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ADMINISTRATION SETS FOR INTRAVENOUS FLUIDS USED IN THE REPUBLIC OR IRELAND

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SUMMARY

Three types of administration sets for intravenous fluids currently used in the Republic of Ireland were examined. They were found to differ in almost all aspects of construction. Some of these differences affected their performance when attached to three types of plastic intravenous fluid containers frequently used in hospitals.

Braun sets were the only ones found capable of penetrating without difficulty the entry ports of all the containers. The closure piercing tips on both Travenol and Terumo sets were readily deformed, proving to be too weak for those container ports incorporating a thick rubber closure. Such deformation must make set attachment and changing of containers difficult on the ward and must increase the risk of touch contamination of connection sites.

The drop counter delivery of individual sets was found to be variable and a mean of 17 drops per ml suggested as being realistic.

The screw clamp flow regulator fitted to the Travenol set proved to be very difficult to regulate and the sets fitted with roller clamps were preferred. These also were found to maintain better the flow rate of the i.v. fluid. All set types were similar in that they showed an intrabatch variation with regard to establishment and maintenance of the flow rate and in that they lost the greatest percentage in flow rate during the first 30 min after setting up. The Braun and Terumo sets lost 33 and 37 percent of the original flow rate, respectively, during this period, while Travenol sets lost 55 percent. These findings underline the fact that on the ward the flow rates should be checked frequently and readjusted accordingly.

One of the prerequisites of a flow control clamp is that it should be capable of controlling as required the flow of fluid passing through the set. It is obvious that the clamps currently fitted to the administration sets used in Ireland are unable to do this.

INTRODUCTION

The use of intravenous fluids has become an important aspect of patient care in hospitals where they are routinely infused by means of gravity-fed administration sets

(solution sets). These sets are plastic, cheap, disposable and available in adult and paediatric forms. They are imported into Ireland from a number of countries and are consequently of variable specifications. No additional specifications need to be compiled with in Ireland and the solution sets once registered by the Department of Health, are not subject to any further control. The body under whose jurisdiction they would fall for evaluation is the National Drugs Advisory Board. However, it cannot control the sets while empty because they are not classified as 'drugs', becoming so only when filled and attached to the patient. The solution sets available are thus of variable origin, specifications and design.

These differences between the sets could lead to the development of two major problems when they become connected to the currently used plastics intravenous fluid containers, which are also of variable origin, specification and design. Firstly, difficulties met while attaching the solution set to the plastic container could lead to excessive handling of the connection sites, which could result in microbial contamination of the intravenous fluid delivery system. Such 'touch' contamination has been reported with set-container combinations used in England (Newman et al., 1975) and the United States (Letcher et al., 1972; Poretz et al., 1974; Hanson and Shelley, 1974). The second problem is the maintenance of the desired flow rate of the intravenous fluid. It is recognized both in practice and under laboratory conditions that the flow rates of standard gravity-fed solution sets cannot be accurately maintained (Flack and Whyte, 1974; de Saintongne et al., 1974; Demoruelle et al., 1975). On the ward this can to some extent be overcome by frequently checking and readjusting the flow rate.

Although a variation in flow rate within wide limits appears to be tolerated for most cases of routine intravenous therapy (de Saintongne et al., 1974) it is important that a constant fluid flow rate is maintained for critically ill patients and those receiving such i.v. fluid additives as antibiotics (Plaut and Hayes, 1969); anticoagulants (Salzman et al., 1975), electrolytes, cancer chemotherapy agents (Coggin, 1973), lignocaine (Aps et al., 1975) and oxytocin (Hamlett, 1972) as well as hyperalimentation fluids (Dudrick and Rhoads, 1972; Johnson et al., 1975). At the present time such a constant flow rate can only be achieved by using in conjunction with the solution sets some sort of electromechanical device (Flack and Whyte, 1974; Salzman et al., 1975; Coggin, 1973; Hamlett, 1972; Monahan and Webb, 1972; Wright, 1975).

