The College of Emergency Medicine

Clinical Audits

Paracetamol Overdose Clinical Audit 2013-14

National Report

Contents

Executive summary

This is the fourth time that this national audit has been run. Changes in guidance from the Medicines and Healthcare products Regulatory Agency (MHRA) mean that the results are not easily comparable with previous audits. There is wide variation in practice. There are some departments which are performing excellently at caring for these patients. There are a number of areas of particular concern.

1. Recording of capacity in patients who declined treatment was sometimes documented poorly.
2. There was wide variation in the provision of N-acetylcysteine for patients with toxic levels.
3. The MHRA guidelines were almost always never completely complied with. This may reflect failings in documentation, poor knowledge or that the guidelines are simply unachievable.

We are grateful for the enormous amount of work that individual clinical departments have put into producing this audit. Collecting data on its own is insufficient to improve patient care, we call on audit leads to share the results of this audit within their own departments and identify opportunities to improve care.

Introduction

This report shows the results from an audit of the treatment for paracetamol overdose against the clinical standards published by the College of Emergency Medicine (CEM) Quality in Emergency Care Committee (QEC). The report compares your Emergency Department (ED) with the other EDs that made audit returns and with the results of the previous audit conducted in 2008/9.

Nationally, 8403 cases from 178 EDs (including 84% of relevant EDs in England) were submitted, but 184 cases were excluded due to incorrectly entered data. Therefore a total of 8219 cases were included in the audit.

CEM Standards

1. Plasma levels should not be measured earlier than 4 hours after the estimated ingestion time
2. Staggered overdoses - treatment started within one hour of arrival
3. Patients arriving < 8 hours after ingestion - treatment given as per the 2012 MHRA guideline.
4. Patients arriving 8 to 24 hours after ingestion - treatment started before blood results available if there is a clear history of > 6 g ingestion (or 75 mg/kg whichever is the smaller).
5. Patients presenting > 24 hours. INR, urea and electrolytes bicarbonate & LFTs performed and recorded in the notes.

Audit background and methodology

All EDs in the UK were invited to participate in May 2013. Data was collected using a new online data collection tool.

Participants were asked to collect data from ED/hospital records on 50 cases of adults (18 years of age or older) who presented with paracetamol overdose between 1st August 2013 and 31st March 2014. EDs that did not see 50 eligible patients within the timescale were able to include cases from before 1st August 2013. 2013/14 is the fourth time the College has conducted a clinical audit on paracetamol overdose.

In September 2012 the MHRA issued guidance about a new nomogram that removed the 'high risk' line on the nomogram, clarified the definition of staggered overdoses and reduced the rate of infusion of the first bag of N-acetylcysteine.

The CEM clinical standards were revised in 2013 following the publication of this guidance. Full details of the methodology and criteria can be found online at https://cem.l2s2.com.

Format of this report

The table overleaf shows the national audit results. Previous results from 2008 are shown alongside, if available. By showing the lower and upper quartiles of performance as well as the median values, the table indicates the variations in performance between departments.

More detailed information about the distribution of audit results can be obtained from the charts on subsequent pages of the report. Please bear in mind the comparatively small sample sizes when interpreting the charts and results. This analysis is performed on the understanding that the figures are accurate but that we realise that the figures we see in this analysis may not represent accurate real-time data recording. Also note that data quality was variable, and incomplete records often led to poorer performance figures.

Summary of results

See Chart	Case Mix	CEM Standard	National Results					
			Lower quartile		Median *		Upper quartile	
			2013	2008	2013	2008	2013	2008
	Number of patients audited		**47**	48	**49**	50	**50**	50
1,2	Who presented within 1 hour of ingestion (%)		**4**	10	**8**	14	**12**	18
3	Who presented within 8 hours of ingestion (%)		**49**		**59**		**65**	
4	Who presented within 24 hours of ingestion (%)		**59**		**67**		**72**	
5, 6	Who took a staggered overdose (%)		**12**	4	**17**	8	**22**	12
	Assessment and Treatment (%)							
7	Overdose size recorded (% of all cases)		**84**		**89**		**92**	
8	Overdose size more than 6g or 75mg/kg (% of all cases)		**59**		**66**		**75**	
9	Declined treatment (% of all cases)		**2**		**4**		**8**	
10	*of which* had capacity to consent (%)		**0**		**40**		**78**	
11, 12	Received plasma level test in ED (% of all cases)		**86**	72	**92**	79	**96**	80
13, 14	*of which* plasma level tested earlier than 4 hours after ingestion (excludes staggered doses)	**0**	**3** -	3	**7** ↓	8	**11** ↓	13
15, 16	Where tested within 8 hours of ingestion *and* plasma concentration above treatment level (% of all cases)		**8**	11	**13**	17	**19**	22
17, 18	*of which* received N-acetylcysteine (NAC) within 8 hours of ingestion	**100**	**25** ↓	50	**50** ↓	73	**71** ↓	86
19	Where dose >6g (or 75mg/kg) and over 8 hours since ingestion		**4**		**8**		**12**	
20	*of which* received N-acetylcysteine (NAC) within 1 hour of arrival	**100**	**0**		**0**		**0**	
21	Staggered overdoses receiving NAC within 1 hour of arrival	**100**	**0**		**0**		**2**	
	Compliance of treatment with MHRA guidelines #							
22, 23	Yes - recommended treatment received #	**100**	**68 #**	73	**76 #**	83	**84 #**	90
	Partially in accordance with recommended treatment #		**8 #**	6	**15 #**	10	**22 #**	20
	No - serious omissions in treatment		**0 #**	0	**2 #**	0	**7 #**	3

Legend

↓ = Red arrow denotes deterioration in performance since previous audit

↑ = Green arrow denotes improvement in performance since previous audit

\- = Blue hyphen denotes no change in performance since previous audit

Notes about national results

* The median value of each indicator is that where equal numbers of participating EDs had results above and below that value.

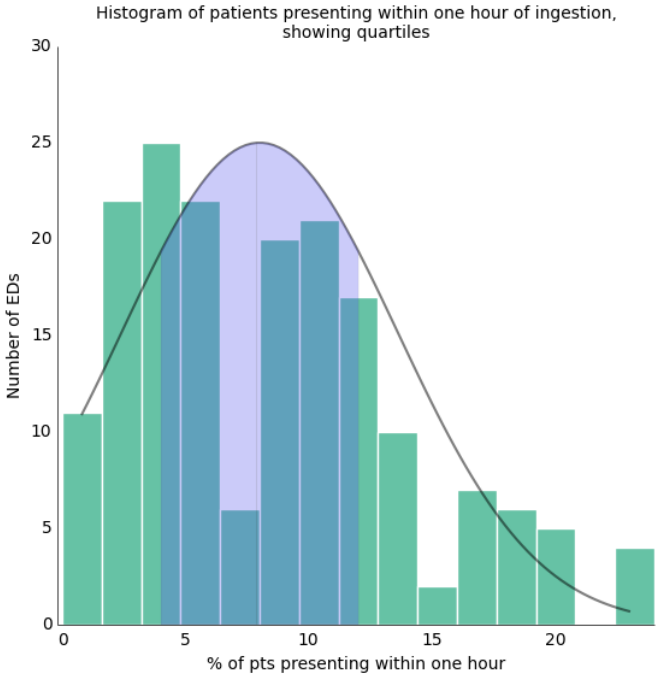
These median figures may differ from other results quoted in the body of this report which are mean (average) values calculated over all audited cases.

The lower quartile is the median of the lower half of the data values.
The upper quartile is the median of the upper half of the data values.

The treatment guidelines were changed following the 2008 audit, and therefore are not directly comparable to the 2012 audit figures. The 2008 compliance figures relate to the guidelines in place at the time.

Types of chart in this report

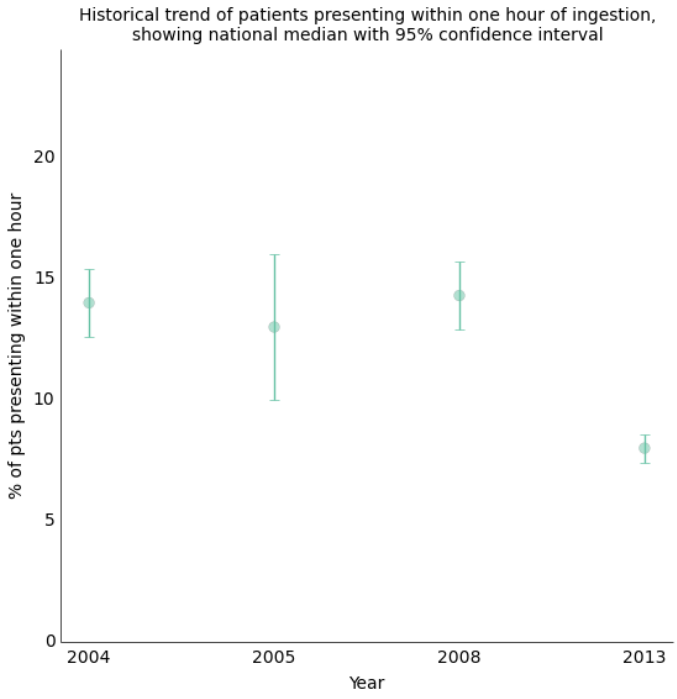
Two types of chart are used throughout this report, **histograms** and **trend charts**.



