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WEIGHT PREDICTION IN CHILDREN IN THE EMERGENCY DEPARTMENT

Michael David John Wells

A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, in partial fulfilment of the requirements for the degree of Master of Science in Medicine in Emergency Medicine.

Johannesburg, 2009

DECLARATION

I, Michael David John Wells, declare that this research report is my own work. It is being submitted for the degree of Master of Science in Medicine (Emergency Medicine) in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

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_____

DEDICATION

This work is dedicated to my children Terran and Calleigh.

And to other children like them who might potentially receive better emergency medical care through research like this.

PUBLICATIONS ARISING FROM THIS STUDY

Wells M, Kramer E. Optimizing emergency drug dosing in children. Acad Emerg Med 2008; 15(12):1325.

ABSTRACT

Objectives: to establish the accuracy and reliability of a new device, the PAWPER tape (PT), for length-based weight estimation in children; to assess whether the addition of a measure of body habitus could improve the accuracy of weight estimation; and to compare the performance of the PT with that of the Broselow tape (BT).

Design: prospective, cross-sectional, descriptive study.

Setting: emergency departments (EDs) of two Johannesburg private hospitals.

Patients: children aged from 1 month to 12 years who were not in need of emergent medical management.

Methods: each child had their weight estimated by both the BT and the PT (which included a method for adjusting the predicted weight according to body habitus). These predicted weights were then compared against measured weight to determine the bias and precision of the estimation techniques.

Main Results: the PT performed as well or better than the BT in every analysis performed. The mean percentage error (MPE) was -3.8% vs 0% and the absolute MPE was 9.1% vs 4.5% for the BT and PT respectively ($p<0.0001$). The BT predicted weight to within 10% of actual weight in 63.6% of children and the PT in 89.2% ($p<0.0001$). The difference between the performances of the BT and PT was most pronounced in children >20kg, and in children above or below average weight-for-length.

Conclusions: The PT was a reliable weight estimation device that performed well in this population, often with a greater degree of accuracy than the BT. The inclusion of an appraisal of body habitus in the methodology considerably improved the accuracy of weight estimation.

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NOMENCLATURE

Abbreviations

ABW	adjusted body weight
ALS	advanced life support
AMPE	absolute mean percentage error
APLS	advanced paediatric life support
BMI	body mass index
BMI%	body mass index-for-age centile
BT	Broselow tape
CI	confidence intervals (95%)
cm	centimetre/s
CPR	cardiopulmonary resuscitation
DF	degrees of freedom
DWEM	devised weight-estimating method
ED	emergency department
ETT	endotracheal tube
g	grams
HCP	healthcare providers
HS	habitus score
IBW	ideal body weight
ICU	intensive care unit
IV	intravenous
IO	intraosseus
kg	kilogram

L	large
LBW	lean body weight
M	medium
mg	milligrams
ml	millilitres
MPE	mean percentage error
NCHS	national centre for health statistics
PA	percent agreement
PALS	paediatric advanced life support
PAWPER	paediatric advanced weight prediction in the emergency room
PE	percentage error
PREM	paediatric resuscitation emergency management
PT	PAWPER tape
PTHS	PAWPER tape including habitus score
S	small
SD	standard deviation
SEM	standard error of the mean
TBW	total body weight
µg	micrograms
UK	United Kingdom
USA	United States of America
WHO	world health organisation
XL	extra-large
XS	extra-small

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PREFACE

I have been an ardent supporter of the Broselow tape for the last 15 years, but recently there has been mounting evidence of inaccuracies in weight estimation systems that are commonly used in the ED, including the Broselow tape.[1] The underlying concepts of the PAWPER tape were conceived in response, based on currently available evidence,[2] in order to reduce medication errors in critically ill or injured children that might occur as a consequence of an inaccurate estimate of weight.

The Broselow tape is the best device currently available for estimating children's weight in emergencies, but it has been shown to be inaccurate in several studies in contemporary populations.[3] It has also addressed the issue of drug dosaging and resuscitation equipment sizing but the manner in which drug dosages are presented is problematic. The need for calculations in the preparation and delivery of medications, one of the main causes of medication errors, has not been resolved. James Broselow himself advocated the use of additional reference material with the Broselow tape (1), and a companion manual to the Broselow tape was developed in 2006 (2).

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[1] See introduction and literature review for an exposition, with supporting references, of the errors of weight estimation systems used in the ED.

[2] Current evidence (see below) suggests that the resuscitation of critically ill or injured children should be team-based and that it should incorporate resuscitation aids into the team dynamic. The aids should include simple methods of weight estimation and guidelines on drug dosaging and administration, equipment size selection and other information that might be useful in a paediatric resuscitation.

[3] See below for further discussion and references.

In an attempt to address some of the issues confounding weight estimation in the ED, I developed the theoretical principles underlying the PAWPER tape system and created a weight-estimation tape based on these concepts. The validation of this system is the essence of this thesis. The *Emergency drug dosing in children* booklet (3) was developed to be used in conjunction with the PAWPER tape to provide an evidence-based system of drug dosage and administration guidelines for the paediatric resuscitation situation, as there is no drug dosage information on the PAWPER tape itself.

The PAWPER tape was inspired by the Broselow tape, the derived weight-estimating system (DWEM) (4) and some work I had done on veterinary "condition scoring". Based on the proven success of the DWEM habitus assessment I thought that this could be expanded and incorporated into a tape-system that might prove to be of some value...

A brief description of the design philosophy and statistics of the PAWPER tape is included in Appendix 1 and a short summary of the format and evidence behind the Emergency drug dosing in children *series is described in Appendix 2.*

Chapter 1 INTRODUCTION

1.1 Motivation and rationale for this research

1.1.1 The importance and relevance of weight estimation in the ED

Calculating, prescribing, preparing, and delivering accurate drug doses to children in the ED can be challenging at the best of times and consequently medication errors in children have been shown to be very common (5). The additional emotional stress and cognitive load of a paediatric resuscitation make the risk of incurring errors even higher (6, 7) and these errors are more likely to result in adverse events (patient harm) in the very young patient and the critically ill or injured child or infant with significant physiological insult (8). There are a large number of sequential steps that must each be successfully completed to avoid drug dose-related errors and there is potential for medication error at any stage of the drug identification, dose calculation, drug dilution or drug/dilution delivery (see Figure 1-1) (9).

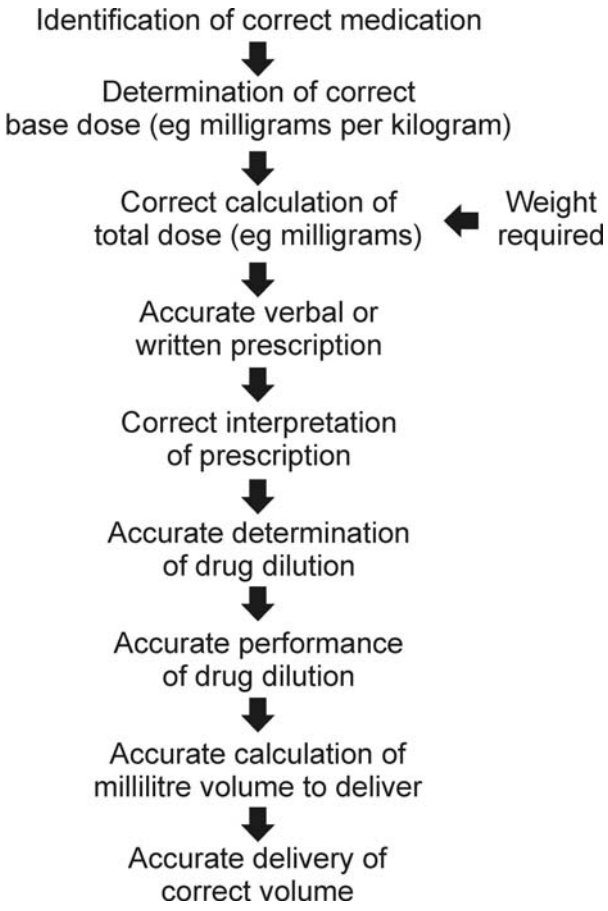

Figure 1-1 The sequential steps required for the correct calculation, dilution, preparation and delivery of medications to children during emergency medical management or resuscitation.

The correct determination of the total drug dose to deliver (usually expressed in g, mg or µg) depends on having an accurate quantification of the child's weight (in kg), since most agents administered in children have a dose based on body weight. Figure 1-2 illustrates an example of the process of drug dose calculation from the base dose (usually expressed in g/kg, mg/kg or µg/kg) to the final volume (in ml) to administer.