Objectives

Three types of commercially available solution sets were examined in order to determine:

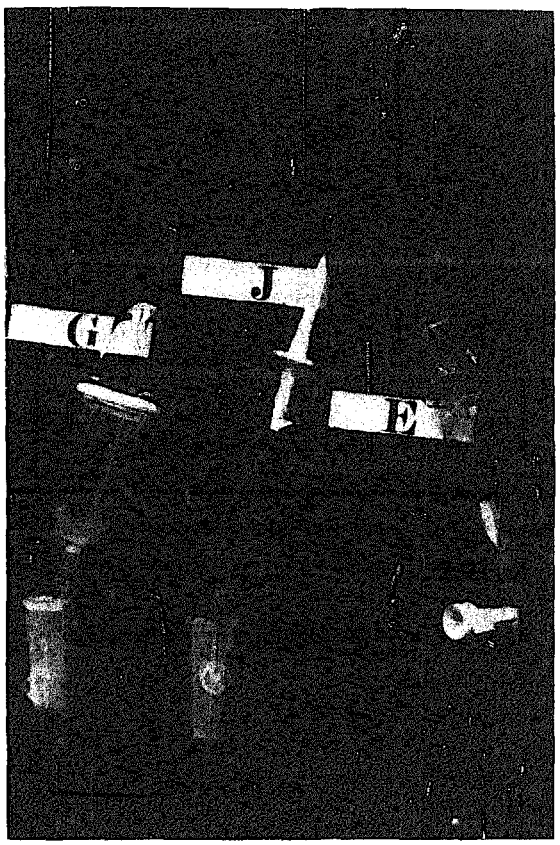
(i) how they differed from each other in construction;

(ii) if any difficulties were encountered when the sets were connected to the most commonly used types of plastics containers for i.v. infusion fluids; and

(iii) how exactly the sets maintained the flow rate initially established, when attached to the containers.

MATERIALS AND METHODS

The solution sets examined were (Fig. 1):



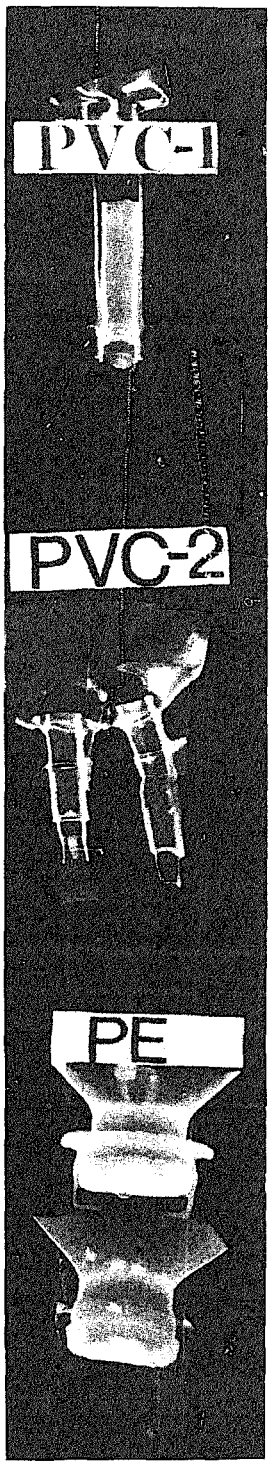


Fig. 1. Constructional features displayed by the administration sets for i.v. fluids examined (for identification see text).

Fig. 2. Longitudinal section through container entry ports showing construction (for identification see text).

(1) Administration Set for Intravenous Fluids manufactured by Baxter Division, Travenol Labs., Ltd. in England (Set E);

(2) Disposable Solution Administration Set manufactured by Jintan Terumo Co. Ltd. in Japan (Set J); and

(3) Intrafix for Infusion manufactured by B. Braun Melsungen in West Germany (Set G).

These sets were fitted with the two types of flow regulators currently used. Set E incorporated the screw clamp, where a pencil-shaped prong can be screwed in and out. Turning the screw alters the flow rate of the fluid by changing the pressure applied by the prong against the side of the tubing causing it to collapse and decrease the lumen size. Sets G and J were fitted with roller clamps which incorporate a compression wheel which rolls along an inclined plane to increasingly collapse the tubing, thereby decreasing the fluid flow.

