harm between 2000 and 2009. This increase was significant in men, with a 4.1% increase over the study period, but not in women (figure 1A, B). There was a significant increase of 5.4% between 2000 and 2009 in men aged 35–54 years (figure 1A). No change in the frequency of alcohol involvement in self-harm following the introduction of the new

Table 1 Alcohol involvement at first assessed episode of self-harm 2000–2009

	Men		Women		All	
	Total number of patients	Number involving alcohol N (%)	Total number of patients	Number involving alcohol N (%)	Total number of patients	Number involving alcohol N (%)
Statistic	8595	5409 (62.9)	11 186	6145 (54.9)	19 789	11 556 (58.4)
Age (years)	$\chi^2=128$, $p<0.001$					
18–24	2243	1266 (56.4) ---	3725	1781 (47.8) ---	5968	3047 (51.1) ---
25–34	2359	1555 (65.9)	2778	1576 (56.7)	5137	3131 (60.9) +
35–54	3290	2240 (68.1) +++	3870	2456 (63.5) +++	7160	4696 (65.6) +++
55+	703	348 (49.5) ---	813	332 (40.8) ---	1516	680 (44.9) ---
Statistic	$\chi^2=141$, $p<0.001$		$\chi^2=259$, $p<0.001$		$\chi^2=413$, $p<0.001$	
Ethnicity						
White	7140	4557 (63.8)	8996	5220 (58.0)	16 136	9777 (60.6)
Non-white	509	213 (41.8)	967	240 (24.8)	1476	453 (30.7)
Statistic	$\chi^2=97.8$, $p<0.001$		$\chi^2=388$, $p<0.001$		$\chi^2=497$, $p<0.001$	
Method of self-harm						
Self-poisoning	6837	4377 (64.0)	9804	5424 (55.3)	16 641	9801 (58.9)
Self-injury	1359	779 (57.3) --	937	475 (50.7) --	2296	1254 (54.6) --
Both methods	399	253 (63.4)	445	246 (55.3)	844	499 (59.1)
Statistic	$\chi^2=21.8$, $p<0.001$		$\chi^2=7.43$, $p<0.05$		$\chi^2=15.4$, $p<0.001$	

Statistically significant results in bold.

-/+ = Standardised residual greater than +/-1.96 ($p<0.05$); -/+ = Standardised residual greater than +/-2.58 ($p<0.01$); -/+ = Standardised residual greater than +/-3.29 ($p<0.001$).

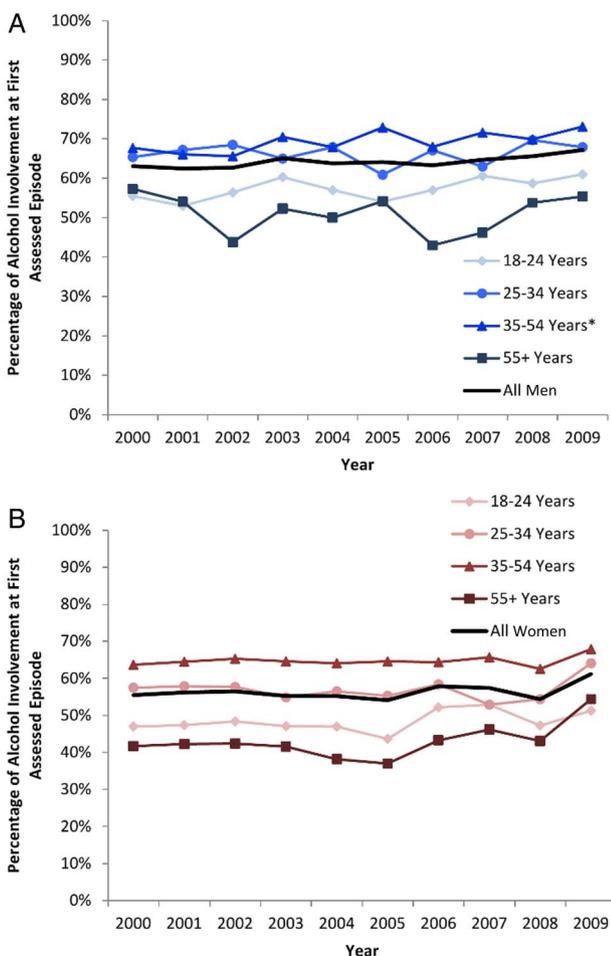


Figure 1 Trends in alcohol involvement in self-harm 2000 to 2009. (A) Men. (B) Women.

licensing laws in November 2005 was found (58.2%, $n=7419/12\ 753$ vs 58.8%, $n=4137/7036$; $\chi^2=0.725$, $p=0.40$).