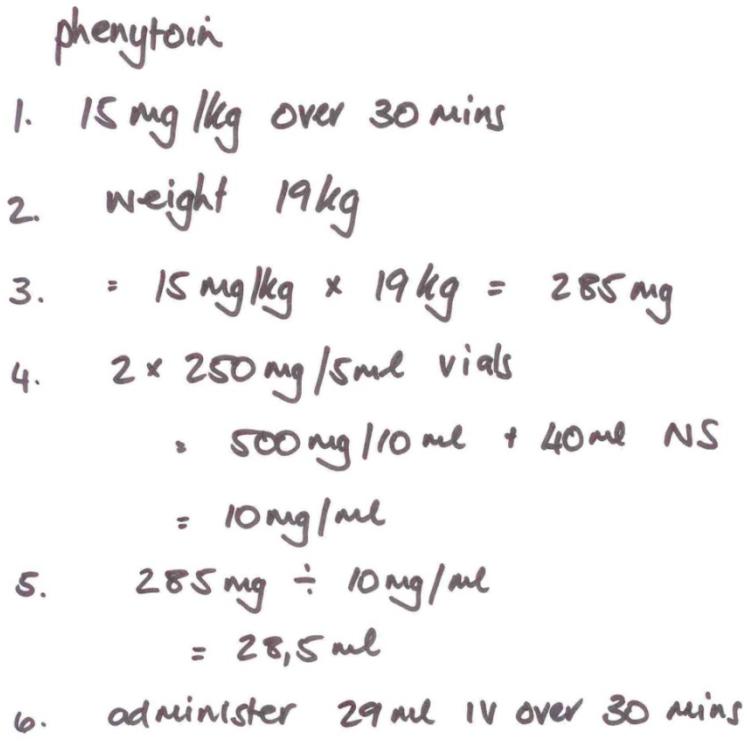

Figure 1-2 An example of the calculations required for the accurate drug delivery of phenytoin.

Line 1 the **base dose** in mg/kg and, in this case, the required infusion time for this medication. In paediatric emergency medicine almost all dosage references are based on a "per-weight" base (eg. mg/kg) rather than a total amount.

Line 2 the **weight** of the patient – this must be obtained either by measurement or by some reliably accurate method of estimation.

Line 3 the arithmetic required to obtain the total amount of drug-mass to administer from the product of the **weight** and the **base dose**.

Line 4 the preparation of an appropriate dilution of phenytoin from the available adult preparation, in a volume that is appropriate for the type of drug and required rate of administration.

Line 5 the calculation of the volume of diluted drug required for to deliver the correct dose of phenytoin.

Line 6 the end result of the calculations and decisions required for this drug administration.

An accurate measure of body weight is therefore an essential element of the drug dose computation process (10):

- To ensure the effectiveness of the delivered medication (to make certain that a sufficient amount of medication is administered to achieve the desired pharmacodynamic objective in the patient with a life-threatening condition).
- To prevent the potential complications and side-effects of overdosing the patient, already vulnerable as a result of immaturity, critical illness or injury, with a potentially harmful medication.

The ideal solution is to actually measure the weight of a child on an accurate scale before drugs are prescribed in the ED, but this is often impossible because of spinal immobilisation precautions, ongoing CPR, emergent airway management or other acute medical interventions (11). Under these circumstances an accurate, rapid estimation of weight is needed, as the safety and effectiveness of emergent interventions may ultimately depend on the accuracy of the weight estimation (12).

Most paediatric medication errors and most cases of resultant patient harm have been shown to be related to incorrect dosaging (8, 9, 13-47) and, since drug dose calculation is dependent on weight estimation, the importance of an accurate, resilient[4] method to estimate weight is thus apparent.

[4] Resilience in this context refers to a weight-estimation system that remains accurate under potentially adverse conditions: emergency use by intellectually stressed healthcare providers in patients with a wide variety of confounding variables such as age, ethnicity, gender, socioeconomic status, body habitus and underlying illness.

Contemporary, commonly used methods to estimate children's weight in the ED have been shown to lack the desired accuracy and consistency of performance, principally because of the wide variability of body habitus that is not accounted for in these weight-estimation systems (48). Therefore there is a need for a new or a modified methodology to improve the ability of the emergency physician to accurately predict weight. This device or methodology, however, needs to be developed as part of a comprehensive, evidence-based approach to reducing medication errors in children.

1.1.2 Introducing the PAWPER tape

The PAWPER tape (see Appendix 1 for the design methodology and details of its use) is a new device that was created and designed to estimate weight in children based on their length, with an integrated weight modification system based on body habitus to compensate for children who are large or small for their length. It was designed and constructed from a set of principles on a purely theoretical basis and it has yet to be subjected to objective clinical testing.

It is a single-use device which functions exclusively as a weight-estimation apparatus. It is intended to be used in conjunction with additional reference material, specifically the *Emergency drug dosing in children* series (3), which provides information on drug dosage and delivery, equipment sizes and other data relevant to a paediatric resuscitation (see Appendix 2 for the details of this reference system).

The PAWPER tape has the potential to be used in the prehospital environment, the ED and the ICU to provide an accurate estimation of weight to facilitate accurate emergency drug dosage calculation, when weight cannot be measured.

1.2 Statement of the problem

The problem is simply that current methods of weight estimation are not accurate enough. The PAWPER tape design was based on principles that theoretically should improve the accuracy of length-based weight estimation because of the inclusion of a measure of body habitus into the system. The performance of this tape needs to be tested under scientific conditions by evaluating its reliability and accuracy (in terms of bias and precision) and by comparing its predictive ability against that of the currently best device available, the Broselow tape.

1.3 Aim and objectives

1.3.1 Study aim

- To validate the PA WPER tape system for weight prediction against measured weight, in a population of children seen in emergency departments.
- To compare the PAWPER system with the Broselow Tape in terms of accuracy of weight prediction in the same population.

1.3.2 Study objectives

1. To compare weight prediction by the PAWPER tape against measured weight in a population of children attending the EDs of two private hospitals in Johannesburg, South Africa;
2. To assess whether the accuracy of weight prediction is increased by the addition of a measure of body habitus to the prediction technique.
3. To determine whether or not it is reliable enough and accurate enough to decrease the error of weight estimation in overweight or underweight children.
4. To compare weight prediction by the PAWPER tape with weight prediction by the Broselow tape in these children.

Chapter 2 LITERATURE REVIEW

2.1 A brief history of weight estimation methods in children

Prior to the mid-1980s age-based formulas and educated guesses were predominantly used for weight estimation in children undergoing emergency medical treatment or resuscitation (49). The earliest record of age-based weight estimation formulas was published by Alexander Weech in 1956 (50), who produced a series of equations to predict weight and height in children in both metric and imperial units. These formulas include the one later to become known as the APLS formula. Whether this formula was derived by Weech or has an earlier origin is unknown, but it appears to be remarkably accurate when applied to a table of weight-for-age measurements discovered in a 1952 paediatric textbook (11). It seems likely that the APLS formula was developed sometime between 1952 and 1956, derived from this data obtained from post-war children in the United Kingdom. Formulas by Traub and Johnson (51) and Traub and Kichen (52) were developed in the early 1980s, but are complex and not well suited, or intended, for use in the ED.

In 1986 Jeffrey Garland and colleagues published the Devised Weight-Estimating Method (DWEM) (4) which was the first and only technique to date to include a measure of body habitus in a weight estimation technique.

In 1988 Peter Oakley published a reference table of weight-for-length for children. He was one of the first researchers to recognise that delays in essential

resuscitative measures may occur as a result of indecision in weight determination (53) and that overall treatment can be improved by the use of resuscitation aids.

It was also in 1988 that Deborah Lubitz published the first validation study on the Broselow Paediatric Emergency Tape, developed by James Broselow, which was based on the 50th centile of the 1979 NCHS weight-for-length growth charts (49). The following two decades were dominated by the Broselow tape and many of the weight estimation techniques introduced subsequently did not become popular because of the success of the Broselow tape. The Broselow tape has undergone several changes in each new version over the years, but the underlying principles have remained the same.

In 1990 Anthony Haftel and collaborators developed the “hanging leg-weight” technique for weight estimation in children. This technique was completely unlike anything that had been used before, but has never attracted further interest, even as a validation study.

Despite many studies demonstrating the inaccuracy of age-based weight prediction formulas, a number of new formulas were developed in different populations over the next decade: the Leffler formula in 1997 (54), the Shann formula in 2000 (55), the Argall formula in 2003 (56), the Nelson formula in 2004 (57), the Luscombe formula in 2007 (11) and the Tinning (Best Guess) formulas in 2007 (58). None of these formulas have been proved to be accurate in a population outside of the study population from which it was created, and few have even undergone validation studies in the same or different populations.

In 2005 a novel technique using foot-length to predict the weight of children under the age of 2 years was developed in India (59). This technique is promising but still needs validation.

Six further tape-based weight prediction systems were developed after the Broselow tape:

1. the Lo tape / rod modification which was developed in Hong Kong in 1995 (60);
2. the Blantyre tape which was developed by Elizabeth Molyneux in Malawi in 1999 (61);
3. the Kloeck tape which was developed by Walter Kloeck in South Africa in 2000 (62);
4. the Sandell tape which was developed in 2004 by Julian Sandell for use primarily by prehospital personnel in the UK (63);
5. the Paediatric Resuscitation Emergency Management (PREM) tape system, developed by Joe Brierly in 2005 (64);
6. the Paediatric Advanced Weight Prediction in the Emergency Room (PAWPER) tape, developed by myself in 2008, which is the object of this validation study.

