

Illegibility of drug ampoule labels

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Complaints about the difficulty in reading drug ampoule labels are common in both published reports¹ and casual conversation. By contrast the Medicines Control Agency informed us: "The Medicines (Labelling) Regulations of 1976 as amended requires them [medicine labels] to be clear, legible and readily discernible so as to be easily read ... under normal conditions of purchase or use." We decided to investigate the position.

Methods and results

Thirty three ampoules were examined. We measured the height (of a capital letter or "riser" such as the letter l) and length of a drug's generic and proprietary names and dose using callipers with a vernier scale. The maximum available length for writing and the colours of the type and background were also recorded (table).

On ampoules of less than 2 ml six of the seven generic drugs had names written in type that was less than 1.6 mm high (size of entries in the telephone directory) while two were less than 1.2 mm high (size of share prices in *The Times*). Five of the six proprietary drugs had generic names less than 1.2 mm high; four of the six had larger proprietary names.

We inspected 10 ampoules of 2 ml or 2.5 ml. The two generic drugs had names between 2.1 mm (size of type on the front page of *The Times*) and 1.6 mm. Six of the eight proprietary drugs had a generic name less than 1.2 mm high; five had quite large proprietary names (greater than 2.1 mm), yet one was less than 1.2 mm.

Inexplicably some larger ampoules used small type. Dosage was in smaller type than the proprietary name

in 18 of 22 ampoules and was most commonly the same size as generic names.

Contrast was poor when typeface and background were both dark or both light, when print was very thin, or when details on the other side of the ampoule obscured the writing on a clear label. Nearly half of the ampoules (14) were considered to have poor contrast.

In nine of the 13 ampoules of less than 2 ml the ratio of generic name length to available length was less than or equalled 0.5 (average ratio 0.46).

Comment

Factors affecting the ability to read an ampoule include the size, boldness and contrast of the type, the visual acuity and power of accommodation of the reader, and the illumination. Untoward anaesthetic incidents often include drug errors,^{2,3} which clearer labelling might prevent. Two frequent, potentially lethal, drug errors concern potassium chloride⁴ and adrenaline. Our samples of both were particularly poorly labelled. The adrenaline typeface, on clear glass with very confusing writing behind, equalled the smallest we examined. The potassium of potassium chloride was just 1.2 mm and occupied only a quarter of the available length.

Most doctors would agree that the most important of all the data on an ampoule is the generic name and dose and that the proprietary name is less important. It is worrying that these were so often small and unclear, despite additional usable space. Surely these findings conflict with the guidelines of the Medicines Control Agency.

Although final responsibility for checking ampoules is the administering clinician's, ampoule labels should be large and bold with good contrast to make this as easy as possible—especially for older doctors.

In the United States standards were set in 1983 and revised in 1989.⁵ Seventeen of our 22 ampoules of 2 ml