Histogram charts are used to show the distribution and frequency of results. Each histogram shows the number of EDs per % of patients as the height of each block.

The light purple area shows the interquartile range. The grey line in this area shows the median.

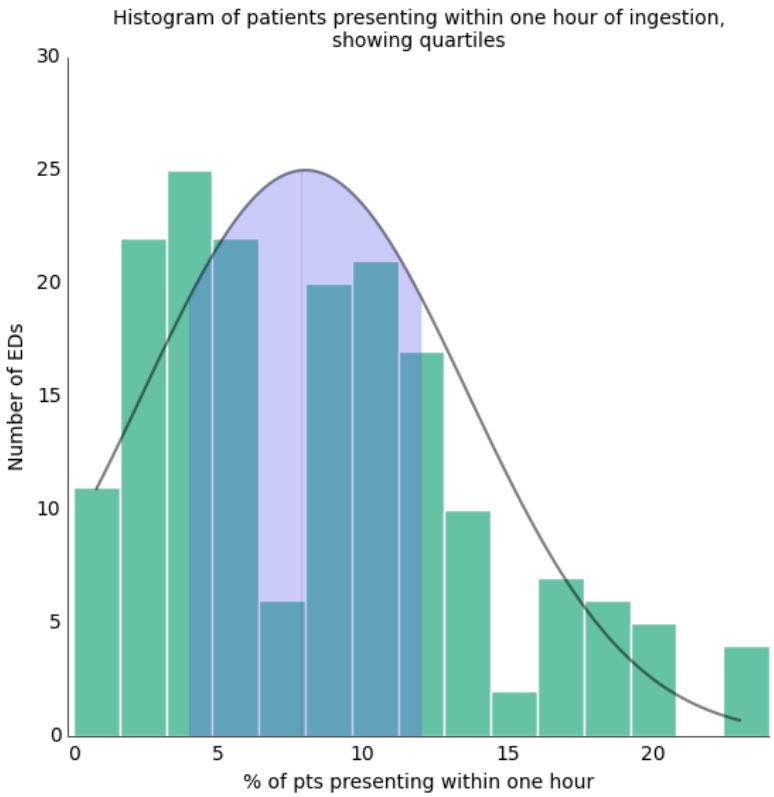
The curved line shows the normal distribution of data.



Trend charts show the median for all EDs as a dot, with 95% confidence level indicated by the green line. The median for each audit year is indicated.

SECTION 1: Casemix

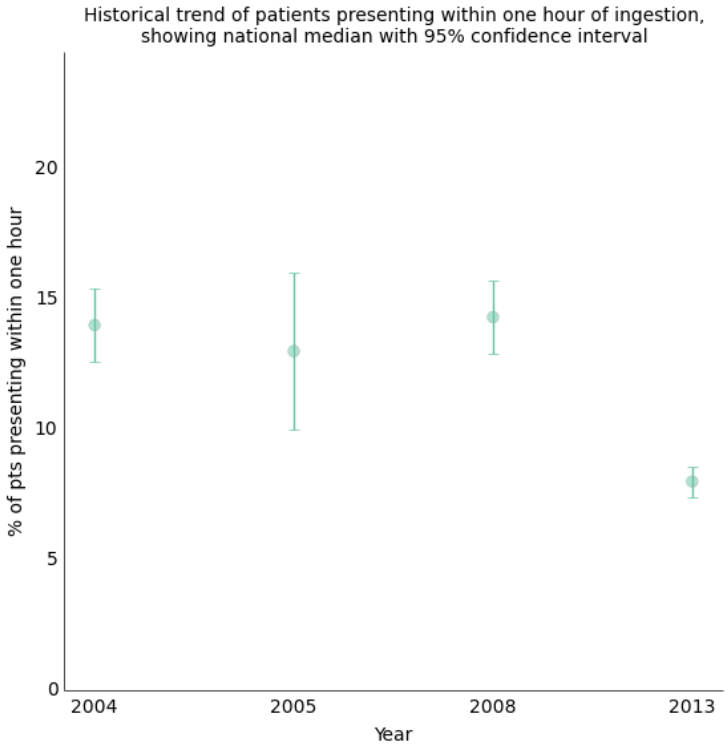
CHART 1: % Patients presenting within 1 hour of ingestion



Few patients tend to present at an ED within 1 hour of ingestion. Oral activated charcoal may be given as treatment if presenting within this timeframe to reduce drug absorption[1].

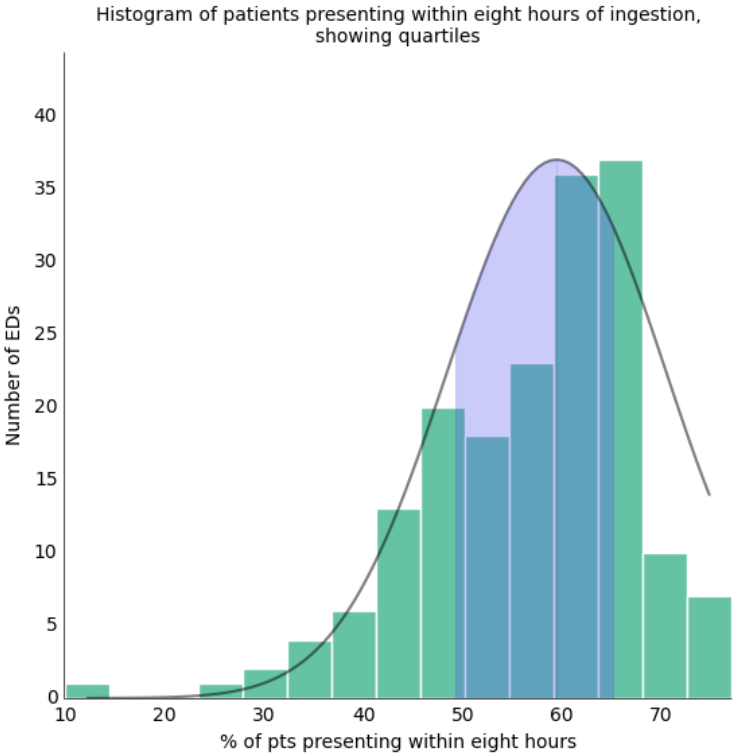
The percentages for this group ranged from 0 to 24 between EDs, with a median of 8.

CHART 2: Trend chart of patients presenting within 1 hour of ingestion – data from 2004, 2005, 2008 and 2013



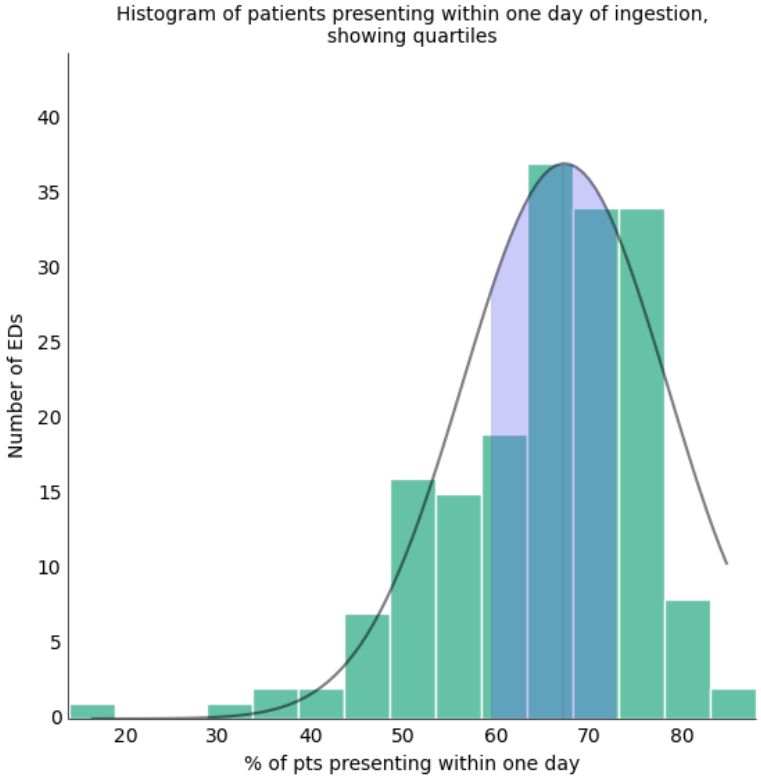
The percentages of patients presenting within 1 hour of ingestion has remained similar for 2004, 2005 and 2008 but decreased slightly for 2013.