The plastics, collapsible, intravenous fluid containers used for the evaluations were (Fig. 2):

(1) a semi-rigid, translucent polyethylene bottle (PE) manufactured for Antigen Ltd., Roscrea, Ireland by B. Braun Melsungen in West Germany. Here the administration set port and additive port are combined, consisting of a rubber closure (5 mm thick in bottles with metal caps and 3 mm thick in 'new' bottles with an all-plastic cap), separated from the contents by a puncturable plastic diaphragm;

(2) a flexible, transparent polyvinyl chloride bag (PVC-1) 'Steriflex' manufactured by Allen and Hanbury's Ltd. in England. Here the administration set port and additive port are also combined consisting of the plastic diaphragm and a rubber closure, 2 mm thick at the centre; and

(3) a flexible, transparent polyvinyl chloride bag (PVC-2), 'Viaflex' manufactured in England by Baxter Division, Travenol Labs. Ltd. Here the administration set port and additive port are separate. Both ports are separated from the contents by a plastic diaphragm but included in the additive port is a resealable rubber closure, 3.5 mm thick.

Attachment and flow rate determination

An adult, gravity-fed administration set for i.v. infusion shows the features illustrated in Fig. 3. Two solution sets from each manufacturer were examined for some of these constructional features. To study possible attachment difficulties and flow rate maintenance, 5 solution sets from each manufacturer were used. Each set was connected to one of the plastics containers filled with 1000 ml Sodium Chloride Injection (0.9% w/v) B.P. using the procedures recommended by the manufacturers. The container was then suspended from a long pole so that the vertical portion of the tubing was about 100 cm long. The flow regulator clamp was opened allowing just enough fluid through to flush air out of the set and then clamped shut. The flow rate, approximating a desired 50 drops per min was then established as quickly as possible. Drops were visually counted for exactly 1 min. Flow rates were recorded every 30 min over a 7-h period. No cannulae were attached at the distal ends of the sets. The liquid dripping from the needle adaptor was collected in a beaker placed on a balance, enabling one to record the weight of fluid dripped out. Atmospheric pressure was maintained at the adapter exit.

Analysis of variance was used to analyzed all flow rate data.

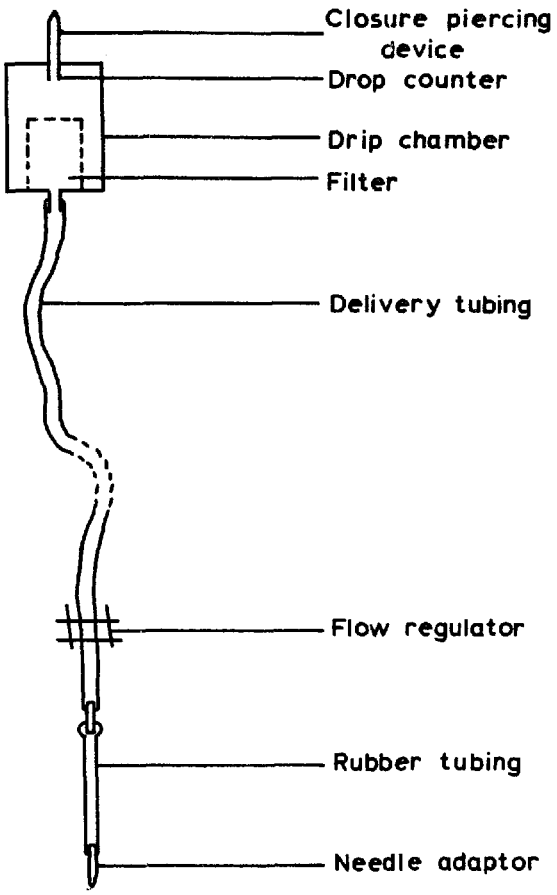


Fig. 3. Schematic drawing of a gravity-fed adult solution set.

Supplementary experiments

Extra flow rate determinations. The procedures outlined above were used. In the first experiment the flow rate was readjusted after half an hour to approximately the original rate, so that the container drained more rapidly and any 'emptying effects' on the flow rate could be observed. Three sets from each manufacturer were used. In a second experiment an Intrafix-Air Infusion set (manufactured in West Germany by B. Braun Melsungen) was connected to a polyethylene container. This set was identical to Set G except that it incorporated in the piercing spike an air-inlet fitted with a membrane filter. The flow rate was recorded with three of these sets and compared with those observed when Sets G were similarly connected to the polyethylene containers.

Drop counter delivery determination. In order to determine the drop counter delivery per ml of fluid the number of drops delivered in 2 min was counted and the weight of fluid delivered in the same period measured. This was converted to volume on the basis of an experimentally determined specific gravity and the drop size (drops per ml) calculated.