Data on 33 ampoule labels. Drug names are written as they appear on the labels

Name	Type height (mm)			Length (mm)			Colour				Manufacturer	
	Generic	Proprietary	Ampoule size (ml)	Generic	Proprietary	Dose	Generic	Proprietary	Available	Print		Background
ADRENALINE			1	1.0		1.0	8.0		20.0	Black	Clear*	Antigen
ATROPINE 1.2 mg			1	1.4		1.1	8.5		18.0	Black	Clear*	Antigen
ATROPINE 600 µg			1	1.2		1.2	6.8		19.0	Thin black	Clear*	Phoenix
EPHEDRINE			1	2.0		1.9	12.0		15.0	Black	White	Macarthy
MORPHINE			1	1.1		1.1	7.1		17.5	Black	White	Evans
NEOSTIGMINE			1	1.2		1.2	10.0		20.0	White	Brown	Antigen
PETHIDINE 50 mg			1	1.3		1.0	10.3		20.0	Red	Clear*	CP
Betamethasone	Betnesol		1	1.0	2.0	1.0	11.0	9.6	20.0	Black	Clear*	Glaxo
Glycopyrrolate-neostigmine	Robinul-Neostigmine		1	1.1	1.2	1.1	8.0 and 17.1	5.8 and 10.0	19.0	White	Pale green†‡	A H Robins
Hydrocortisone 100 mg	Solu-Cortef		1	1.0	2.0	2.0	9.3	14.5	50.0	Black and red	White	Upjohn
Naloxone	NARCAN		1	1.0	1.4	1.4‡	5.0	7.0	20.0	Black	Brown†	Du Pont
PAPAVERETUM	OMNOPON		1	1.9	2.5	2.5	14.3	13.0	18.6	Red	Clear*	Roche
Tubocurarine	Jexin		1.5	1.1	2.5	1.5	12.0	7.9	34.0	Red	Clear	Duncan and Flocc
LIGNOCAINE			2	1.6		1.6	12.0		25.0	Black	Clear*	Phoenix
PETHIDINE 100 mg			2	1.8		1.5	14.0		25.0	Red	Clear*	CP
ALCURATIONIUM	ALLOFERIN		2	1.8	2.8	1.2	13.0	13.0	18.0	Black	Dark brown†	Roche
Alfentanil	Rapifen		2	1.0	2.5	1.0	5.8	12.0	21.0	Dark grey	Cream	Janssen
Diazepam	Diazemuls		2	1.1	1.8	1.1	7.5	10.0	25.0	Black	Clear	Dumex
Droperidol	Droleptan		2	1.0	2.5	1.0	6.2	15.4	21.0	Dark grey	Pale green†	Janssen
Fentanyl	Sublimaze		2	1.0	2.5	1.0	4.4	14.3	21.0	Dark grey	Pink	Janssen
Gentamicin	Cidomycin		2	1.0	1.0	1.0	8.4	9.4	20.0	Blue	White	Roussel
Suxamethonium	Anectine		2	1.7	1.7	1.7	14.0	7.2	18.0	Black	Yellow	Calmic
Atracurium	Tracrium		2.5	1.1	2.1	1.1	9.6	10.0	18.0	Black	White	Calmic
GLYCOPYRROLATE	ROBINUL		3	1.6	2.5	1.6	13.0	20.0	30.0	Pale green	Clear†	A H Robins
POTASSIUM CHLORIDE			5	1.2		1.2	19.6 and 9.0		35.0 and 35.0	Black	Clear*	Phoenix
WATER FOR INJECTIONS			5	1.7			14.0		35.0	Black	Clear	Antigen
DOXAPRAM	DOPRAM		5	1.1	2.5	1.1	8.5	13.4	27.0	Pale blue	White/clear‡	A H Robins
Metoprolol	Betaloc		5	1.8	3.4	1.8	14.5	14.5	35.0	Black	Clear	Astra
MIDAZOLAM	HYPNOVEL		5	1.8	2.7	2.7	11.0	13.0	18.0	Red	Clear	Roche
Vecuronium	Norcuron		5	1.6	2.5	2.0	14.0	13.0	30.0	Black	White	Organon
Bupivacaine	Marcain		10	1.4	3.0	1.4	12.0	12.5	50.0	Black	Clear	Astra
Etomidate	Hypnomidate		10	1.5	2.6	1.5	11.0	20.0	30.0	Dark grey	Pale blue	Janssen
Propofol	Diprivan		20	2.5	5.6	2.5	10.5	37.5	65.0	Dark green	Clear-white	ICI

*Poor contrast between colour of print and background.

†Very poor contrast between colour of print and background.

‡NARCAN quantity (400) is 1.4 mm but unit (µg/ml) is only 0.6 mm.

§Dopram is on white background, remaining type is on clear background.

¶Background for generic name clear.

or less failed to meet this standard's requirement that generic names and dose should be 1.5 mm or more and 10 out of 11 ampoules of greater than 2 ml failed to meet its minimum of 2.5 mm. We believe that a British standard for size and clarity of drug ampoule labels is urgently required.

1 Ananthanaryan C. Similarity between ephedrine and atropine ampoules. *Regional Anesthesia* 1991;16:189-90.

- 2 Ferner RE. Errors in prescribing and giving drugs. *Journal of the Medical Defence Union* 1992;No3:60-3.
 3 Medico-pharmaceutical Forum. *Dangerous mistakes in drug administration*. London: Royal Society of Medicine, 1979.
 4 Hill G. The KCI killer. *Journal of the Medical Defence Union* 1990 Spring:10-1.
 5 American Society for Testing and Materials. *D4267-89 Standard specifications for labels for small-volume (100 ml or less) parenteral drug containers*. Philadelphia: ASTM, 1989. (Available from 1916 Race Street, Philadelphia, PA 19103, USA, and from American Technical Publishers, 27-29 Knowl Piece, Wilbury Way, Hitchin, Herts SG4 0SX.)

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Value of pulsus paradoxus in assessing acute severe asthma

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The "pulsus paradoxus" of acute severe asthma is an exaggeration of the normal fall in systolic blood pressure during inspiration. Its size is thought to relate to the severity of the attack.¹⁻³ Disagreement exists about how often it is present and the level which should be considered abnormal.¹⁻³ We describe observations of pulsus paradoxus and other indicators of severity of attack recorded in a national study of inpatient asthma.

Subjects, methods, and results

We studied all patients admitted to 36 British hospitals with acute severe asthma in the two months before publication of the 1990 asthma guidelines.⁴ We collected data from case records using a structured questionnaire that included measurements made on admission (heart rate, respiratory rate, pulsus paradoxus, and peak expiratory flow) and treatment given (including need for intensive care and intermittent positive pressure ventilation). Statistical analyses were by analysis of variance or χ^2 tests as appropriate.