Alcohol misuse and self-harm

Over a third of patients (36.1%; $n=6637$) were known to be misusing alcohol. It was more common in men than women and in those aged 35–54 years; it was least common in those aged 18–24 years and 55 years and over. Alcohol misuse was also more prevalent in white ethnicities and patients who were unemployed (table 2). Self-injury was significantly more common in women misusing alcohol, although this was not the case for men (table 2).

Alcohol misuse became more common between 2000 and 2009, increasing from 35.2% in 2000 to 43.4% in 2009. This trend was particularly marked in women, for whom there was an increase of 8.7% between 2000 and 2009, (men: 43.6–51.8%; women, 28.7–37.4%) (figure 2). A significant increase was found in all age groups for women (figure 2B) but only in men aged 25–34 years and 35–54 years (figure 2A).

Alcohol and repeat self-harm

Repetition of self-harm within 12 months of first assessed episode was more frequent in both genders when alcohol had been involved in the first assessed self-harm episode, and especially when alcohol was being misused (table 3).

Alcohol and mortality

Of the 17 842 individuals who had an assessed episode between 2000 and 2007, 1233 (6.9%) had died by the end of 2009 (1.8% were lost to follow-up). Alcohol involvement at the time of self-harm was not associated with an increased likelihood of death (table 4A). Death was more common in those misusing alcohol than in those who were not (table 4A).

A third of those who died had an external cause of death (14.6% suicide; 12.4% accidental; 7.3% undetermined).

Table 2 Alcohol misuse at first assessed episode of self-harm 2000–2009

	Men		Women		All	
	Total number of patients	Alcohol misuse N (%)	Total number of patients	Alcohol misuse N (%)	Total number of patients	Alcohol misuse N (%)
Statistic	7893	3551 (45.0) $\chi^2=475$, $p<0.001$	10 501	3086 (29.4)	18 394	6637 (36.1)
Age (years)						
18–24	2095	817 (39.0) ---	3565	880 (24.7) ---	5660	1697 (30.0) ---
25–34	2154	1011 (46.9)	2585	747 (28.9)	4739	1758 (37.1)
35–54	3011	1505 (50.0) +++	3610	1307 (36.2) +++	6621	2812 (42.5)
55+	633	218 (34.4) ---	741	152 (20.5) ---	1374	370 (26.9) ---
Statistic	$\chi^2=92.5$, $p<0.001$		$\chi^2=147$, $p<0.001$		$\chi^2=260$, $p<0.001$	
Ethnicity						
White	6663	3070 (46.1)	8517	2659 (31.2)	15 180	5729 (37.7)
Non-white	484	129 (26.7)	954	120 (12.6)	1438	249 (17.3)
Statistic	$\chi^2=68.8$, $p<0.001$		$\chi^2=144$, $p<0.001$		$\chi^2=237$, $p<0.001$	
Employment						
Unemployed	2598	1341 (51.6) +++	2590	951 (36.7) +++	5188	2292 (44.2) +++
Employed	3177	1320 (41.5) -	3926	1104 (28.1)	7103	2424 (34.1) -
Household duties	21	4 (19.0)	1074	255 (23.7) -	1095	259 (23.7) ---
Retired	268	68 (25.4) ---	358	54 (15.1) ---	626	122 (19.5) ---
Registered sick/disabled	1136	525 (46.2)	1125	345 (30.7)	2261	870 (38.5) +
Student	290	92 (31.7) ---	1008	217 (21.5) ---	1298	309 (309) ---
Other	173	61 (35.3)	122	42 (34.4)	295	103 (103)
Statistic	$\chi^2=136$, $p<0.001$		$\chi^2=155$, $p<0.001$		$\chi^2=398$, $p<0.001$	
Method of SH						
Self-poisoning	6289	2826 (44.9)	9214	2655 (28.8)	15 503	5481 (35.4)
Self-injury	1230	564 (45.9)	869	297 (34.2) ++	2099	861 (41.0) +++
Both methods	374	161 (43.0)	418	134 (23.1)	792	295 (37.2)
Statistic	$\chi^2=0.95$, $p=0.622$		$\chi^2=12.5$, $p<0.005$		$\chi^2=26.21$, $p<0.001$	