The development of the Lo rod system was described in the Hong Kong journal of Emergency Medicine in 1995 and the development of the Blantyre tape was described in the Lancet in 1999. None of the other tapes have been scientifically validated or have yet been published in the scientific peer-reviewed literature, however.

2.2 Resuscitation aids in paediatric emergency care

2.2.1 The history and relevance of resuscitation aids

The first mentions in the scientific literature of the need for a method to expedite drug dosage determination in the emergency management of children were in the late 1980s. Garland (4), Oakley (53) and the Broselow tape team (49) each developed weight estimation systems primarily as a means of improving the resuscitative treatment process in children, rather than simply to establish the weight alone. Since 2002 there has been an increasing emphasis on the need to use supplementary resources during the resuscitation of children (6, 7, 65, 66). The intellectual and emotional stress that emergency physicians experience during the resuscitation or emergency management of children in the ED may negatively impact on their ability to provide optimum treatment - partly through delays in determining drug doses, fluid volumes and flow rates or equipment sizes (6, 7, 53). Although there is considerable uncertainty about the actual dosages of many drugs that are used in emergencies, some experts believe that “cognitive paralysis” or “paralysis by indecision” resulting in a delay to institute treatment may be a more significant risk of poor outcome than an error of dosage (12). The use of resuscitation aids should be considered mandatory in the emergency management of children: they reduce delays in medication delivery; they reduce dosaging errors; and they increase the confidence of the treating team in their management (6, 65). The choice of a weight-estimation system should also include a consideration of how that system functions as a resuscitation aid, or as part of a resuscitation aid.

From 2004 there has been a paradigm shift towards the use of a *complete* weight estimation system / resuscitation aid system ie. a system that estimates weight and provides detailed and comprehensive information about drug dosaging so that no calculations of any form are required. The Sandell tape accommodated additional information by "supersizing" – it is a tape the size of an A4 book. Three other systems make use of two separate items to present the necessary information: the PREM tape comes with accompanying booklet (64); in 2006 the Broselow tape team introduced a booklet to be used with the Broselow tape, the *Broselow paediatric resuscitation medication/infusion guide* (2); the PAWPER tape was designed to be used together with the Emergency drug dosing in children booklet (3). Weight estimation systems have now become established as fully fledged resuscitation aids and new methodologies should incorporate the principles of resuscitation aids into their operation.

2.2.2 Weight estimation devices as resuscitation aids

The emergency management of children is improved by the use of resuscitation aids and by the use of a device that delivers an accurate estimation of weight. These can be combined into a single device or a single system to achieve the desired reduction in errors and thus optimum outcomes in management (67, 68).

There is a wide range of devices that have been proposed to decrease errors in drug dosaging and therefore function as resuscitation aids in one form or another. These devices include:

- Novel pieces of equipment or methods to package or administer intravenous medications such as colour-coded prefilled syringes and devices to measure and control the volume of drug administered (69-74).
- Standardised proforma medication prescription sheets (75, 76).
- Computerised drug calculation systems (19, 32, 77-80).
- Resuscitation cards with standardised drug dosages (81, 82).
- Tape and reference systems such as the Broselow, PREM and PAWPER tapes (1, 7, 45, 83-90).
- Hospital-wide integrated colour-coded systems (normally based on the Broselow tape).

Resuscitation aids should be directed towards the entire team and not just the doctor because evidence has shown that team-based resuscitation in paediatrics is safer and more effective than the traditional “doctor-solely-in-charge” approach (44, 91-93). An aid should therefore include not only information on emergency equipment sizing and drug dosages (decisions that the doctor might have to make), but exact instructions for drug dilution and volumes to deliver as well (decisions that the professional nurse or technician might have to make) (6, 7, 65, 94).

One key area that has been identified as particularly vulnerable to errors in the ED is any process of calculation, whether from a weight-estimation formula or drug

dosage and dilution formulas. Both doctors and nurses are unable to perform simple arithmetic reliably (95-103), especially under pressure (104). In children even major dose errors can be committed and go unnoticed (100) and may be of such a magnitude that there is a potential for serious harm as a result (13, 16, 69, 105-113). For this reason a resuscitation aid should obviate the need for any form of calculation whatsoever: no formula should be needed for weight estimation or for any step of the drug dose calculation process (7). Thus table-based or tape-based systems, with additional references materials such as booklets, charts or computerised systems are most likely to satisfy the criteria of a comprehensive resuscitation aid. The additional advantages of separating the weight estimation system from the drug dosage / equipment size reference source include (60):

- Local or institutional choices of drugs and drug dosages can be selected for inclusion in the reference.
- Appropriate local nomenclature can be used (eg. lignocaine rather than lidocaine).
- Drug dosage and preparation can be fully pre-calculated and displayed, according to local or institutional pharmacopoeias.
- Changes in local or international drug or drug dosage recommendations can be rapidly implemented.

The ideal resuscitation aid, in whatever form it takes (see Figure 2-1), should provide the following comprehensive paediatric resuscitation assistance (6, 7). It should:

- Eliminate the need for any calculations.
- Assist to change non-automatic thinking and decisions, with respect to drug dosage and equipment sizing, into automatic processes so that critical thinking can be uninterrupted and dedicated to medical management.
- Provide an accurate estimate of weight[5] based primarily on length.
- Provide accurate guidance on resuscitation equipment size eg.
    - Cuffed or uncuffed endotracheal tube size (diameter).
    - Depth of insertion of endotracheal tube.
    - Size and depth of insertion of central venous catheters.
    - Other tubes, catheters and cannulas.
- Provide accurate information on fluid therapy, bolus drug dosages, drug dilution and volume to deliver.
- Provide accurate information on the preparation and delivery of drug infusions.
- Provide accurate information on initial ED ventilator settings.
- Provide useful age-linked reminders with regard to drug dosaging eg. the need for relatively higher doses of suxamethonium in infants.

Comprehensive resuscitation assistance can be provided by a tape-measure or dedicated weight-estimation device and an information source: reference charts or books, colour-coded tapes or point-of-care computerised decision-support or drug dosaging software. Age-based formulas or complex length-based formulas should be avoided because of the potential for error associated with the necessary

[5] It is not yet clear which weight should be used for drug dose determination – total body weight, ideal body weight, lean body weight or an adjusted body weight (see below) – or whether this weight should be different for different drugs and for patients with different body types.

calculations. Every ED that treats emergencies in children should ideally be equipped with some form of appropriate resuscitation aid, and every emergency physician should be familiar with their use.

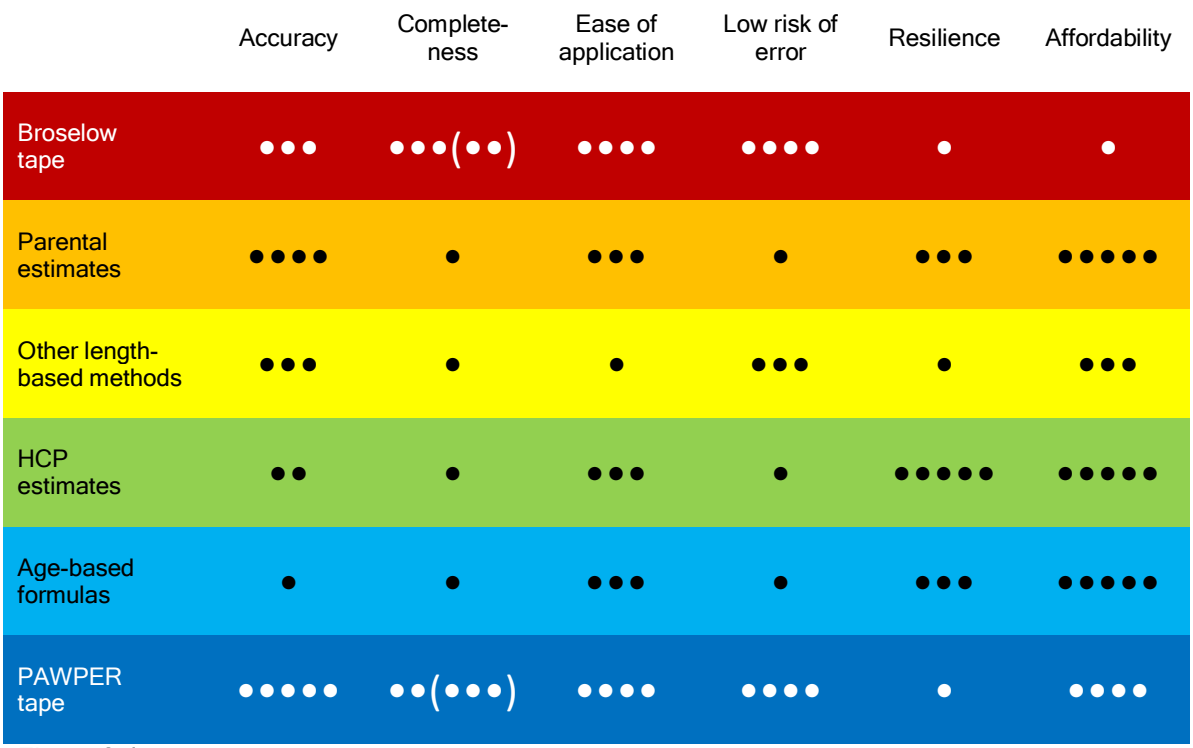

Figure 2-1 Desirable characteristics of weight-estimation systems for use in the ED.