CHART 3: % Patients presenting within 8 hours of ingestion



The percentage of patients presenting within 8 hours of ingestion ranged from 10% to 77% between EDs. The median value was 59%.

CHART 4: % Patients presenting within 24 hours of ingestion

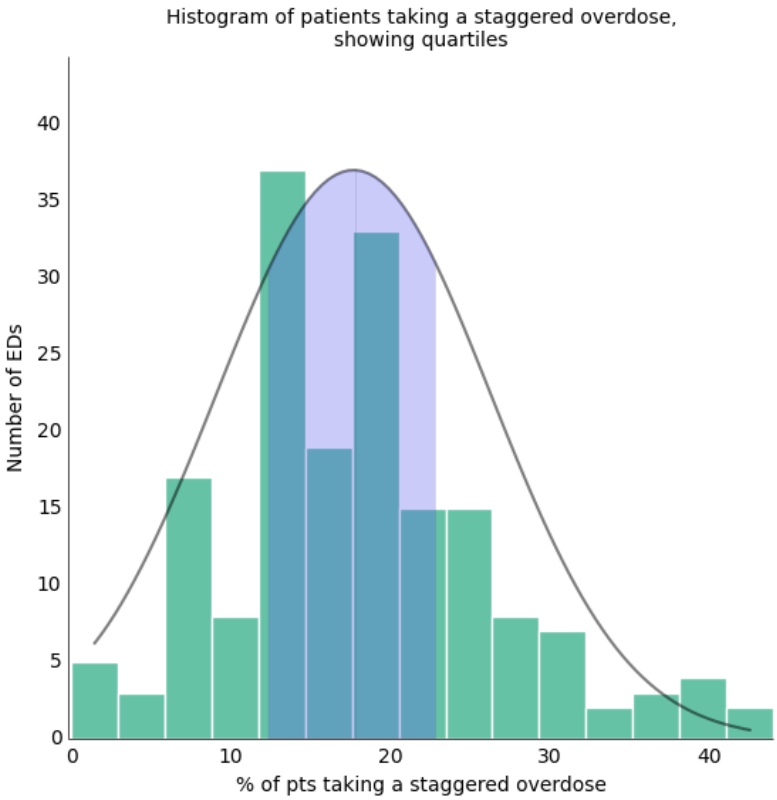


The percentage of patients presenting within 24 hours of ingestion ranged from 14% to 88% between EDs. This group was 67% or more for half of the EDs.

Many of the patients arriving during this time are asymptomatic[2].

Trend charts of patients presenting within 8 and 24 hours of ingestion are not available as data was not collected prior to 2013.

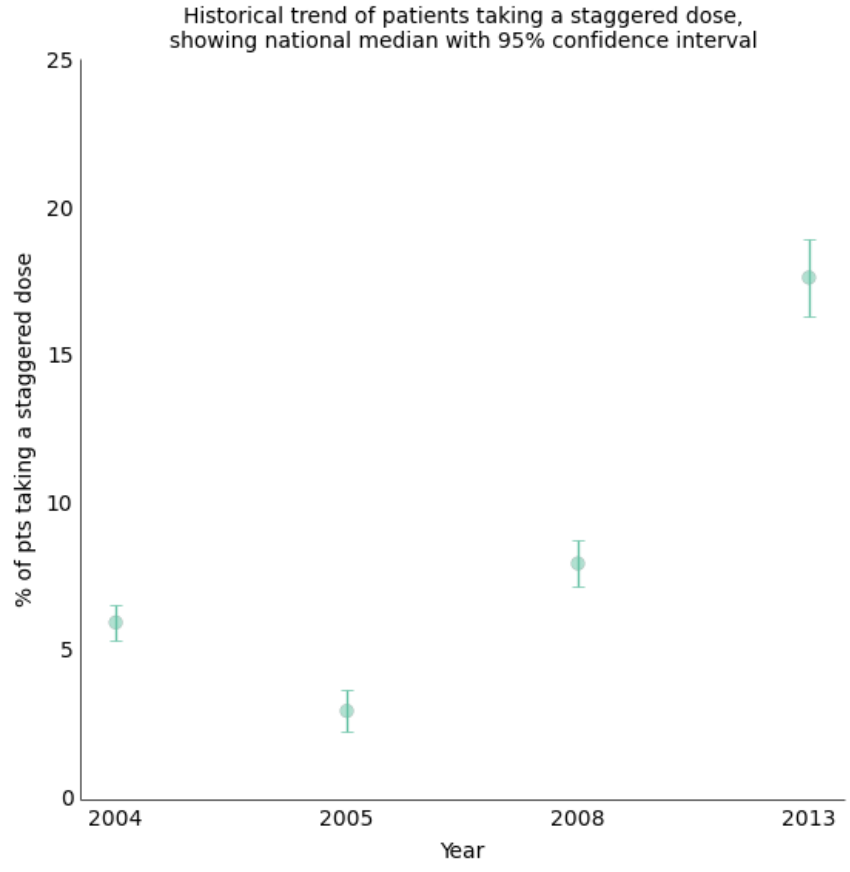
CHART 5: % patients who took a staggered overdose



The percentages of patients presenting with a staggered overdose varied between 0% to 44%.

A tenth of EDs had 30% or more patients in this group.

CHART 6: Trend chart of % staggered overdose - data from 2004, 2005, 2008 and 2013



The number of staggered overdoses has risen since 2005, and almost doubled since 2008.

Staggered overdoses are often the result of treating pain, and are linked with lower survival rates compared to single ingestion[3].

Presentation of patients – commentary and recommendations

This chart appears to show a marked increase in the number of 'staggered' overdose in 2013 compared to the previous audits. Such a sudden change, unless sustained in the future, is likely to be a "special cause variation". Such a variation could arise from a sudden change in reporting.

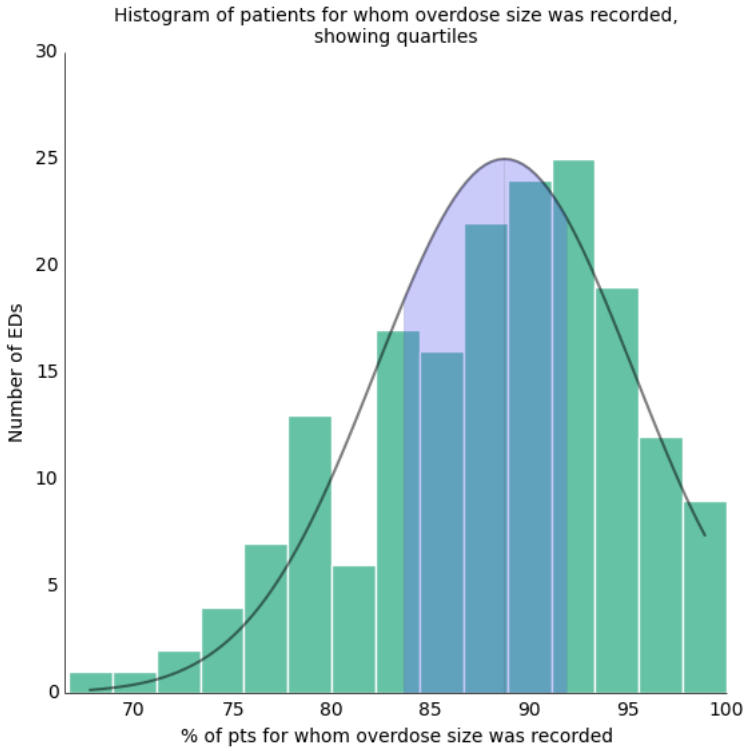
It is extremely likely that this increase could be attributed to the tighter definition of a 'staggered overdose' that was implemented in September 2012 by the MHRA.

As a result, more patients are being identified and treated. As this 'net' is now picking up 30% of patients in some EDs, a future study may wish to examine whether this marked increase in treatment given is resulting in a substantial increase in benefit.