Statistically significant results in bold.

--- = Standardised residual greater than +/−1.96 ($p<0.05$); - - - = Standardised residual greater than +/−2.58 ($p<0.01$); - - - - = Standardised residual greater than +/−3.29 ($p<0.001$).

SH; self-harm.

Following adjustment for age, the risk of death by suicide was significantly elevated for women misusing alcohol but not for men. The risk of accidental death was considerably higher for those misusing alcohol in both sexes, especially for women (table 4B).

DISCUSSION

The majority of self-harm acts in this study involved alcohol, and over a third of patients were known to be misusing alcohol. Factors associated with alcohol misuse included being male, of white ethnicity and unemployed. Age also appeared to be associated with alcohol misuse, with it being more prevalent in those aged 35–54 years and less so for those aged 18–24 years and >55 years. Between 2000 and 2009, there was a small increase in the frequency of alcohol involvement in self-harm acts, especially for men aged 35–54 years, with a more marked increase in the frequency of alcohol misuse, particularly in women. No change in frequency was associated with the implementation of the Licensing Act (2003) in 2005. While alcohol was frequently involved in acts of self-poisoning, in women alcohol misuse was more frequently associated with self-injury than other methods of self-harm. Repeat self-harm within 12 months was more likely in those whose initial self-harm episode involved alcohol and particularly in those misusing alcohol. There was also an increased risk of suicide in women who misused alcohol.

The frequency of alcohol involvement in acts of self-harm in this study was higher than previously reported^{1 2} although there

was only a modest increase in the frequency of alcohol involvement between 2000 and 2009. This probably reflects the recent rise in harmful drinking within the general population.¹⁵ The extent of alcohol involvement in self-harm is important, given that alcohol increases risk in a number of ways. It can increase the lethality of self-harm methods, especially for certain drugs frequently taken in acts of self-poisoning, such as paracetamol and sedatives.² It is also known that intoxicated patients are less likely to receive a full psychosocial assessment following self-harm¹⁶ yet psychosocial assessments have been shown to reduce risk of future self-harm.¹⁷

The proportion of the self-harm population misusing alcohol (excessive drinking, alcohol dependency or chronic alcoholism) also appears to be higher than reported in previous years.^{2 4} Indeed, the frequency of alcohol misuse increased between 2000 and 2009. The increase in alcohol misuse across all age groups of women is particularly important to note given that the majority (~60%) of the self-harm population presenting to EDs are female.³ Traditionally, female patients have been underrepresented within alcohol services, which is often attributed to their being less likely to recognise they have a problem, more likely to experience stigma, and a lack of childcare provision/concerns regarding children being taken into care.¹⁸ If women with alcohol problems are to be successfully engaged by health services, clinicians need to be sensitive to their particular needs and concerns, with any hospital presentation seen as an opportunity for involvement in alcohol reduction initiatives. This is