Determination of force necessary to sever connection. The tightness of the seal formed between the closure piercing device on the set and the container entry port was tested by

determination of the force necessary to sever the connection. The test consisted of adding weights to a 'basket' tied to the set which was attached to the vertically hanging container until the piercing device slipped out of the entry port.

Identification of plasticizer. To identify the plasticizer used in the manufacture of the delivery tubing, pieces of tubing were extracted by shaking with ether, evaporating off the solvent under reduced pressure and applying 1 μl amounts on to glass plates coated to a thickness of 0.25 mm with Silica Gel HF_{254}. The plates were developed with a solvent system of hexane-ethyl acetate, 9 : 1 and the plasticizer spots detected by spraying with a solution of 20% vanillin in ethanol, heating for 10 min at 80°C, spraying again with 4 N sulphuric acid and reheating at 110°C for 30 min (McDonald, 1973).

RESULTS AND DISCUSSION

Construction

Safety filter. Different constructional aspects of the filter are summarized in Table 1. From this it can be seen that Sets G lack a safety filter while the filters incorporated into Sets E and J differ from each other in all aspects. The purpose of the filters is 'to prevent the passage of large particles or blood clots, in the event of the set being used in error to administer blood or blood derivatives' (British Standard 2463, 1962).

Drip chamber and drop counter. The drip chamber is compressible so that it can be partially filled during normal use. The capacity of the drip chambers was found to vary (see Table 2 and Fig. 1). Projecting for a short distance into the chamber is a drip tube (drop counter). The sets were found to differ as regards the tube dimensions and the advertised drops per ml of distilled water delivered (Table 2). On examination of the sets the range of drop sizes delivered showed that with all three types, values for individual sets varied from 15 to 20 drops per ml (Fig. 4), the range allowed by the British Standard (1962). The mean drop counter delivery (drops per ml) of Sodium Chloride Injection B.P. was found to be 17 at flow rates ranging from 25 to 55 drops per minute. At these rates this fluid behaves like distilled water which is used to calibrate the sets (Ferenchak et al., 1971). The results suggest that a drop counter delivery of 17 is more realistic than

TABLE 1

COMPARISON OF SAFETY FILTER FEATURES

	Set E	Set J	Set G
Manufacturer	Travenol	Terumo	Braun
Location	in drip chamber	at distal end of set covering plastic needle adaptor inlet	Absent
Filtering area	7.7 cm^2	2.6 mm^2	
Filament material	nylon	delustered rayon	
Filament diameter	0.135 mm	0.062 mm	
Aperture size of filter	0.21 mm^2	0.16 mm^2	

TABLE 2

COMPARISON OF DRIP CHAMBER AND DROP COUNTER FEATURES

	Set E	Set J	Set G
Manufacturer	Travenol	Terumo	Braun
Volume of fluid necessary to visually half-fill chamber	4–5 ml	5–6 ml	15 ml
Drop counter delivery quoted by manufacturer	15 drops/ml	17 drops/ml	17 drops/ml
Counter orifice diameter			
outer	4.3 mm	3.7 mm	4.4 mm
inner	3.1 mm	2.8 mm	3.0 mm

the value of 15 advertised. An accurate knowledge of this value is necesary for nurses to be able to calculate the flow rate (drops per minute) needed to deliver the prescribed volume of fluid within a specified time.

This method of calculating the flow rate, through widely used, has been shown to be inaccurate in several ways. The rate of drop formation, for example, is known to affect drop size; the faster the rate, the larger the drop size (La Cour, 1966; Ferenchak et al., 1971; Flack and Whyte, 1975). The properties of the particular fluid, such as density and surface tension, also influence drop size. Common infusion fluids, though indis-