SECTION 2: Assessment and Treatment

Overdose size

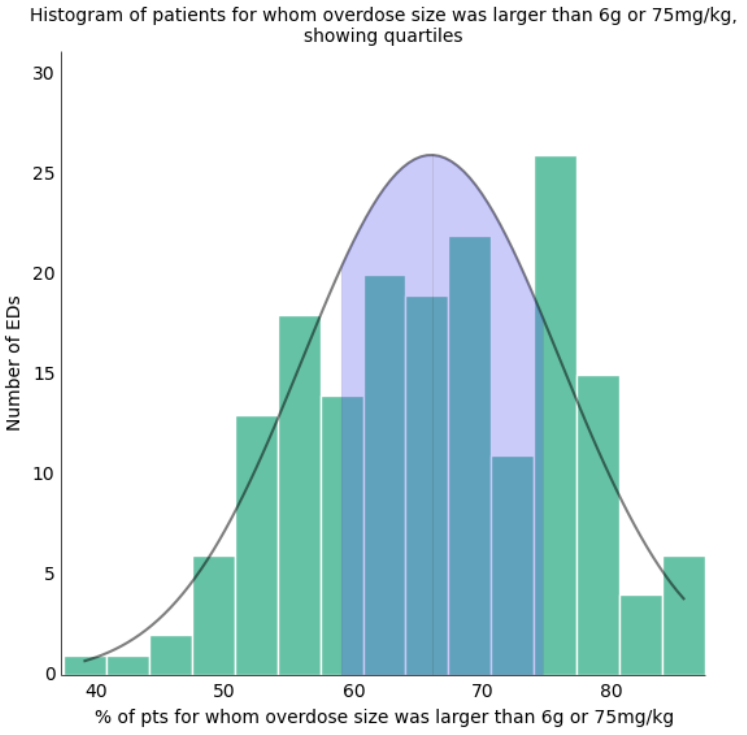
CHART 7: Overdose size recorded



The recording of overdose size varied from 67% to 100% patients between EDs, with a median of 89%.

5 EDs noted overdose size for all of the cases submitted.

CHART 8: Overdose size more than 6g or 75



The minimum and maximum percentages of patients presenting with a large overdose were 38% and 87%, with a median figure of 66%.

Overdose size - commentary and recommendations

Overdose size is sometimes difficult to ascertain accurately.

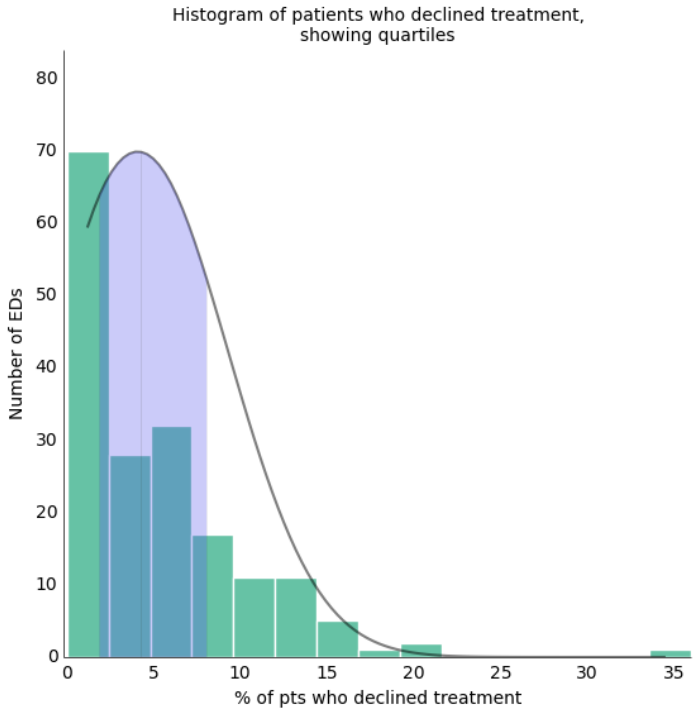
Treatment dose and time is determined by patient weight and plasma levels, so overdose size is not used clinically and therefore may not be collected as accurately.

All EDs should ensure a plasma test is performed if unable to ascertain overdose size. Having a treatment pathway proforma in place will assist with this.

Some examples of local guidance are shared on the CEM website.

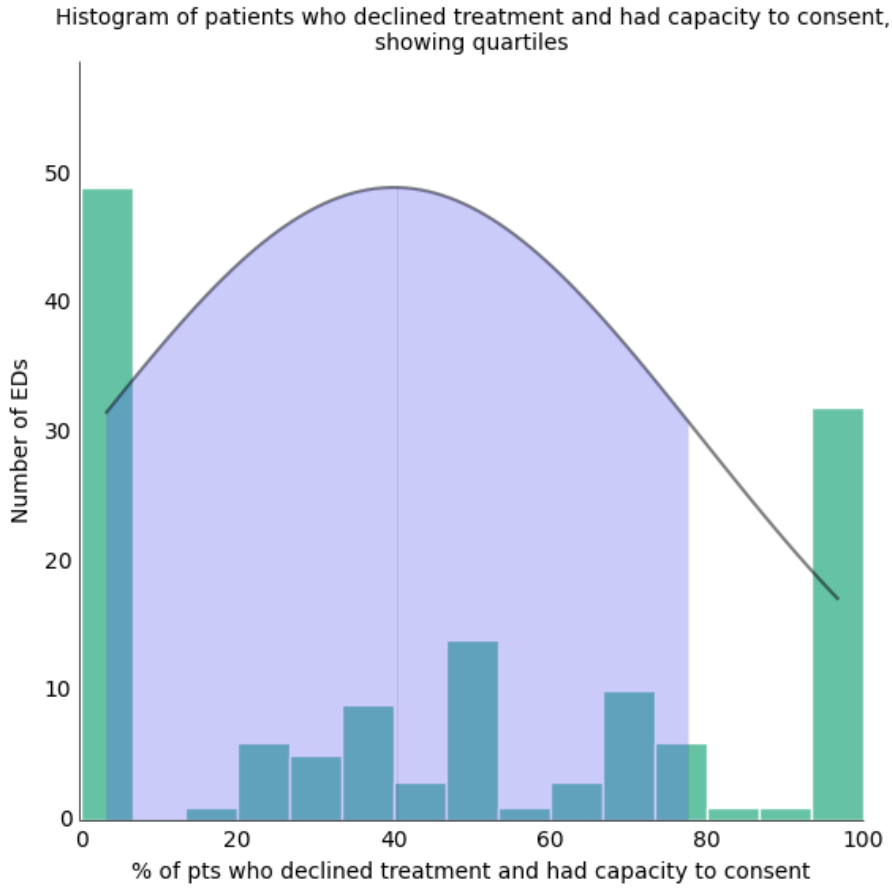
Declined treatment and capacity to consent

CHART 9: Patients who declined treatment



Patients who declined treatments ranged from 0% to 36%, with a median of 4%.

CHART 10: Of the patients who declined treatment, those who had documented capacity



Of the patients refusing treatment, 32 EDs (18%) recorded if the patient had or lacked capacity to consent in all cases. 49 (28%) EDs did not record the patient's mental capacity to consent.

Assessing capacity is important for deciding on whether to proceed with treatment, but the patient's wishes should also be respected[4].

Declined treatment and capacity to consent - commentary and recommendations

This is an important issue that was a good standard to audit, and based on this performance will need re-auditing soon.

Whatever the clinical status of a patient, to decline treatment without capacity being recorded

- is clinically indefensible
- is legally indefensible

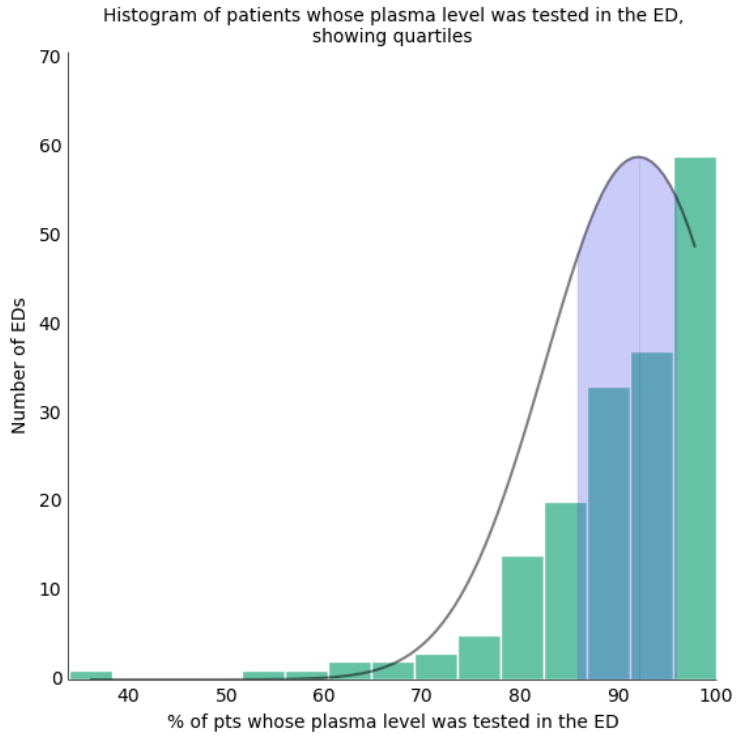
And therefore is a good candidate for being a 'never' event.