Accuracy the precision and reliability of weight estimation;

Completeness the fulfilment of the requirements of a resuscitation aid; the Broselow and PAWPER tapes get a higher score (parentheses) if their companion manuals are included;

Ease of application the simplicity of the system and whether calculations of any sort are required;

Low risk of error the potential of confounding variables to impact negatively on the performance of the system;

Resilience the value of the system if some or all of the equipment is unavailable or performs incorrectly;

Affordability the relative cost of the entire system.

2.3 Weight estimation methods for use in paediatric emergencies

A number of different methods have been used to estimate the weight of children under circumstances when drugs need to be administered and weight cannot be measured. The methods currently available to the emergency physician to estimate the weight of children are described below.

The evaluation of the performance of weight estimation systems is a matter of little agreement in the scientific literature. There is a large variation in statistical analyses used in different studies, but the best overall single indicator of performance is probably the proportion of children that receive an estimation of weight that is within 10% of actual weight. Firstly, most authorities agree that an error limit of 10% is acceptable (114) although a dissenting argument has been made to use a limit of 20% (61). Secondly, authorities disagree on what constitutes an acceptable proportion of children achieving weight estimation within 10% of actual weight. Some authors have regarded 60% as an indicator of poor performance (115) while others have suggested that this is an overly stringent limit (66). Proportions of 75% to 80% have been described as moderate (116) or good (48). A limit of 60% seems to be the lowest cut-off point of acceptable performance with values below this indicating unacceptable performance.[6]

[6] There is no valid statistical foundation to the cut-off limits that have been reported in the literature. The original validation study of the Broselow tape demonstrated 55% to 60% of patients with a weight estimation within 10% of actual weight. Since the Broselow tape has been the gold standard in weight prediction for 2 decades it seems reasonable to use these cut-off limits as the minimum acceptable for any weight estimation system.

2.3.1 Estimation of weight by the healthcare provider

The ability of advanced life support paramedics, professional nurses and doctors to accurately estimate the weight of paediatric patients with emergent presentations is very limited (117-122). Studies have shown that only between 25% and 50% of children receive an estimated weight that is within 10% of their actual body weight. The average error in weight estimation ranges from 15% to 20% for an individual patient; the error is smaller in infants and larger in older children (119). This means that the accuracy of weight estimation by healthcare personnel is of moderate accuracy at best.

The mental mechanics of weight estimation by the healthcare provider has been shown to fall into one of two different patterns (123):

- The use of a formula (such as the APLS formula) to provide a starting point for the weight estimate, with a subsequent adjustment of this estimate according to the estimators assessment of the relative size for age of the child. If the age is not known then the age is often estimated, and the formula applied before the final modification of the estimate. This method incorporates an assessment of body habitus into the estimate but this has not been demonstrated to be successful.
- A pure “guesstimate” based on spatial awareness (the three dimensional conformation of the child) without resorting to more derivative methods – this is the less commonly used technique, also the less accurate, and one that is sometimes used if the age is not known.

Estimations of children's weights by doctors, professional nurses and ALS paramedics are unreliable and particularly prone to error in stressful situations. No practitioner who regularly manages emergencies in children should have to resort to the unscientific, and proven inaccurate, practice of guessing: every ED should be prepared with appropriate apparatus to weigh children or alternatively accurately estimate weight when measuring weight is not possible.

2.3.2 Estimation of weight by the parent/s.

The utility of parental estimates of their child's weight is dependent on the parent being present and accessible to healthcare personnel at the time of the child's presentation in the ED. The accuracy of prediction is also determined by whether the accompanying parent is the regular caregiver of the child and whether or not the child has had a recent measurement of weight by the parent or in the parent's presence. A recently recorded weight (for example on the road to Health Chart), if available, must be more accurate than any estimation. There are conflicting reports about the ability of parents to accurately estimate the weight of their children, but recent studies have shown that, in general, parents can estimate the weight of their children better than healthcare workers and with sufficient accuracy for acceptable resuscitation drug dosage calculation (48, 54, 124, 125). If length-based methods of weight estimation are available then these should be used in preference to any form of "guesstimate" of weight, except under exceptional

circumstances.[7] A single study, however, has shown that parental estimates of weight can outperform the accuracy of the Broselow tape where 80% of children's weight were predicted to within 10% of actual weight (48). In the absence of a validated tape-based system for weight estimation, a parental estimate of their child's weight should be actively sought out as the second best[8] option.

2.3.3 Estimation using age-based formulas.

There are a number of formulas to estimate body weight based on the child or infant's age in years or months, depending on the formula. Age-based formulas generally have a large bias and poor precision because of large variations in weight-for-age amongst children and infants (126). There is evidence that every age-based formula that has been tested in a study subsequent to the index study has shown moderate accuracy at best with only 30% to 50% of the estimations falling within 10% of actual weight and with many very large errors of estimation (see Table 2-1).

The variability in weight-for-age is significantly higher than that for weight-for-length and therefore none of these age-based formulas have ever been shown to

[7] There are not infrequent occasions when a parent will volunteer a recently measured weight for their child. The emergency physician must decide on the merits of the situation whether to use this weight or rely on a length-based method of weight estimation.

[8] Some authorities might argue that this is the best method of weight estimation that has been demonstrated in clinical studies, and this is probably correct under many circumstances. This parental estimate of weight must still be used with a resuscitation aid to optimise the drug dosage determination and administration and equipment sizing of the child receiving emergency treatment, however.

perform better than length-based systems (10, 12, 71, 117, 118, 127). Furthermore there is speculation that harm may potentially have been caused from the medication errors resulting from inaccurate age-based weight estimations.

Table 2-1 Validation studies performed to assess the accuracy of age-based weight-estimation formulas.

Formula	Population	Error	Reference
APLS	UK	<20% within 10% of actual weight	(11)
	Australia	34% within 10% of actual weight	(48)
	Pacific Islands	95%CI -7.7kg to 13.4kg	(114)
	Australia	MPE -15%	(12)
	Australia	MPE -17%	(128)
	Malawi	MPE 10%	(129)
	India	Mean overestimate 2kg	(130)
Tinning	Australia	42% within 10% of actual weight	(48)
	Australia	MPE 8%	(128)
	Australia	<50% within 10% of actual weight	(131)
Luscombe	Malawi	MPE 17%	(129)
Shann	Pacific Islands	95%CI -8.7kg to 12.3kg	(114)
Argall	Australia	37% within 10% of actual weight	(48)
	Australia	37% within 10% of actual weight	(132)
Traub-Johnson	Australia	MPE -10%	(12)
Traub-Kichen	Australia	MPE -12%	(12)
Nelson	India	Mean overestimate 2kg	(130)
Leffler	Pacific Islands	95%CI -7.3kg to 11.3kg	(114)

Most experts advocate that age-based formulas should only be used if no better weight-estimation system is available (133).[9]

One of the advantages of age-based formula methods is that they are independent of any items of equipment and so constitute a highly resilient weight-estimation technique, as long as the child's correct age is known, the formula is remembered correctly and the arithmetic performed accurately. The memorisation of age-based formulas is encouraged on advanced life support courses, but memory is capricious in emergencies and leads to mistakes (1).

No age-based formula has *ever* been shown to perform with an acceptable degree of accuracy (weight estimation within 10% in more than 60% of the study population) in a validation study. Age-based formulas are used because they are commonly taught in paediatric ALS courses and because they require no equipment to function. *Memorisation*, however, often leads to *mistakes* in an emergency setting (1).

It is not likely that future formulas will prove any more accurate than the current formulas (unless a measure of body habitus or some completely novel variable is

[9] Age-based formulas are popular with emergency physicians and paediatricians (based on the number of new formulas that are published each year) in the face of substantial evidence demonstrating their lack of accuracy. The argument is often offered, "But what do we use if the Broselow tape is not available?" The answer must be that a length-based weight estimation system should never be unavailable. With regards to endotracheal intubation: what if the laryngoscope is not available? In the same way that it is not acceptable practice for a laryngoscope to be unavailable it is not acceptable to fail to have a planned evidence-based approach to weight estimation to implement in the paediatric resuscitation.

included in the formula) because of the inherent variability of weight-for-age.[10] These formulas are dependent on an accurate knowledge of the age of the child.