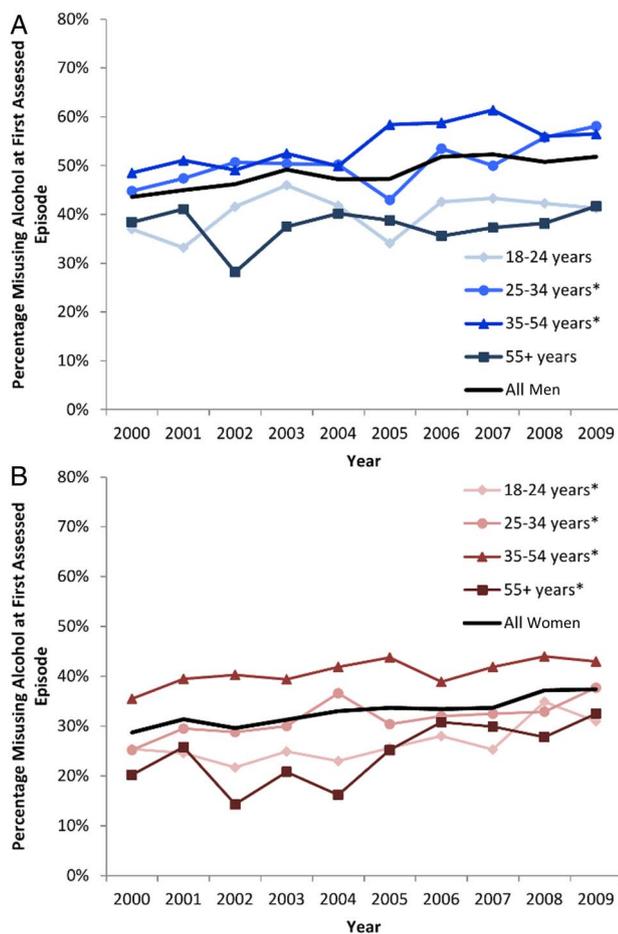


Figure 2 Trends in alcohol misuse in self-harm 2000 to 2009. (A) Men. (B) Women.

particularly important as alcohol use by women may carry an even greater risk of suicide than in men,⁶ although in the present study the elevation in risk was similar for the two genders.

Alcohol misuse was more frequent in women who self-injured. This association has been found previously,¹² and is important to note, given evidence of an increased risk of future suicide associated with self-injury methods.^{19, 20} The higher proportion of self-injury patients who were not assessed and therefore not included in the present study should also be noted. Considering the association between self-injury and alcohol misuse and that these are associated with a decreased likelihood of assessment and an increased risk of self-harm and future suicide, there is a potentially very vulnerable group of individuals not receiving assessment that needs to be a focus of

clinical engagement and future research. Of relevance here is our finding, consistent with previous research^{5, 12} that repeat self-harm was more frequent in patients misusing alcohol. It is clearly essential that alcohol use be considered in the clinical management of self-harm patients. Psychosocial interventions are unlikely to succeed if comorbid alcohol misuse is not addressed. Abstinence from alcohol can be associated with a cessation of self-harm behaviour.²¹ Since even brief interventions can be effective in reducing alcohol misuse,²² the presence of clinicians from local alcohol services within general hospitals has the potential to have a significant impact on those who self-harm and misuse alcohol.

Strengths and limitations

This study is based on people presenting to general hospital following self-harm. Therefore the findings are not necessarily representative of cases within the community. However, as the sample is derived from six hospitals within three cities in England of varying socioeconomic status and service provision, the findings should be generalisable more broadly to self-harm populations who present to EDs.

The study data were derived directly from clinical recording within the six study hospitals and so inevitably there were missing data fields for a small proportion of patients, which we omitted from the analyses.

Only self-harm episodes in which a full psychosocial assessment was conducted could be included in the present study due to the unavailability of information about alcohol use and misuse in those not assessed. This means that a potentially vulnerable subpopulation engaging in self-harm and misusing alcohol has not been included. Furthermore, alcohol use and misuse were not identified using a standardised screening tool or blood tests, which may have resulted in an underestimation of the frequency of alcohol use and misuse, as well as their associations with repeat self-harm and death.²³ Our prevalence figures should therefore be seen as conservative estimates.

CONCLUSIONS

The high prevalence of alcohol use and misuse within the self-harm population in England appears to be increasing, especially in women. We have highlighted a need for further research into a particularly vulnerable group of patients who are misusing alcohol, engaging in self-injurious behaviours and not receiving a psychosocial assessment. The impact of alcohol misuse on repetition of self-harm and mortality demonstrates a real and growing need for clinical services to address comorbid alcohol issues in self-harm patients. Such an approach could reduce patient risk, and could potentially result in a significant reduction in the high clinical demand posed by this patient group.