All EDs should ensure that capacity to consent is recorded in every case of declined treatment where possible.

Audit leads should review the documentation used to check that capacity can be simply recorded.

Plasma levels

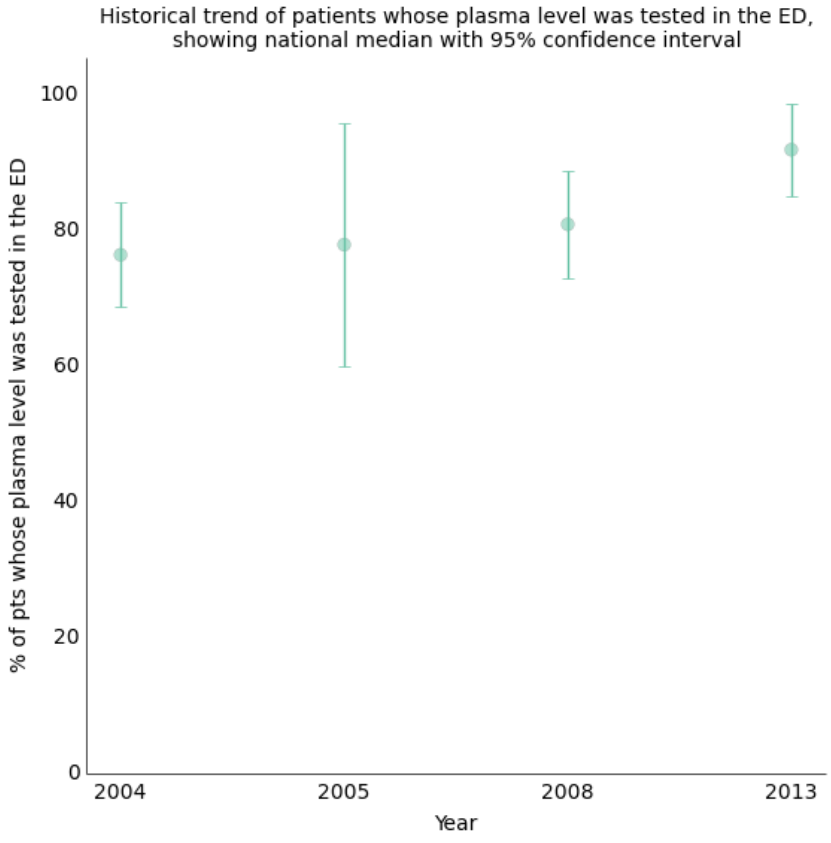
CHART 11: Plasma level testing – Q7



8% of EDs tested plasma levels in 100% of patients.

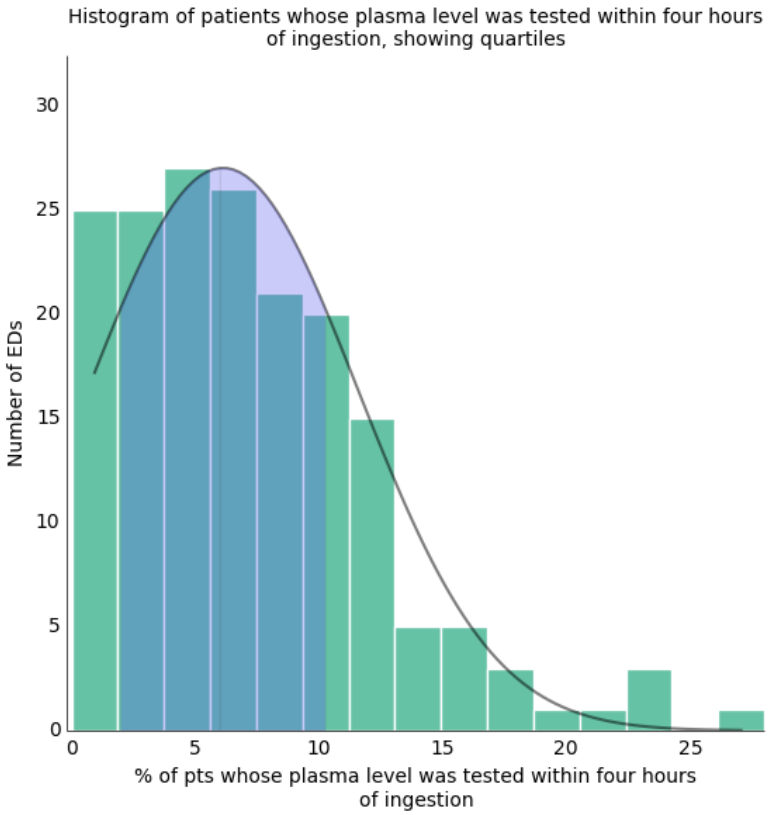
The lowest number in any ED was 38%.

CHART 12: Trend chart for plasma level testing – data from 2004, 2005, 2008 and 2013



The median figure for plasma level tests has risen over the years of the audit. However there are not enough data points to constitute a trend.

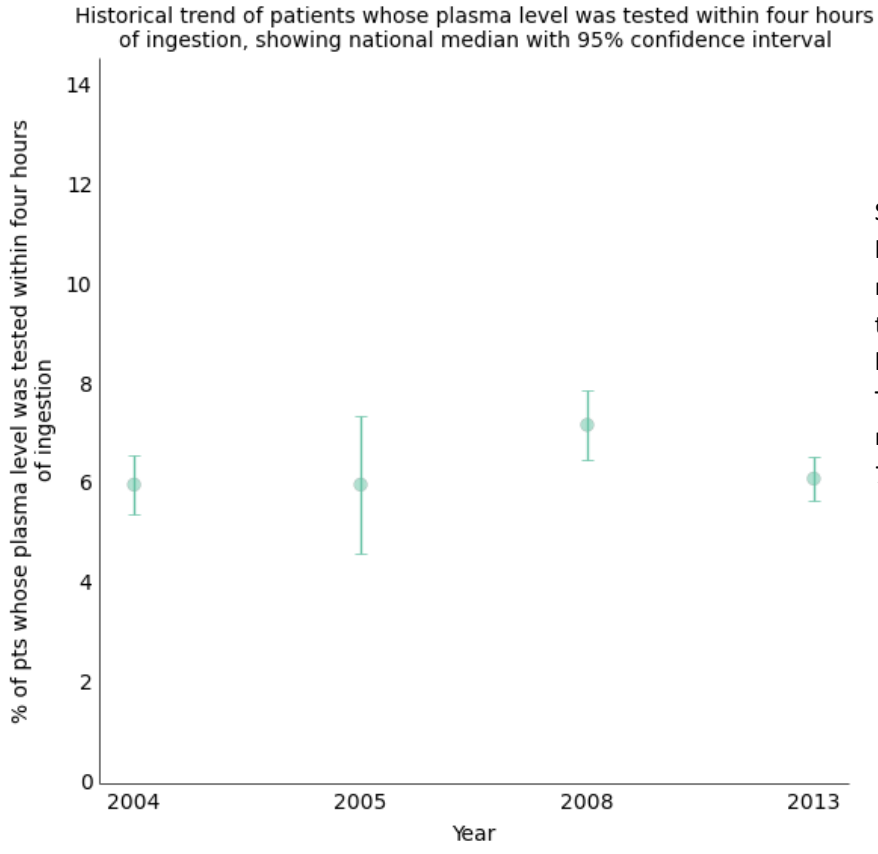
CHART 13: Where plasma level tested earlier than 4 hours after ingestion (excludes staggered doses)



The maximum percentage of patients who had plasma level tested earlier than 4 hours after ingestion was 28.

14% of EDs achieved the CEM standard of testing plasma levels in zero patients earlier than 4 hours after ingestion.

CHART 14: Trend chart of plasma level tested earlier than 4 hours after ingestion - data from 2004, 2005, 2008 and 2013



Since 2004, there has been no change in the number of plasma level tests earlier than 4 hours after ingestion. The median has remained between 6-7%.

Plasma level testing - commentary and recommendations

The trend chart for plasma testing shows a consistent improvement over recent years.