2.3.3.1 The APLS formula

The original age-based formula which is used by the APLS course (134) has origins which are unknown. Subsequent variations of this formula have been developed that have been shown to increase the predictive ability within certain populations.

$$\boldsymbol{Weight\ (kg) = 2 \times (Z + 4)}$$

Equation 2-1 APLS formula for children aged 1 to 10 years.
Z = age in years (to the nearest half year; some texts have this value as the age at the last birthday or completed years of age).

This formula has been shown to significantly underestimate weight in many studies from the developed world (11, 12, 48, 56, 58, 114, 116, 117, 123, 128, 130, 131, 133, 135, 136), but it has proved to be inaccurate even in populations from developing countries with a high proportion of children with a low weight-for-age (129). It should not be used if better methods of weight estimation are available, as it may potentially lead to patient harm through dosaging errors, and

[10] Proponents of age-based formulas support the use of these techniques because of their resilience and ease of use – all they require is the correct age of the child to calculate a weight; no equipment is needed. These formulas are so inaccurate, however, that emergency physicians should make every effort to ensure that they never need to resort to age-based estimations of weight, but always have suitable alternative methods available. Formulas are also dependent on the user remembering them correctly and performing the arithmetic correctly, both of which have been shown to be in doubt in emergency or resuscitation situations.

should not be taught on courses (such as APLS and PALS) as an acceptable method of weight estimation (11, 12). The weight-for-age values calculated using the APLS formula consistently fall below the 50th centile on both the WHO 2006 and the NCHS 2000 weight-for-age charts. Even if the variability of weight-for-age is discounted, this formula cannot be accurate in any population in which these growth references are appropriate (see Figure 2-2).

2.3.3.2 Nelson's formulas

$$\boldsymbol{Weight\ (kg) = \frac{z + 9}{2}}$$

Equation 2-2 Nelson's formula for children aged 3 to 12 months.
z = age in months.

$$\boldsymbol{Weight\ (kg) = 2 \times (Z + 4)}$$

Equation 2-3 Nelson's formula for children aged 1 to 6 years.
Z = age in years.

$$\boldsymbol{Weight\ (kg) = \frac{(Z \times 7) - 5}{2}}$$

Equation 2-4 Nelson's formula for children aged 7 to 12 years.
Z = age in years.

This method has only been evaluated in only one published study from a population of Indian children which showed poor overall accuracy (a mean error of 5.2 ± 4.3kg) and particularly in children under 12 months and over 7 years of age (130).

2.3.3.3 Argall's formula

$$\boldsymbol{Weight\ (kg) = 3 \times (Z + 2)}$$

Equation 2-5 Argall's formula for children 1 year to 10 years of age.
Z = completed years of age.

This formula was developed from a sample of children in the United Kingdom (UK) in a study that was primarily aimed at evaluating the APLS formula, but was never validated in other populations in the UK by the authors or others. It has been evaluated in study populations outside the UK with poor results (only 37% of children received a weight estimate that was within 10% of their actual body weight) (130, 132) and is little used in clinical practice.

2.3.3.4 Luscombe's formula

$$\boldsymbol{Weight\ (kg) = (3 \times Z) + 7}$$

Equation 2-6 Luscombe's formula for children aged 1 to 10 years.
Z = completed years of age.

This formula was also derived in a population of children in the UK. It has not been formally validated outside of the original study population other than to show an significant overestimation of weight in children from Malawi (129). A small study (published as an abstract) has shown that this formula might be the best to use for UK populations (123), but this remains to be established.

2.3.3.5 Shann's formula

$$\boldsymbol{Weight\ (kg) = (2 \times Z) + 9}$$

Equation 2-7 Shann's formula for children aged 1 to 9 years.
Z = age in years.

$$\boldsymbol{Weight\ (kg) = (3 \times Z)}$$

Equation 2-8 Shann's formula for children aged >9 years.
Z = age in years.

The Shann formula has been shown to perform better than other age-based formulas in Maori and Pacific Island children (114). The analysis in this study was methodologically incomplete and therefore the conclusions might not be valid. This formula has not found widespread acceptance.

2.3.3.6 Leffler's formula

$$\boldsymbol{Weight\ (kg) = \frac{z + 8}{2}}$$

Equation 2-9 Leffler's formula for children <1 year of age.
z = age in months.

$$\boldsymbol{Weight\ (kg) = (2 \times Z) + 10}$$

Equation 2-10 Leffler's formula for children aged 1 to 10 years.
Z = age in years.

The Leffler formula has been evaluated in only a single study since its publication in 1997. In this study it was shown to perform no better than the Shann and APLS formulas, demonstrating a significant error in both bias and precision (114).

2.3.3.7 Best Guess (Tinning's) formulas

$$\boldsymbol{Weight\ (kg) = \frac{z + 9}{2}}$$

Equation 2-11 Best Guess formula for children ≤12 months of age.
z = age in months.

$$\boldsymbol{Weight\ (kg) = (2 \times Z) + 10}$$

Equation 2-12 Best Guess formula for children aged 1 to 5 years.
Z = age in years.

$$\boldsymbol{Weight\ (kg) = 4 \times Z}$$

Equation 2-13 Best Guess formula for children aged 6 to 14 years.
Z= age in years.

The "Best Guess" formulas were recently developed in Australia. Two validation studies published at the same time as the original article failed to show acceptable accuracy of these formulas. Only 30.5 to 53.1% of the overall study population receiving a weight estimate within 10% of actual body weight (128, 131) in one study and only 60 to 75% receiving a weight estimate within 20% of actual body weight in the other study. They have also been tested in a UK population with a similarly inaccurate performance: only 42% of the study population had a weight estimate within 10% of actual weight (48).

Figure 2-1 shows a graph of the weights predicted by the different age-based formulas together with the 50th centile of the NCHS 2000 weight-for-age chart. The newer formulas (those developed after the turn of the century) are well above the 50th centile. This reflects the increasing weight of children in developed nations from which these regression formulas were derived.

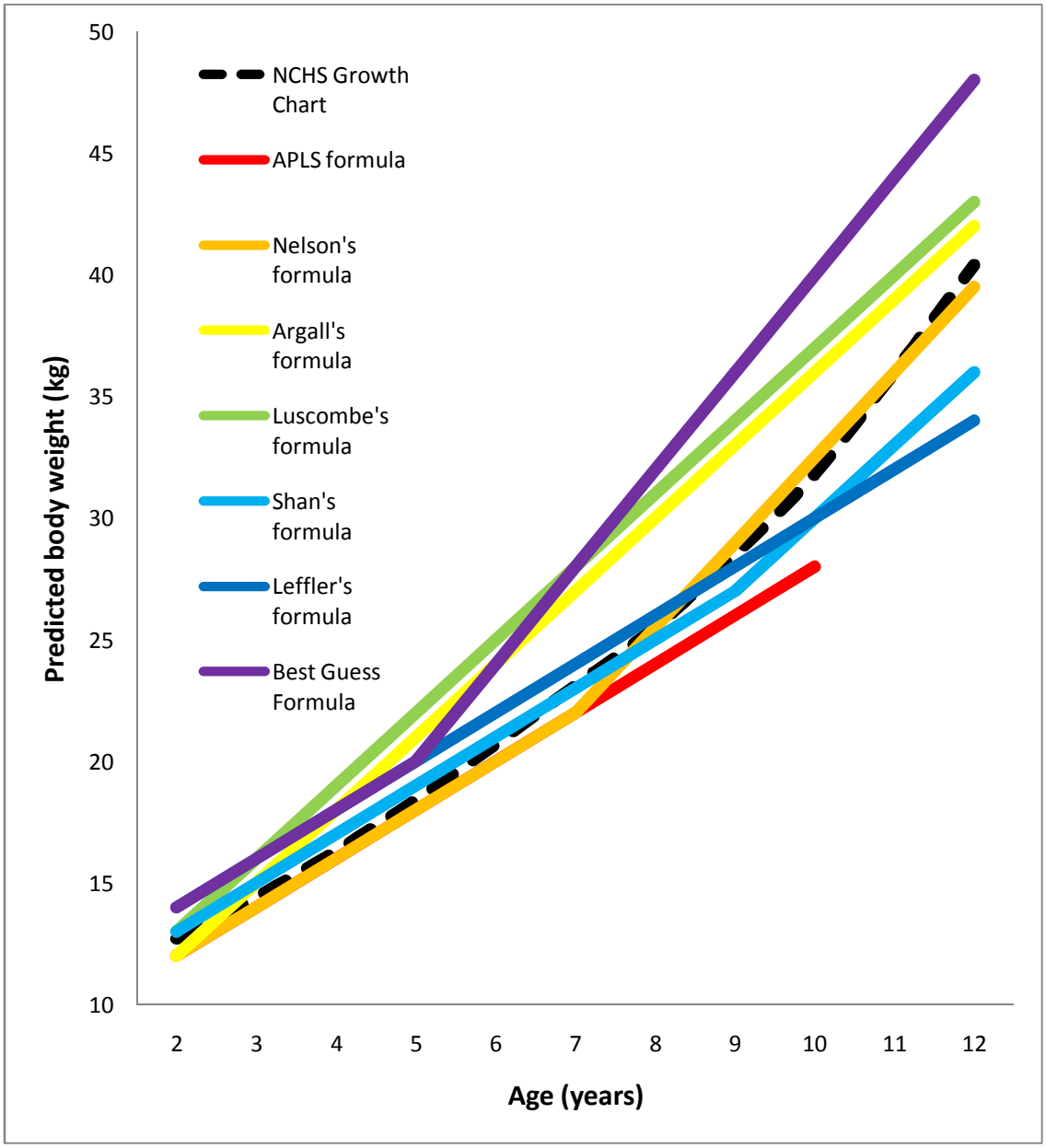

Figure 2-2 A line-plot of each of the age-based weight estimation formulas superimposed on the 50th centile of the NCHS 2000 weight-for-age chart.