In all, 766 patients were admitted with asthma (median age 41 (range 18-91 years, 61% female). Heart rate was recorded in 759 but significant tachycardia (> 110 beats/min) was found in only 253. Peak expiratory flow was recorded in 663 patients, of whom 477 had a value of 200 l/min or less. Respiratory rate was recorded in 442 patients and pulsus paradoxus in 314. Paradox of 10 mm Hg or greater was present in 142 patients. Both peak expiratory flow and paradox were recorded in 290 patients, who were otherwise comparable with the whole cohort. Paradox of 10 mm Hg or greater was found in 21 of 68 patients with a peak expiratory flow greater than 200 l/min, 62 of 139 with a flow of 100-200 l/min and in 53 of 83 with a flow less than 100 l/min. When systolic paradox was high

(≥ 25 mm Hg), peak expiratory flow was always low (table). Patients with a paradox of 10-24 mm Hg were not significantly more likely to have a low peak expiratory flow than patients with no paradox.

Fourteen patients had paradox greater than 10 mm Hg as the only abnormal feature on admission. Most had a peak expiratory flow of 200-250 l/min. None of these 14 required intensive care or intermittent positive pressure ventilation.

Comment

Our data confirm the reported association between worsening obstruction of airflow and increasing incidence of pulsus paradoxus. However, the association is weak; the sign was not found in a third of patients with the severest obstruction and was found in a third of those with peak flow above 200 l/min. Only severe paradox (≥ 25 mm Hg) was a reliable indicator of severe asthma.

The large swings in intrathoracic pressure in acute severe asthma are thought to cause the pulsus paradoxus. But the size of the pressure swing differs depending on patients' respiratory muscle geometry, fatigue, and level of respiratory drive. For example, severely ill patients are unable to generate high pressures and may not show paradox. Alternatively, the poor association may simply reflect the circumstances in which the measurement is made. When assessing a distressed tachypnoeic patient in a busy emergency department it is not easy to interpret blood pressure swings on a sphygmomanometer. This may explain why the association between peak flow and paradox is strong only when the paradox is high.

In summary, systemic paradox is a poor guide to the severity of acute asthma in individual patients. It compares poorly with the measurement of peak flow, which relates directly to airway calibre. Pulsus paradoxus should be abandoned as an indicator of severity of attack, as endorsed by the revised British Thoracic Society guidelines.⁵

Participating physicians: Drs D Bell, A Brewis, C Bucknall, I Campbell, H Clague, K Connolly, I Coutts, G Crompton, J Delaney, C Evans, A Ferguson, J Friend, H Gribbin, B Harrison, A Henderson, Professor S Holgate, Drs S Kenwright, J MacFarlane, M Mathiah, M Morgan, P Ormerod, C Pantin, M Partridge, S Pearce, M Pearson, M Phillips, M Rudolf, D Stableforth, J Stark, C Swinburn, G Thomas, A Wardman, R White, S Williams, T Williams, and R Wolstenholme.

Relation between pulsus paradoxus and other indicators of severity of asthma. Values are numbers (percentages) of patients

	Paradox recorded (mm Hg)			Total	Paradox not recorded
	>25	10-24	<10		
Peak expiratory flow < 200 l/min	36/36 (100)	79/100 (79)	107/154 (69)	222/290 (77)	259/373 (69) [†]
Respiratory rate > 25 breaths/min	22/27 (81)	50/74 (68)	64/109 (59)	136/210 (65)	109/232 (47)
Heart rate > 110 beats/min	24/38 (63)	37/104 (36)	42/171 (25)	103/313 (33)	111/446 (25)
Required intensive care	2/2 (100)	4/8 (50)	4/5 (80)	10/15 (67)	11/17 (65)

* $\chi^2 = 2.4$, $p = 0.13$ compared with patients with paradox of 10-24 mm Hg.

[†] $\chi^2 = 3.8$, $p = 0.51$ compared with patients who had paradox recorded.

- 1 Knowles GK, Clark TJH. Pulsus paradoxus as a valuable sign indicating severity of asthma. *Lancet* 1973;iii:1356-9.
 2 Edelson JD, Rebeck AS. The clinical assessment of severe asthma. *Arch Intern Med* 1985;145:321-3.
 3 Cochrane GM. Pathophysiology. In: Brewis RAL, Gibson GJ, Geddes DM, eds. *Respiratory medicine*. London: Baillière Tindall, 1990:614.
 4 British Thoracic Society, Royal College of Physicians of London, King's Fund Centre, National Asthma Campaign. Guidelines for management of asthma in adults—acute severe asthma. *BMJ* 1990;301:797-800.
 5 Guidelines on the management of asthma. *Thorax* 1993;48(suppl):S1-24.

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