It may be that this improvement has been driven by clinical standards improving, however it is equally plausible that compliance with the four-hour care standard has led to:

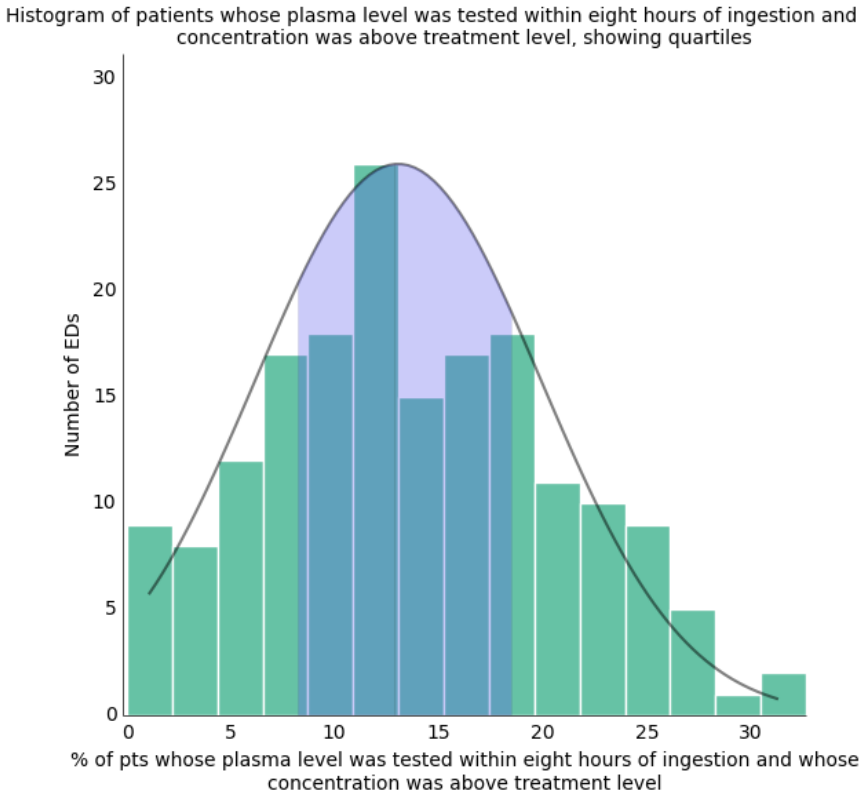
- increasing standardisation of caresets and
- increasing numbers of patients having early assessments and venesection.

The CEM standard of zero patients tested < 4 hours after ingestion may have to be refined as a negative paracetamol level in a patient one hour after overdose ingestion. This is a rational and useful test to perform to exclude paracetamol overdose and allow medical discharge.

EDs appearing above the upper quartile should review their practice and take measures to delay testing. Brief guidance notes could be provided as a reminder.

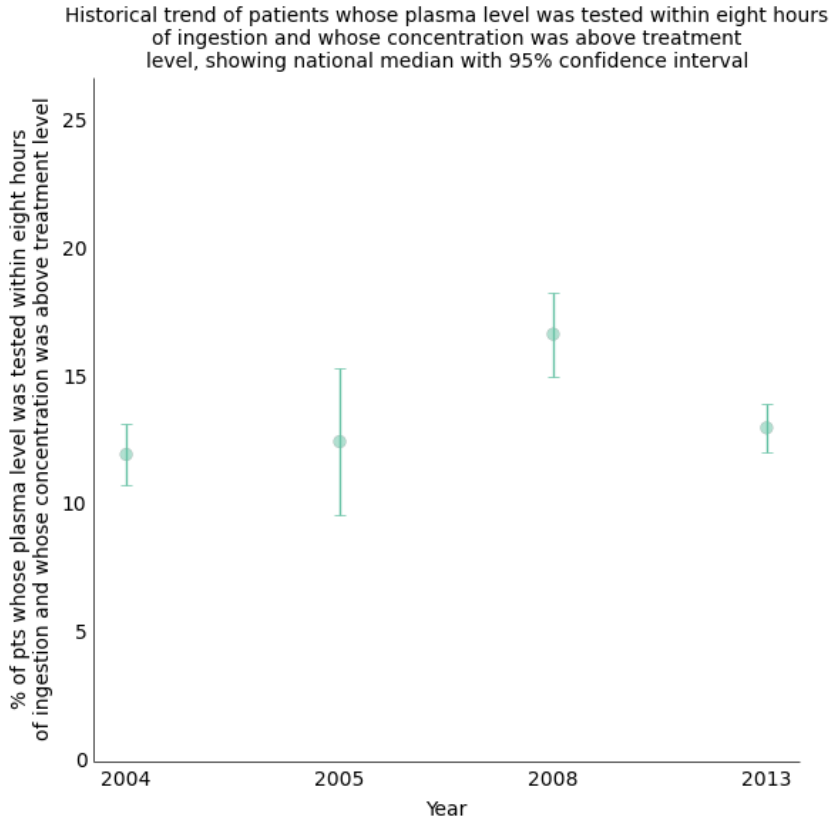
Less than 8 hours from ingestion

CHART 15: Plasma level tested within 8 hours and concentration above treatment level



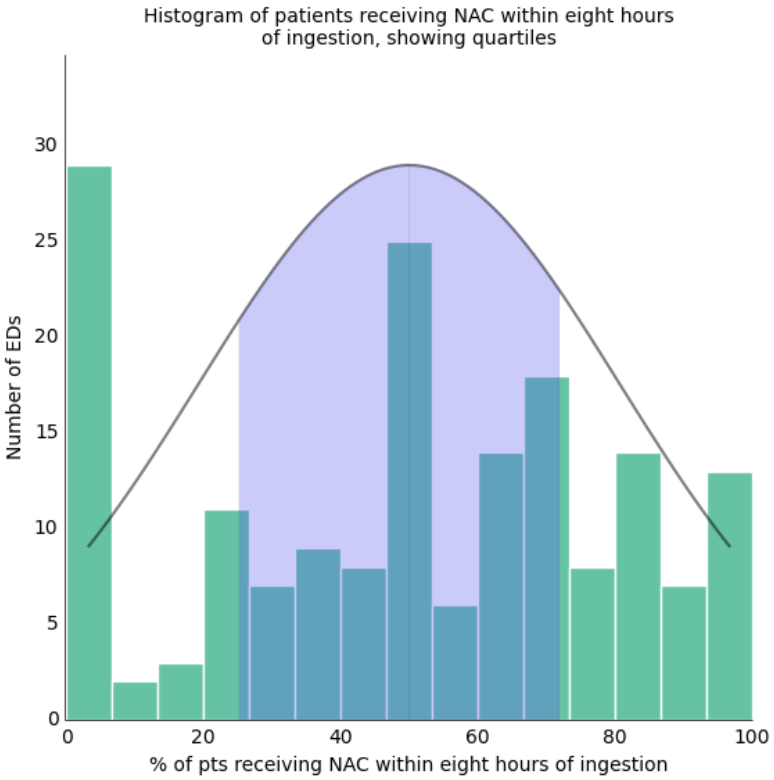
Patients whose plasma level was tested within 8 hours of ingestion and showed a concentration of paracetamol above treatment level ranged between 0%-33%.

CHART 16: Trend chart of plasma level tested within 8 hours and concentration above treatment level – data from 2004, 2005, 2008 and 2013]



Over the years, there was an increase in the median from 2004 to 2008, but this fell in 2013. These changes do not constitute a trend.

CHART 17: Patients receiving NAC within 8 hours of ingestion

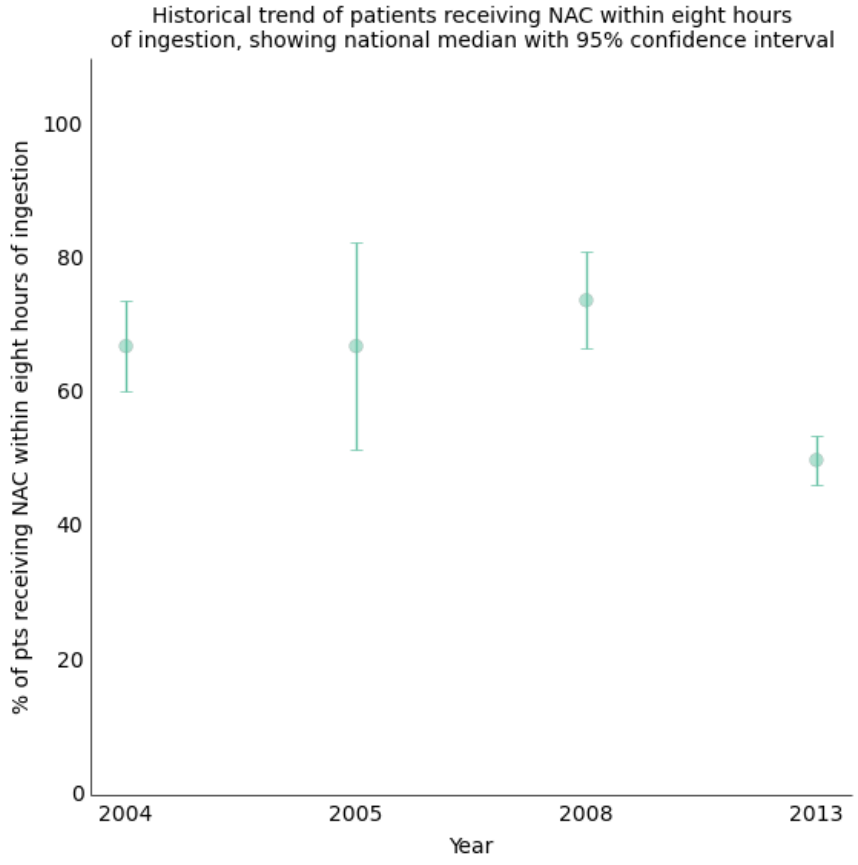


Of the patients whose plasma levels were tested and found to be eligible for treatment, 100% were given NAC treatment by 13 EDs within 8 hours of ingestion. 29 EDs did not administer NAC to any of these patients within this timeframe.