2.3.4 Growth chart methods

The method of using weight-for-age or weight-for-length growth charts to estimate weight from a child's age or measured length is relatively slow compared to the tape-based methods, it requires original copies[11] of the appropriate charts to be readily available, and is generally not suited for use in an emergency setting. The process requires some skill and familiarity with growth charts and the successful completion of a number of steps to successfully read the weight off the appropriate centile[12] of the chart. The use of the growth chart also does not enable the emergency physician to address the variability of weight-for-age or weight-for-length in an evidence-based manner.

Although there are some minor differences between various growth charts derived from different populations across the world, the 50th centiles are fairly similar and the selection of which growth charts to use is not critical (137-140). From a clinical, weight-estimation perspective these differences are insignificant.

[11] Photocopies may be blurred or asymmetrically distorted which may render them inaccurate or impossible to use with any precision.

[12] The 50th centile is normally used to estimate weight using the growth charts method, but a higher or lower centile may be used at the discretion of the emergency physician if the child appears to be large-for-age or large-for-length or small-for-age or small-for-length. There is no formalised evidence to substantiate this method as yet, however.

2.3.5 Tape and table methods

Tape and table methods are techniques which require the healthcare provider to first measure the length of the child, normally with a tape-measure, and then read the estimated weight off a table of weight-for-length values.

2.3.5.1 The Oakley chart

The Oakley method was developed in 1988 using a reference chart from which weight could be read after the child's age was determined or height or length was measured. It is similar in principle to the growth chart method. It has been widely used in some parts of the world, but the chart can only be found in the original publication (116). This method has been found to significantly underestimate the weight of children, especially in children >25kg (12).

This chart is derived from very old growth charts and is a little time consuming to use. In their current form they probably have no further role to play in the ED in a modern, more corpulent population.

2.3.5.2 The DWEM table

The devised weight-estimating method (DWEM) was developed in 1986 and validated in a small population of 258 children. The authors produced a table of

weights for children with slim, average and heavy frames at 50mm intervals of length based on the 5th (slim), 50th (average) and 95th (heavy) 1979 NCHS weight-for-length growth chart centiles. This method involves measuring a child's length, assessing their frame size and habitus and then reading the appropriate weight off the table. Although this is a technique that has been validated, and shown to perform marginally better than the Broselow tape in other studies (12, 118), it has not seen much clinical use since its inception, perhaps because it is a little more complex than other methods. It was developed before the Broselow tape appeared in the scientific literature in 1988 and may well have been more widely used if not for the success of the Broselow tape.

The DWEM technique has proven itself in several studies to be the most accurate weight-prediction system ever developed, outperforming even the Broselow tape when the two methods were compared in the same population of children (12). It requires a copy of the tables, and the skill to be able to make accurate habitus assessments, however. This technique has been underused in the ED.

2.3.6 Other length-based methods

There are two other length-based formulas for predicting body weight in children developed by Scott Traub in the early 1980s, both of which are equations designed to predict a child's weight at the 50th centile of the 1979 NCHS weight-for-length growth charts from a measurement of length. They have appeared only once in the scientific literature (see below) since their original publication and are not in general clinical use.

2.3.6.1 The Traub-Johnson formula

$$\boldsymbol{Weight\ (kg) = 2.05 \times e^{0.02X}}$$

Equation 2-14 The Traub-Johnson formula for children aged 1 to 18 years.
X = height or length in cm.

2.3.6.2 The Traub-Kichen formula

$$\boldsymbol{Weight\ (kg) = 2.396 \times 1.0188^{X}}$$

Equation 2-15 The Traub-Kichen formula for children over 74cm and aged 1 to 17 years.
X = height or length in cm.

These two formulas were evaluated in a recent study in Australia along with the APLS formula, the Oakley and DWEM tables and the Broselow tape (12). Although included in the data presented in the study, the authors made no comment about the performance of these older formulas. While they concluded that the Broselow tape and DWEM methods were the most accurate, a review of the data that they included in their paper showed that the Traub-Johnson and Traub-Kichen formulas performed as well as the Broselow tape in children between 10 and 40kg and performed poorly in children over 40kg. This data was incomplete, however, and does not allow for sound conclusions.

These equations are intimidating to the non-mathematically inclined emergency physician and require the use of a scientific calculator. This makes them

vulnerable to failure (the inability to use them) and to errors which might not be readily or intuitively detectable.

2.3.7 Tape methods

2.3.7.1 The Broselow tape

The Broselow tape was first introduced in 1988 as a rapid method of determining drug dosages and emergency equipment sizing in paediatric emergencies based on the patient's length as measured directly using the tape itself. The Broselow tape is in effect a full-scale depiction of the NCHS 2000 weight-for-length growth chart, with the weight divisions of the tape representing the 50th centile. The tape is calibrated in kilograms rather than any measurement of length, and information relating to drug dosaging or equipment sizing may be found within each weight division (or within each colour zone on the latest version of the tape). This is a rapid easy-to-use system that has remained mostly unchanged for the last 2 decades and has gained world-wide popularity; the companion manual providing more complete drug dosage and infusion information was introduced in 2006 (2).

In the original validation study the weight estimations by the Broselow tape were within 10% of actual weight in just under 60% of the study population, but within 10% of actual weight in only about 50% of the children over 25kg of body weight. The main weakness of the Broselow system, which is the same for all length-

based systems[13] with the exception of the DWEM table, is the inability to account for weight variability in children who have a higher or lower than average weight-for-length.

Many studies have shown the Broselow tape to be superior to age-based formulas for estimating weight in children (10, 12, 49, 66, 73, 114-116, 127, 130, 136, 141-146), but only two reliable studies (48, 74, 142) have actually shown the Broselow tape to perform with accuracy close to that demonstrated in the original study (49). At least four well-structured studies have shown the Broselow tape to significantly underestimate weight, especially in overweight children and in any children >25kg (12, 56, 118, 147).

The advocates of the Broselow tape have, with considerable justification, promoted the use of the tape as a valuable resuscitation aid rather than just a method to estimate weight (1, 6, 7, 65, 66, 72, 83, 84, 86, 87, 130, 141, 145, 146, 148-156). The Broselow tape has a recently-released companion booklet, the *Broselow paediatric resuscitation medication/infusion guide* (2), which was designed to provide additional information on drug preparation prior to administration (dilution and volume to be delivered) and drug infusion preparations. The combined use of this booklet with the Broselow tape fulfils all of the requirements of an ideal resuscitation aid.

[13] Age-based systems are vulnerable to error in children who are small-for-age or large-for-age; length-based systems are similarly susceptible to error in children who have a lower or higher than average weight-for-length. The DWEM system is unique amongst all the weight estimation systems in that it includes more than a single variable in the weight prediction methodology (length and body habitus).

The Broselow tape remains the best method of weight estimation in the ED to date because of its role as a resuscitation aid and because there is no other system that estimates weight more accurately (94).

Since the Broselow tape has been the most widely used weight estimation device for the last two decades, it has also been the object of the most critical review in the scientific literature. It is only relatively recently that concerns have been raised about the accuracy of weight estimation by the Broselow tape (10, 12, 74, 114, 115, 118, 133, 142, 147, 157) primarily because of the increasing prevalence of obesity in children (115). To a lesser extent, because of the increasing focus on the use of complete resuscitation aids, the *format* of drug dosage presentation that is used on the Broselow tape has been debated (71, 77, 94, 158, 159).