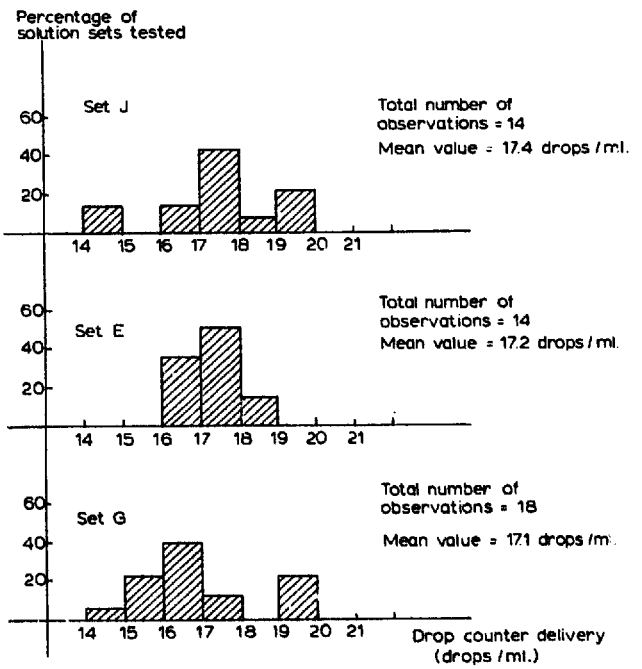


Fig. 4. Distribution of drop counter delivery values.

tinguishable from distilled water at slow flow rates behave differently at high rates, thus bringing into doubt the validity of the drop counter delivery value. It has, in fact, been suggested (Flack and Whyte, 1975) that the drip delivery stated by manufacturers should be quoted at a given flow rate. Parenteral feeding solutions also differ at all rates, forming drops smaller than both common i.v. fluids and distilled water.

Variations in drop counter orifice dimensions have also been shown to lead to changes in drop sizes (Ferenchak et al., 1971; La Cour, 1965, 1966; Flack and Whyte, 1975). It was found that the smaller the differences between the external and internal diameters of the drop counter tip, the more accurate the drop delivery. A difference of 0.1 mm was suggested and the ideal tip proposed by La Cour in 1966. It is obvious from the sets examined that this suggestion has not been accepted by the manufacturers of solution sets.

Closure piercing device. These were found to be of variable design (Fig. 1). The piercing device on Set G was very rigid and capable of piercing without deformation all the container entry ports. With Set E problems were encountered only on insertion into the PE-'old' type container, where the tips proved to be too blunt to penetrate without difficulty the 5 mm thick rubber closure. Sets J were inserted readily and without deformation, only into PVC-2 bags, the piercing tips being easily bent or broken off after a single insertion into both PE and PVC-1 containers (Fig. 5). Discussions with hospital personnel have shown that similar difficulties are encountered in practice when using the above set and container combinations (Hook, unpublished data). It is insertion difficulties such as these which can lead to excessive manipulations during the setting up of intravenous fluids and changing of the containers, with the attendant risk of touching the connection sites and introducing microbial contamination into the delivery system. Both in England (Newman et al., 1975) and America (Poretz et al., 1974) one of the microorganisms most frequently isolated from contaminated delivery systems was found to be *Staphylococcus epidermidis,* an organism commonly considered to be non-pathogenic but which under certain circumstances could become more virulent (Cruickshank, 1965; Crowe and Ward, 1977). Set insertion difficulties are admittedly only one source of microbial contamination in an i.v. fluid delivery system (Editorial, 1976). However, once the system has become contaminated with organisms capable of growing in the fluid they can survive for many days in the set (Michaels and Ruebner, 1953; Maki et al., 1973).

The D.H.S.S. specification (1975) states that 'the connection between the closure piercing device and the container closure should not work loose during normal use and should withstand a gradually applied pull of 25 Newtons for 10 sec'. A modified test was applied designed to determine the force necessary to immediately sever the connection. The results are shown in Table 3. It can be seen that there were almost no differences between the set types in combination with a single container type, but obvious differences were apparent between the container types. The PVC-1 port formed the weakest connection in all cases, a weakness which could in practice lead to ready disconnection of the sets while in use.

Delivery tube. Table 4 shows the differences found. The tubing should be made of plasticized polyvinyl chloride (D.H.S.S. Specifications, 1974, 1975). On analysis the plasticizer used in the manufacture of the three set types was found to be di-2-ethylhexyl-