The CEM standard is for 100% of patients to be treated within 8 hours.

Treatment by N-acetylcysteine is usually effective if given within 8 hours of the overdose. The risk of serious side effects is low[5].

CHART 18: Trend chart of patients receiving NAC within 8 hours of ingestion – data from 2004, 2005, 2008 and 2013



Over time, the median for this cohort has remained similar for 2004 and 2005. It peaked at 73% in 2008 and is at its lowest at 50% in 2013. These changes do not constitute a trend.

Patient receiving NAC less than 8 hours from ingestion - commentary and recommendations

The most recent figures fall short of the recommended standards, and are poor overall.

There is a clear failure to treat eligible patients within 8 hours of overdose. We know that the liver stores of glutathione become depleted at approximately 8 hours and liver damage starts to occur, so this is a significant endpoint.

This audit does not tell us any change in the absolute number of patients being treated with NAC.

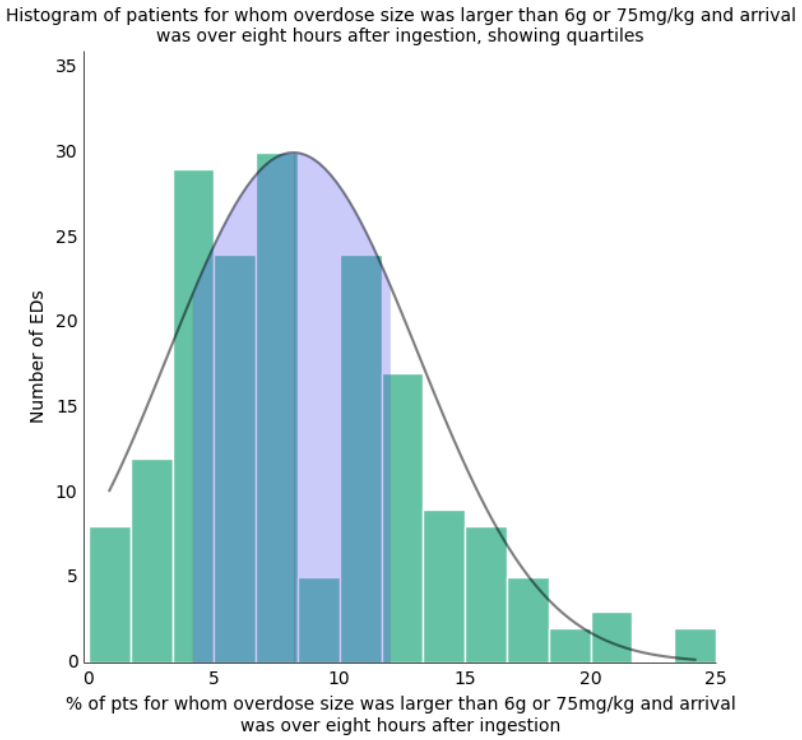
As we have demonstrated that the percentage being screened with plasma levels has increased, and we know the threshold for treatment has reduced, it is likely that the numbers of patients who have needed treatment has increased substantially. Treatment timings were often not recorded which led to omission of cases which may actually have fallen within this timeframe.

It would be good to repeat this audit soon.

All EDs should look at their processes and take action where necessary, particularly those in the lower quartile or below. A treatment pathway summary can assist with this.

Patients with large overdose presenting more than 8 hours from ingestion

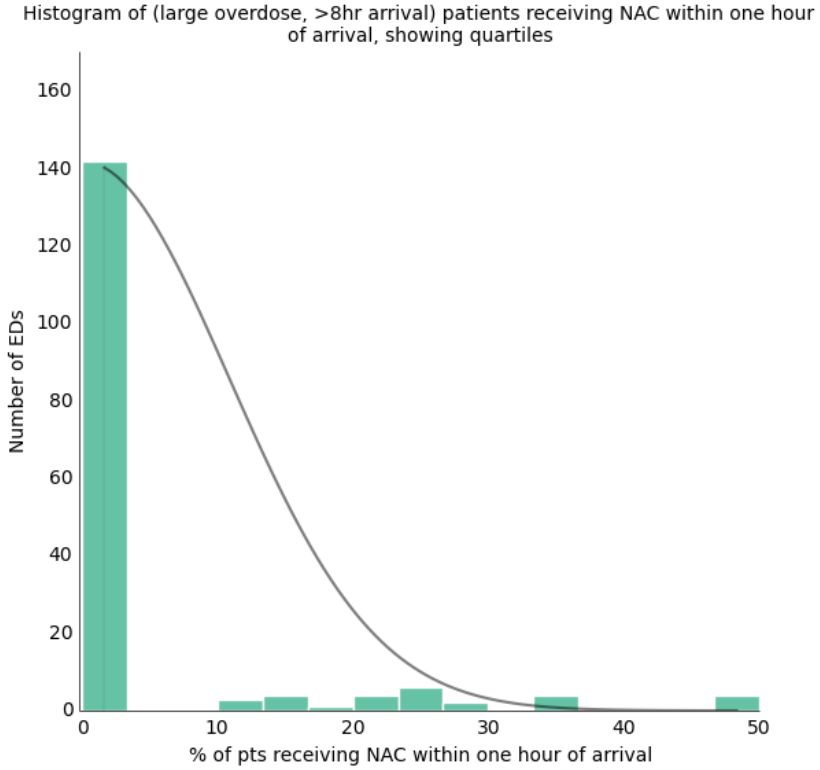
CHART 19: Patients for whom overdose >6g (or 75mg/kg), presenting over 8 hours since ingestion



The maximum number for any ED within this cohort was 25%. The minimum was 0% in 8 EDs.

It is not possible to compare results from earlier audits as a large overdose was previously defined as over 12g.

CHART 20: Patients (large overdose presenting after 8 hours ingestion) who received N-acetylcysteine (NAC) within 1 hour of arrival



Of this cohort, those who were treated with NAC within 1 hour of arrival varied from 0% - 50% between EDS.

80% of EDs did not administer treatment to any patients within 1 hour.

None of the EDs met the CEM standard of 100%.

Patients presenting after 8 hours ingestion with large overdose who received N-acetylcysteine within 1 hour of arrival – commentary and recommendations

Again, these figures are far lower than anticipated, with **no** EDs meeting the standard.

It is possible that the target is being met in some hospitals, but that the time of administration is not accurately recorded.

At this point, we need to consider:

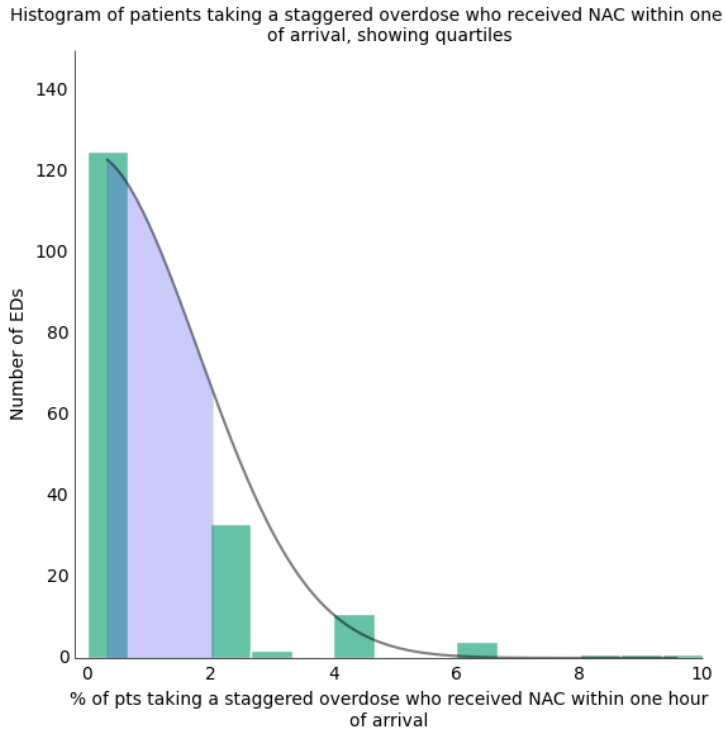
- Is the target the correct target to have?
- Is the target rooted in sound pathophysiology?
- Is the target realistic?
- Is the target achievable?