Some of the concerns relevant to the use of the Broselow tape in South Africa include:

- It has not been formally validated in a South African population.
- It has been shown to underestimate weight in overweight children (115) and overestimate weight in underweight children (10). As a result it has proved to be inaccurate in populations where a significant proportion of children are above average weight-for-length (populations with a high prevalence of overweight and obese children) (114) or below average weight-for-length (populations with a significant number of malnourished children) (10, 61). Since the number of overweight children is increasing in many countries worldwide, including South Africa (160), the potential for an escalating underestimation of weight is concerning. There is also, on the other hand, a sizeable population of

undernourished children in South Africa who are at risk of having an overestimation of weight. Our population is thus at risk at both ends of the spectrum for inaccurate weight estimation. Ethnicity may also have a role in the accuracy of the performance of the Broselow tape as it has been shown to be more accurate in some populations than in others. It underestimates weight in Maori and Pacific Island populations (114), overestimates weight in Indian children (10) and it performs with the same degree of precision in Korean (143, 144) and Hong Kong children (116) as it did in the original study population. How this might apply to an ethnically heterogeneous population like that found in South Africa is unknown. Although the divisions of the Broselow tape have been updated as a result of new information from the most recent NCHS 2000 growth charts, its design characteristics – to never overestimate weight[14] – make it vulnerable to errors in underestimating weight.

- The Broselow tape contains drug information for drugs that are not available in South Africa (eg. fosphenytoin), or drugs that are known by a different generic name in South Africa (eg. epinephrine instead of adrenaline). The lack of "internationalisation" or the production of an international edition has been criticised for this reason (10, 116).

[14] Although not stated in any of the literature from the manufacturers of the Broselow tape, it is likely that this was a deliberate design to avoid the possibility of overdosing children as a result of overestimating weight. This design philosophy has two interlinked potential problems: firstly there is an increased likelihood of underestimating the weight of children who are on or above the 50th centile of weight-for-length; secondly, there is a consequent risk of administering medications in a dose that might not be effective, or not optimally effective, to the potential detriment of the emergency management. There is no evidence to show which approach (*must avoid overdose* or *must avoid lack of efficacy*) is correct or that actual patient harm has occurred from under- or overdosing based on tape-predicted weight.

- The tape also contains drug dosage information with no guidance about the preparation, dilution and delivery of the drug. Institutional, local or national policies may vary on the exact method of drug preparation and delivery in children, but this information should ideally be presented in such a manner as to make calculations unnecessary and errors negligible. The companion reference to the Broselow tape, the *Broselow paediatric resuscitation medication/infusion guide*, was developed to supplement the information of the Broselow tape in this respect (6, 65, 66).

2.3.7.2 The Blantyre tape

The Blantyre tape was developed in Malawi in 1999. The authors developed the Blantyre tape because the Broselow tape overestimated weight in their community and because they did not have the same drugs available that were represented on the Broselow tape (61). It is a hand-drawn tape with divisions at 50mm intervals corresponding to a weight reflecting 85% to 90% of the 50th centile of the NCHS 2000 weight-for-length chart. The validation study of the tape had some methodological flaws in the design and analysis, most notably that a large margin of error in weight estimation (20%) was considered acceptable. The tape is still in use in the Queen Elizabeth Central Hospital in Blantyre but has not been tested in subsequent studies.

2.3.7.3 The Sandell tape

The Sandell tape is similar to the Broselow tape in that it contains information on drug dosages and emergency equipment sizes related to body length. It is a book-sized fold-out tape based on the 1996 UK growth charts and was designed principally for the prehospital environment. There are no published studies in the peer-reviewed literature describing its development or assessing its accuracy. It is used by ambulance services in the UK and is endorsed by the Joint Royal Colleges Ambulance Liaison Committee.

2.3.7.4 The PREM tape

The Paediatric Resuscitation Emergency Management (PREM) tape system was also designed in the UK, based on the UK 1996 growth charts, and is different to the other existing tapes in a number of important aspects: firstly, the tape is disposable; secondly, this tape is used exclusively for weight estimation; and thirdly there is an accompanying booklet designed to be used with the tape to assist with drug dosaging and equipment sizing. However, there are no published studies in the peer-reviewed literature describing its development or validating its accuracy.

2.3.7.5 The Kloeck tape

The Kloeck tape is an inexpensive, laminated paper tape that was developed in South Africa by Walter Kloeck because of the prohibitive cost of the Broselow tape. One side is printed as a regular tape-measure and the other side has the same colour zones as the Broselow tape. A child's length will determine into which colour zone they fall; their position within the zone will determine their weight (eg. if a child's heel crosses the tape at the beginning of the yellow zone, their weight is 12kg; if at the middle, 13kg; if at the end, 14kg). This tape-based technique has not been validated in a clinical study.

2.3.7.6 The PAWPER tape

2.3.7.6.1 Characteristics of the PAWPER tape

The PAWPER tape was developed in South Africa by the principal investigator in order to increase the accuracy of emergency weight estimation in children. This is done by including both a measure of length and of body habitus in the methodology. With the PAWPER tape once a length-based weight has been estimated in a child (in much the same manner as any of the other tape systems) this weight can be modified according to the child's body habitus. The weight can be adjusted up or down or left unchanged based on whether the child is thought to be overweight, underweight or of average weight, respectively. The weights for children with above or below average weight-for-length can be found on the tape itself, within each weight division.

There is a good deal of evidence that children should be resuscitated in teams and that the team should make use of resuscitation aids (see section 2.2.2) (92, 93). There is no ideal, complete, self-contained resuscitation aid available yet. Most currently used systems employ a combination of resuscitation aids to optimise medical therapy in children: a tape-based system for weight estimation and then a supplementary reference source for additional critical information that might be required during a paediatric resuscitation (94). The manufacturers of the Broselow tape have adopted this system.[15] Although this may have the disadvantage of requiring two separate items of emergency equipment, it has the considerable advantage of ensuring a rapid and accurate method of weight estimation combined with a comprehensive and evidence-based drug dosaging guideline system that can be used by the entire resuscitation team.

The PAWPER tape itself contains no additional information on drug dosaging or equipment sizing because it was designed to be used in conjunction with an accompanying resuscitation aid booklet (3) that provides comprehensive information on drug dosaging and equipment selection.

[15] The Broselow tape system has equipment size and drug dosage information on the tape itself with additional instructions for dilution and delivery to be found in the companion manual.

2.3.7.6.2 How does the PAWPER tape differ from the Broselow tape?

The reasoning and motivation behind the construction of the PAWPER tape is somewhat different to that of the Broselow tape. In many ways it is easiest to emphasise some of its features by differentiating them from the Broselow tape:

1. In the patent applications, the Broselow tape is described as primarily a device to predict medication doses and equipment size based on a child's length. The PAWPER tape is designed solely to estimate weight in children with the drug dosaging information obtained from the *Emergency drug dosing in children* booklet, or similar reference material.
2. The Broselow tape is a multi-use device, and costs about R500. The PAWPER tape is a single use, disposable device, projected to be available at a cost of less than R10.
3. The Broselow tape is based on the American NCHS 2000 growth charts. The PAWPER tape is based on the WHO 2006 growth charts.
4. The PAWPER tape reflects the 50th centile in the centre of each weight division; the Broselow tape reflects the 50th centile at the distal edge of the weight division. In other words, the PAWPER tape would predict an actual weight of 13.8kg to be 14kg, while the Broselow tape would be more likely to predict an actual weight of 13.8kg to be 13kg. See Figure A1-1.
5. The Broselow tape has no means of increasing the weight estimation accuracy in children who are large or small for length. The PAWPER tape includes approximations of the 5th, 15th, 85th and 95th WHO 2006 weight-for-length centiles, with a method to adjust the weight according to the frame size or degree of adiposity of the patient.