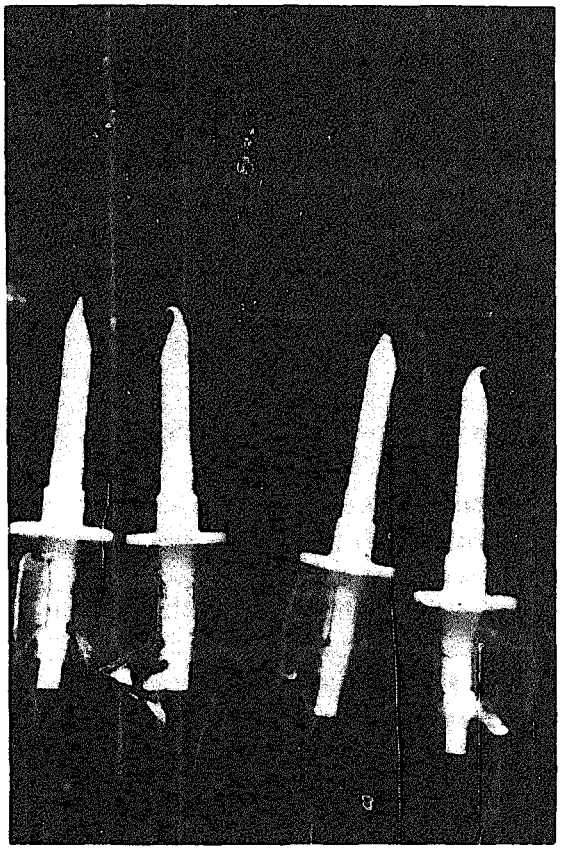


Fig. 5. Deformation of closure piercing devices caused by a single insertion of Sets J into polyethylene plastic containers.

TABLE 3

FORCE (NEWTONS) REQUIRED TO SEVER CONNECTION BETWEEN SOLUTION SET PIERCING DEVICE AND PLASTICS CONTAINER ENTRY PORT

Set	Containers		
	PE (Braun)	PVC-2 (Viaflex)	PVC-1 (Steriflex)
	Force required		
G (Braun)	21.6 [a]	>31.4 [b]	15.7 [b]
J (Terumo)	19.1 [a]	>31.4 [b]	14.4 [b]
E (Travenol)	19.6 [c]	>31.4 [c]	16.0 [c]

[a] Mean of 2 values.
[b] Mean of 3 values.
[c] Mean of 6 values.

TABLE 4

COMPARISON OF DELIVERY TUBE FEATURES

	Set E	Set J	Set G
Free length (cm)	147	143	151
Fluid capacity (ml)	9	7	10
Thickness of tubing wall (mm)	0.62	0.76	0.53
Diameter of lumen (mm)	2.84	2.45	2.97

phthalate (DEHP) a compound whose possible toxicity has recently been reviewed (Editorial, 1975).

Volume of fluid used to fill the set. This, on average, was found to be 13 ml in the case of Sets E, 12 ml in Sets J and 25 ml in Sets G. With Sets G this volume was in excess of the fluid overfill found in the PE containers and meant that once the sets were connected and the flow rate established the bottles contained less than the 1000 ml volume required.

Flow regulator. The screw clamp on Set E was found to be very difficult to regulate. Both hands were needed to establish the flow rate and the prong had to be screwed in to its maximum before the flow of fluid was stopped. This in some cases deformed the delivery tubing to such an extent that flakes of plastic were dislodged by the screw turning against the tubing. How severely the tubing was damaged was not investigated. The screw clamps also showed a greater tendency to slip, causing an increase in the flow rate. Out of 31 initial flow rates established the clamps slipped 6 times. In contrast, the roller clamps only slipped once (in Set G) out of a total of 66 initial flow rates observed. They were also much easier to regulate and did not greatly deform the plastic tubing. The flow regulator is a device which should be capable of stopping the flow of i.v. fluid completely, and of continuous use throughout an infusion without damaging the tubing (D.H.S.S. Specification, 1974). The devices examined complied with these requirements, though the effect of the screw clamp on the tubing needs further examination.

The third prerequisite of the device is that it should be capable of controlling the flow of fluid as required. For the experimental work on flow rates it was desired to establish as quickly as possible an initial flow rate of 50 drops per minute. This turned out to be very difficult to achieve. Effects of the container and set on the initial flow rate were not expected and did not show up when data was analyzed as a 3 X 3 factorial experiment. All data are therefore combined in the histogram (Fig. 6).