If the answer is 'yes' then maybe there is a need for some pilot study work to demonstrate that by streamlining the process e.g. integrating into initial assessment, compliance with this standard is feasible.

All EDs should assess the reasons for their scores, and take action where necessary - particularly those with a score equal to or below the median.

Staggered overdoses

CHART 21: Staggered overdoses receiving NAC within 1 hour of arrival



Up to 10% of patients presenting with a staggered overdose were treated with NAC within 1 hour, with the majority of EDs treating 0% within 1 hour.

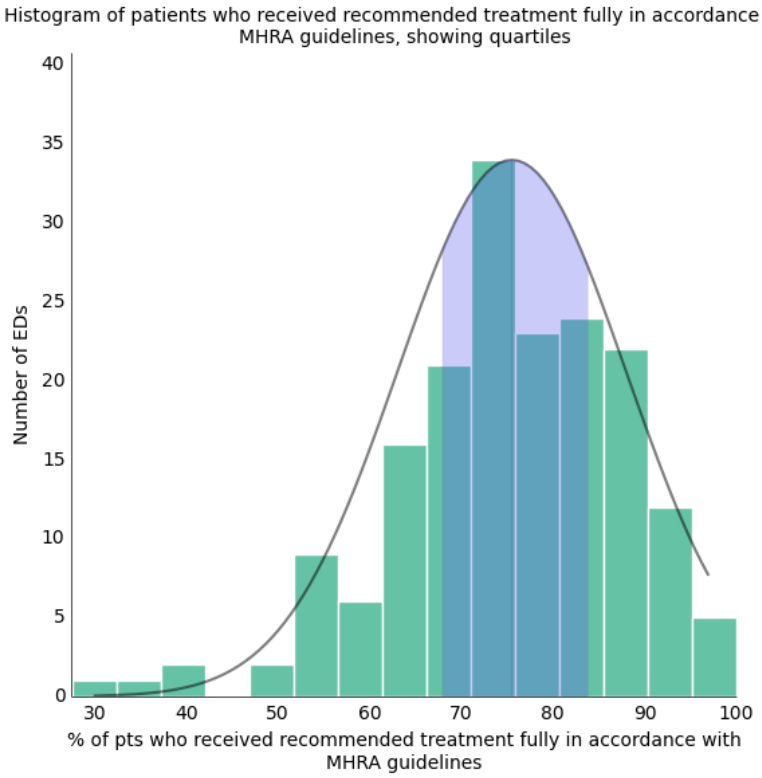
None of the EDs met the CEM standard of 100%.

Staggered overdoses – commentary

See comments on page 22 regarding patients presenting >8 hours with large overdose.

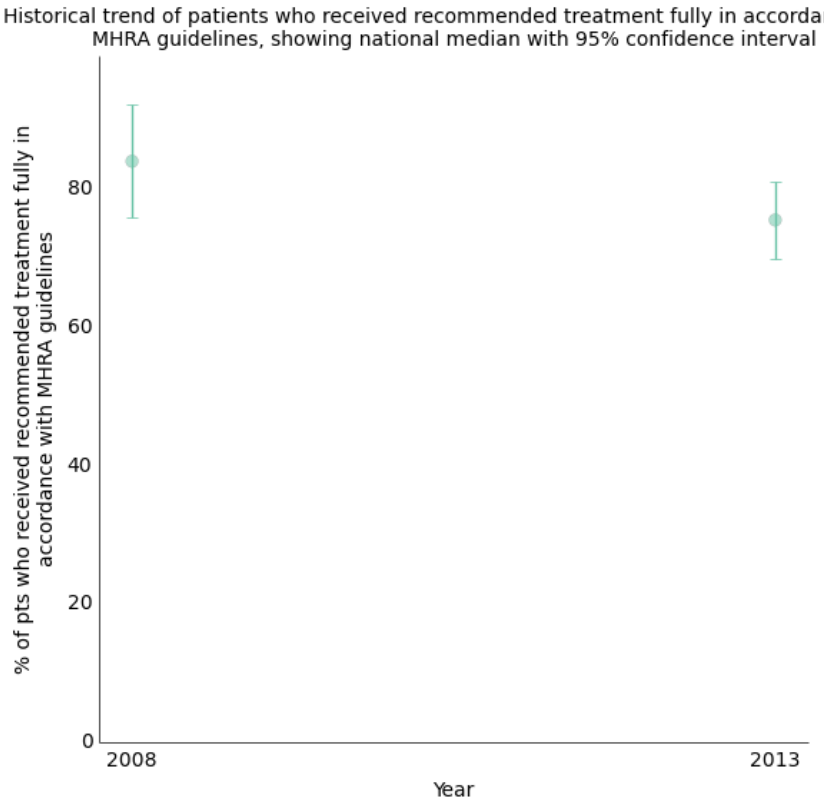
SECTION 3: Compliance with MHRA guidance

CHART 22: Compliance of treatment with MHRA guidelines



Only 1 ED out of 178 met the CEM standard of being 100% compliant with MHRA treatment guidelines.

CHART 23: Trend chart of compliance of treatment with MHRA guidelines - data from 2008 and 2013



A slight decrease in compliance with MHRA guidelines was observed between 2008 and 2013.

Please note that the results for 2008 and 2013 are not directly comparable due to the change in guidelines. The 2008 compliance figures relate to the guidelines in place at the time.

Compliance with MHRA guidance - commentary and recommendations

The average compliance with MHRA guidance was low overall at 75% with regard to the CEM recommended standard of 100% patients being treated as advised.

Poor or incomplete data records will produce a lower score.

However it is probable that most EDs are not meeting the targets. As raised previously, it needs to be considered whether the target is realistic.

EDs with scoring below the median should investigate their processes, and take steps to improve their performance.

All EDs should look at improving the data entered in patient records, particularly with the recording of treatment administration times. The use of a structured proforma may support this.

SUMMARY OF RECOMMENDATIONS

- All Emergency Department clinicians should carry out a plasma test if unable to ascertain overdose size. Having a treatment pathway proforma in place will assist with this.
- All Emergency Department clinicians should ensure that capacity to consent is recorded in every case of declined treatment where possible. Audit leads should review documentation to ensure that capacity can be simply recorded.
- Emergency Departments appearing above the upper quartile for plasma level tests taken earlier than 4 hours after ingestion should review their practice, and delay testing. Brief guidance notes could be provided as a reminder.
- All Emergency Departments, particularly those falling below the lower quartile, should aim to treat patients with N-acetylcysteine within 8 hours of ingestion. A treatment pathway summary can assist with this.
- Patients presenting after 8 hours ingestion with a toxic (large or staggered) overdose who received N-acetylcysteine within 1 hour of arrival: all Emergency Departments should assess the reasons for their scores, and take action where necessary - particularly those with a score equal to or below the median.
- Compliance with MHRA guidelines: Emergency Departments performing below the median should investigate their processes, and take steps to improve their performance.
- All audit leads should look at improving the detail and accuracy of data entered in patient records. A structured proforma may support this.

Useful resources

Examples of local guidance, treatment pathways and proformas can be found under the 'Local Guidelines' section of the CEM website:

- Paracetamol poisoning proforma to guide ED management of oral ingestions in adults (Leicester Royal Infirmary, 2012)
- Paracetamol poisioning proforma – post NAC (Leicester Royal Infirmary, 2012)

References

Paracetamol overdose: new guidance on treatment with intravenous acetylcysteine (MHRA, September 2012)

CEM Clinical Standards (College of Emergency Medicine, August 2014)

Paracetamol overdose: new guidance on the use of intravenous acetylcysteine (College of Emergency Medicine, 2012)

[1]Yeates PJA, Thomas SHL. Effectiveness of delayed activated charcoal administration in simulated paracetamol (acetaminophen) overdose. British Journal of Clinical Pharmacology. Jan 2000; 49(1): 11–14.

[2]Heard K, Dart R. Acetaminophen (paracetamol) poisoning in adults: Treatment (Uptodate, Oct 2013)

[3]Craig D, Bates C, Davidson J, Martin K, Hayes P and Simpson K. Staggered overdose pattern and delay to hospital presentation are associated with adverse outcomes following paracetamol-induced hepatotoxicity. British Journal of Clinical Pharmacology, Volume 73, Issue 2, pages 285–294, February 2012

[4]Self-harm: Summary of management and treatment (NICE, July 2004)

[5]Simplification of the treatment of paracetamol overdose: public and patient summary (MHRA September 2012)

Thank you for taking part in this audit. We hope that you find the results helpful.

However, should you have any queries about the report please e-mail audit@collemergencymed.ac.uk or phone 020 7400 6108

Details of the CEM Clinical Audit Programme can be found under the clinical audit section of the CEM website at www.collemergencymed.ac.uk.