Table 3 Prevalence of alcohol use and misuse in association with repeat self-harm within 12 months

	Men		Women		All	
	Total number of patients	Repeat self-harm N (%)	Total number of patients	Repeat self-harm N (%)	Total number of patients	Repeat self-harm N (%)
Alcohol involvement	4977	1038 (20.9)	5659	1118 (19.8)	10 636	2156 (20.3)
No alcohol involvement	2955	555 (18.8)	4687	806 (17.2)	7642	1361 (17.8)
Statistic	$\chi^2=4.97, p<0.05$		$\chi^2=11.09, p<0.001$		$\chi^2=17.34, p<0.001$	
Alcohol misuse	3266	778 (23.8)	2835	681 (24.0)	6101	1459 (23.9)
No alcohol misuse	4023	668 (16.6)	6878	1072 (15.6)	10 901	1740 (16.0)
Statistic	$\chi^2=59.03, p<0.001$		$\chi^2=96.58, p<0.001$		$\chi^2=161, p<0.001$	

Table 4 Alcohol use, misuse and mortality (2009 follow-up)

	Men		Women			All			
	Total number of patients	Death N (%)	Total number of patients	Death N (%)	Total number of patients	Death N (%)	Total number of patients	Death N (%)	
<i>(A) Prevalence of alcohol use and misuse in association with death</i>									
Alcohol involvement	4504	427 (9.5)	5198	245 (4.7)	9702	672 (6.9)			
No alcohol involvement	2679	276 (10.3)	4230	210 (5.0)	6909	486 (7.0)			
Statistic	$\chi^2=1.29$, p=0.26		$\chi^2=0.32$, p=0.57		$\chi^2=0.07$, p=0.79				
Alcohol misuse	2971	327 (11.0)	2592	171 (6.6)	5563	498 (9.0)			
No alcohol misuse	3621	308 (8.5)	6274	249 (4.0)	9895	557 (5.6)			
Statistic	$\chi^2=11.72$, p<0.001		$\chi^2=28.08$, p<0.0001		$\chi^2=61.83$, p<0.001				
	Men			Women			All		
	N	Adjusted OR†	95% CIs	N	Adjusted OR†	95% CIs	N	Adjusted OR†	95% CIs
<i>(B) Cause of mortality, adjusted for age</i>									
Alcohol involvement									
All external causes	260	1.19	0.91 to 1.54	132	1.17	0.83 to 1.67	392	1.26*	1.02 to 1.55
Suicides and undetermined	162	1.03	0.75 to 1.42	85	0.87	0.57 to 1.34	247	1.04	0.80 to 1.34
Accidental	98	1.51	0.97 to 2.35	47	2.09*	1.11 to 3.94	145	1.79**	1.25 to 2.57
Natural causes	443	1.10	0.89 to 1.38	323	1.33*	1.04 to 1.72	766	1.25**	1.06 to 1.48
Alcohol misuse									
All external causes	241	1.49**	1.15 to 1.92	128	2.33***	1.63 to 3.32	369	1.97***	1.61 to 2.43
Suicides and undetermined	147	1.06	0.76 to 1.47	83	1.75**	1.12 to 2.72	230	1.43**	1.10 to 1.86
Accidental	94	2.53***	1.64 to 3.89	45	3.84***	2.09 to 7.03	139	3.32***	2.34 to 4.71
Natural causes	394	1.65***	1.32 to 2.07	292	2.11***	1.61 to 2.76	686	1.98***	1.67 to 2.35

*Significant at 0.05 level; **Significant at 0.01 level; *** Significant at the 0.001 level.

†Multinomial logistic regression analyses.

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Competing interests None.

Ethics approval The self-harm monitoring systems in Oxford and Derby have ethical approval from local Health Research Ethics Committees (NRES Committee South Central, Berkshire and Derbyshire Research Ethics Committee respectively). In Manchester the project was reviewed by South Manchester Research Ethics Committee and was deemed not to require approval as the monitoring is conducted as part of a clinical audit system.

Provenance and peer review Not commissioned; externally peer reviewed.

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