The manner in which the initially established flow rates were maintained showed that individual sets from the same batch produced different flow rate values (Fig. 7). This was observed with all the set types tested and indicated an intravenous batch variation. All flow rate data were analyzed separately as a 3 X 3 factorial experiment, the factors being sets at 3 levels and containers at 3 levels. In addition, the percentage flow rate changes zero to 30, zero to 60 and zero to 240 min were analyzed. Tables 5 and 6 summarize the analysis of variance data. In every case the only effect which was significant at the 5% point was that of the set, the effect of the container on the flow rate being insignificant up to 240 min. Two comparisons were made among the set means using a *t*-test. The first

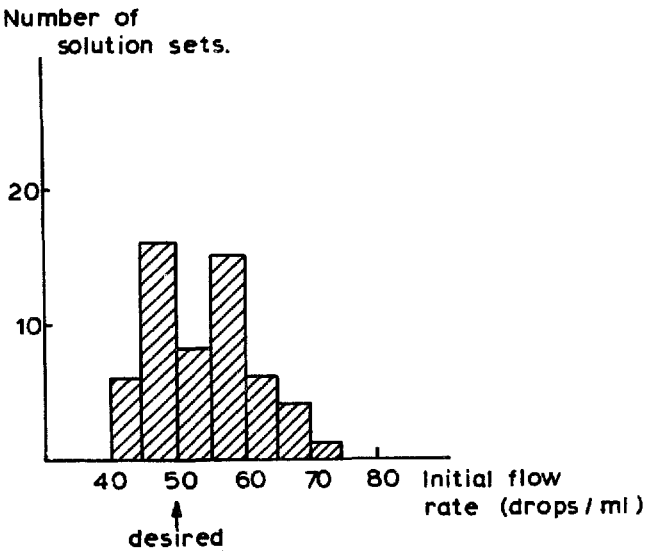


Fig. 6. Histogram showing distribution of initial flow rates established (total number of observations = 51; mean flow rate 52.7; S.D. 7.64).

comparison examined the similarity of response of sets J and G (both fitted with roller clamps) which gave t-values of less than one in every case, confirming the hypothesis that these sets performed in a similar manner. The second comparison was between the average of Sets J and G and the response of Sets E (fitted with a screw clamp) which showed a statistically significant difference ($P < 0.05$). From the results it was concluded that as regards flow rate maintenance both the sets fitted with roller clamps performed better than that fitted with a screw clamp.

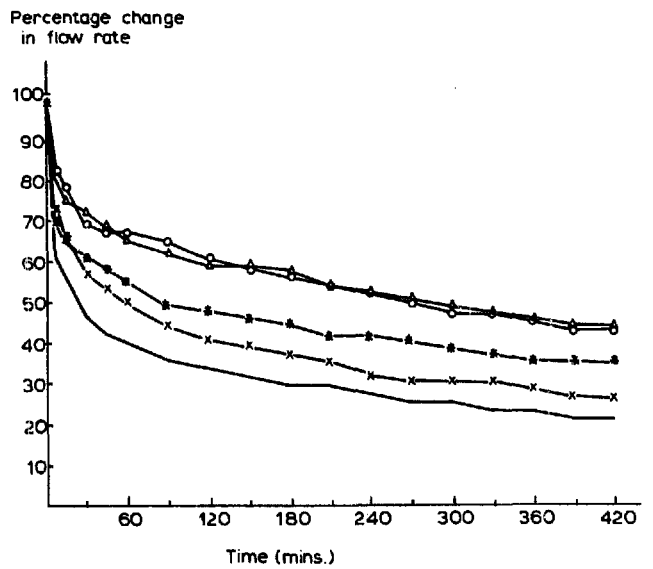


Fig. 7. Graph showing percentage change in flow rate (with respect to zero time) against time, of 5 Sets J in combination with PVC-1 containers.

TABLE 5

ANALYSIS OF VARIANCE FOR FLOW RATES AT 30, 60 AND 240 MIN

Source	d.f.	30 min			60 min			240 min		
		M.S.	*F*	*P*	M.S.	*F*	*P*	M.S.	*F*	*P*
Container	2	69.87			97.06			90.08		
Set	2	549.65	5.5	<0.01	744.56	7.4	<0.01	880.35	10.0	<0.001
Container × set	4	97.87			146.17			54.88		
Residual	34	99.70			104.62			87.84		
Mean flow rates (drops per minute)										
Set J [a] (Terumo)		33.4			30.5			24.6		
Set G [a] (Braun)		36.4			33.2			25.3		
Set E [b] (Travenol)		24.1			18.8			10.9		

[a] Based on 15 values.

[b] Based on 13 values.

TABLE 6

ANALYSIS OF VARIANCE OF PERCENTAGE CHANGE IN FLOW RATES

Source	d.f.	0 to 30 min			0 to 60 min			0 to 240 min		
		M.S.	*F*	*P*	M.S.	*F*	*P*	M.S.	*F*	*P*
Container	2	381.68			488.82			412.60		
Set	2	1716.09	7.7	<0.01	2528.32	9.5	<0.001	2992.67	13.2	<0.001
Container × set	4	325.49			323.45			175.48		
Residual	34	224.08			264.80			227.35		
Mean percentage change in flow rate										
Set J [a]		63.3			57.8			46.5		
Set G [a]		66.6			60.7			46.3		
Set E [b]		45.3			35.4			20.5		

[a] Based on 15 values.

[b] Based on 13 values.

Although the effect of the container on the flow rate was insignificant up to 240 min, after this time an emptying effect could be observed with the semi-rigid polyethylene bottles when between 350 and 250 ml of fluid remained in the container.

At this stage the pressure inside the container was sufficiently reduced to cause a drop in the flow rate (Fig. 8). To overcome this drop (as well as the buckling of the plastic sides encountered with this type of bottle) two procedures have been found to be adopted. In some hospitals the container was vented by inserting a needle into the upper portion of the bottle, thereby increasing the risk of drawing into the container air-borne microbial contamination. In another instance it was found that a glass bottle set would be used, i.e. an administration set fitted with an air-inlet. The results of an experiment set up in the laboratory to evaluate such a system showed that the performance of the set was identical to the ordinary solution set, until about 300 ml of fluid remained in the container. At this stage the pressure inside the container was reduced and air began to enter resulting in the maintenance of the flow rate. As a result of this the manufacturers now recommend that a vented solution set should always be used with this type of container.

All solution sets tested were similar in that they showed a large, but variable, decrease in flow rate during the first 30 min after setting up. During this period between 33 and 55 percent of the initial flow rate was lost. This decrease continued, though more slowly, for the rest of the observation period. Similar results were obtained by workers elsewhere (Flack and Whyte, 1974; Demorueile et al., 1975) who attributed the changes to 'creep' or 'cold flow' of the plastic delivery tubing under stress from the flow regulator. One method of overcoming this decrease in practice is to frequently check and readjust the flow rate back to the desired value. In an additional laboratory experiment this procedure

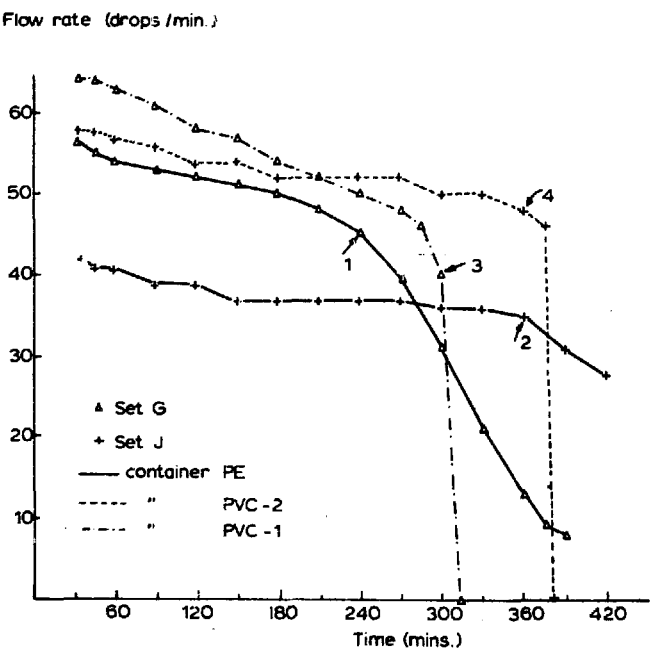


Fig. 8. Graph showing 'emptying effect' of the container on the flow rates. →, indicates volume of fluid left in container 1.265 ml, 2.260 ml, 3.57 ml, 4.53 ml.

was carried out every 15 min and it was found that after 30 min the sets had to be readjusted less frequently. From this one could conclude that on the wards nursing staff should similarly frequently check and readjust the flow rate of any intravenous fluid especially during the first 30 min after setting up.

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