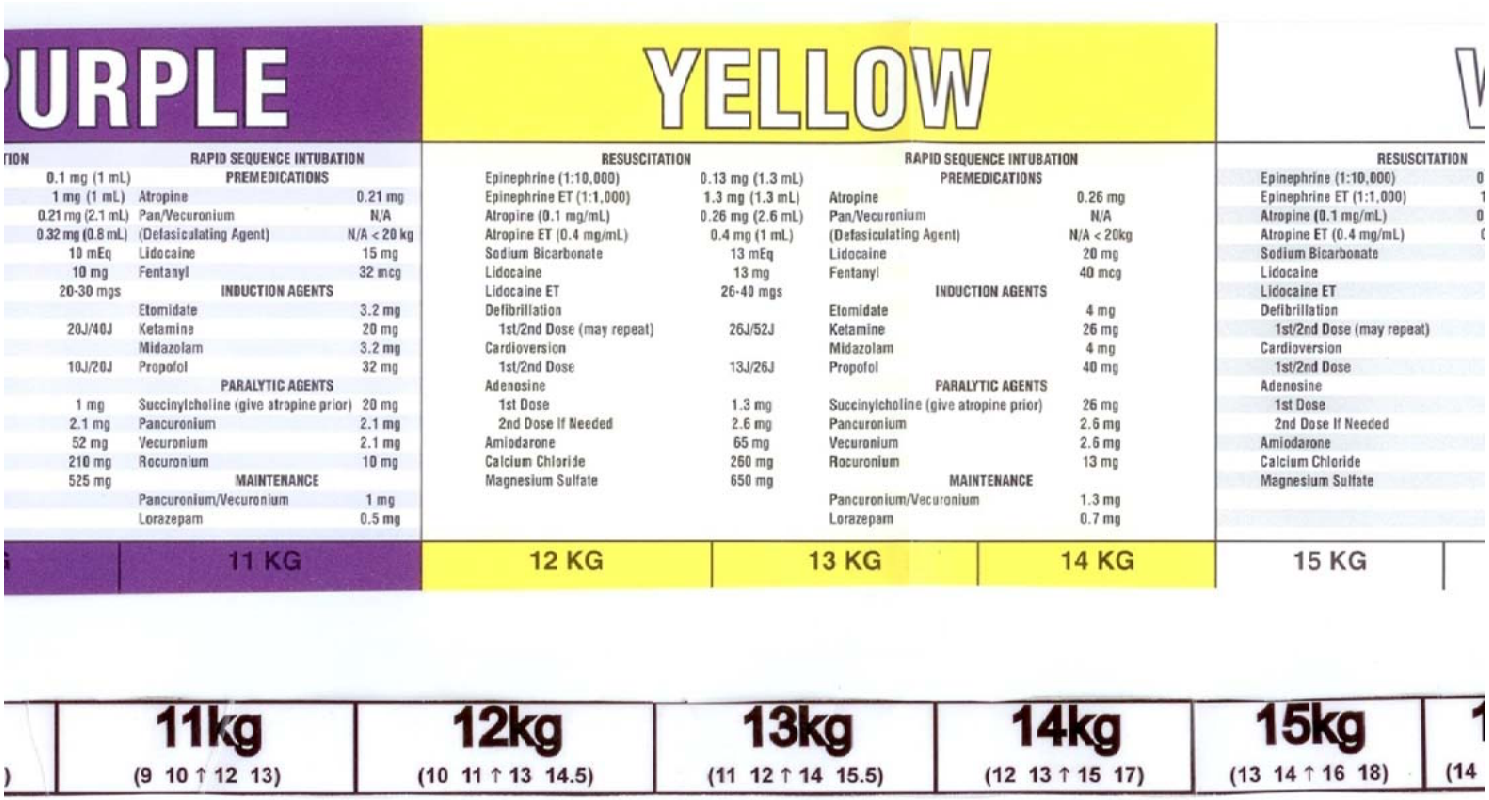

Figure 2-3 A segment of the Broselow and PAWPER tapes.

This image of the 11kg to 15kg segments of the Broselow tape (top) and PAWPER tape (bottom) is shown to allow for comparison between the two tapes. The PAWPER tape is much smaller and is printed on only one side as the information it contains is exclusively for weight estimation: the large numbers are the primary length-based weight estimates and the smaller numbers are the modified weight estimates that correspond to the habitus score 1, 2, 4 and 5. The weight divisions of the PAWPER tape are slightly “left-shifted” compared to the Broselow tape. The Broselow tape is divided into “colour zones” each with separate weight categories. Emergency equipment sizing and basic drug dosaging information for commonly used emergency drugs is provided for each colour zone, with both sides of the tape used for this purpose. Only the drug doses are provided - the user is required to decide on the method of drug preparation, dilution and delivery. *Images of the Broselow and PAWPER tapes used with permission.*

2.3.8 Other methods of weight estimation

2.3.8.1 The hanging leg-weight technique

The “hanging leg-weight” technique was developed in 1990 by Anthony Haftel and a group of emergency physicians from the Los Angeles Children’s Hospital (161). They measured a hanging leg-weight in a group of 100 anaesthetised children with a spring scale: both legs were suspended in a sling around the heels which was then raised to 45° from the horizontal, at which point this weight was recorded. They compared this weight with total body weight and found it to predict body weight accurately, especially in children >10kg body weight. More than two-thirds of children had an estimated weight within 10% of actual body weight using this method.

$$\boldsymbol{Weight\ (kg) = (5.176 \times X) + 3.487}$$

Equation 2-16 The Haftel formula.
X = hanging leg-weight in kg.

This technique has not been validated in further studies since the original publication and is not in widespread clinical use.

2.3.8.2 The infant foot-length technique

In 2006 a group of paediatricians from the KEM Hospital in Mumbai, India, under the leadership of Sandeep Bavdekar, developed a formula to estimate weight in infants up to the age of 2 years by means of a measurement of foot-length (59).

$$\boldsymbol{Weight\ (kg) = -5.15 + (X \times 1.35)}$$

Equation 2-17 The Bavdekar formula.
X = foot length in cm.

Foot-length was shown to be highly correlated with body weight and is an interesting concept for use in infant resuscitations. The authors created a table of foot-length (in 1mm increments from 45mm to 80mm) with the corresponding weight (0.94kg to 5.67kg) and doses of resuscitation drugs. Although this study had some methodological weaknesses in its analysis with respect to the accuracy and precision of the technique, it nonetheless appears to be very promising. It has not been studied subsequently either in India or elsewhere, and would need to be validated in a population without the high prevalence of malnutrition noted in this study.

2.3.8.3 The Carroll technique

Another technique described by Carroll and colleagues in 2001 (162) derived a formula to predict weight from the combination of an age-based weight prediction

formula; shoe-size; and mid-arm circumference. While they described a remarkable concept it would be too cumbersome for emergency use in the ED.

2.4 What degree of accuracy in drug dose determination is required in paediatric resuscitation?

There is very limited data available regarding the optimal drug dose for children for many agents and, in fact, children are in double jeopardy for potential over- and under-dosing (163). If studies have not been done to establish the appropriate dose to achieve therapeutic levels then the child may be at risk of all the potential risks without any of the benefits. The determination of an acceptable accuracy of drug dose administration during paediatric resuscitation may be confounded by additional factors that might change the therapeutic effect of a particular drug:

- The specific drug characteristics. A drug such as phenobarbitone has anticonvulsant activity that is directly related to the serum drug level: the higher the level the greater the effect (without substantial increases in side effects). Thus some overdosing is not likely to have major adverse effects, but will actually increase drug effect. On the other hand, a drug such as aminophylline has a very narrow therapeutic range so that overdosing can have severe toxic side-effects. Other emergency drugs have very wide range between therapeutic levels and toxic levels. Drug levels also relate to factors such as fat and water solubility, rates of redistribution in the body (eg thiopentone) and rates of metabolism and excretion (which are closely related to issues such as renal and hepatic function) (133, 164).

- The available drug preparations. There is a statutory regulation controlling the amount of active drug in any preparation which usually permits a 10% error in drug content. It may not then be useful to have a drug dosing accuracy (or weight estimate) that is more accurate than that (165).
- The method of administration. Whether a drug is given as a standard bolus dose or whether in fact it is titrated to effect (as may be the case with agents such as morphine in the emergency setting) make a significant difference to the required accuracy of drug dose determination (166, 167).
- The resuscitation given to the child. The drug levels in serum are likely to be profoundly altered by large volumes of fluid in resuscitation, by large quantities of protein (as would be given with serum products or albumen) and by other drugs and electrolytes given to the child.
- The pharmacokinetic characteristics of the child in terms of body composition (lean body weight and body fat percentage), age and gender.
- The specific underlying pathological processes that have brought the child to medical attention as well as the non-specific changes that may occur as a result of critical illness (164, 168).

With these factors in mind, there is a range of opinion in the literature as to what level of accuracy is required in dose estimation based on the implications of that accuracy for therapeutic effect.[16] Specifically, the balance between a possible lack of efficacy and a potential toxic effect from overdose is important. Some authorities consider a drug dose accuracy of ± 20% to be acceptable (30, 66, 76, 147, 169)

[16] An actual drug dose that was administered outside of this range would be considered to constitute a medication dosing error.

and some prefer a range of ± 10% (41, 115, 125, 170). The most realistic reports, however, distinguish between limits of tolerance for different types of medications (8). Thus a margin of error of ± 25% would be acceptable for antibiotics, steroids, and opioids, a margin of error of ± 20% tolerable for antipyretics, benzodiazepines, paralytic agents, glucose and anticonvulsants but a margin of error of ± 10% would be required for cardiac arrest medications, induction agents, inotropic or vasoactive medications and insulin.

This concept is important to define the required accuracy of a weight-estimation system (see section 5.2 for further discussion). Since an accuracy of ± 10% is required for the administration of many drugs used in paediatric resuscitations to be acceptable, it is desirable for a weight estimation system to perform with similar accuracy. While there are as yet many factors relating to drug dosage determination that have to be satisfactorily resolved, we can only work to ensure that those within our understanding, such as weight estimation, are optimised.

2.5 Should TBW be the end-point of weight estimation systems in the emergency department?

This is important because it impacts on the assessment of accuracy of weight estimation systems and the development of new systems in the future. The manufacturers of the Broselow tape, in response to recently published reports of poor performance by the Broselow tape in several different populations, have claimed that the tape actually predicts IBW in children. Therefore, although it might

underestimate TBW, it is a good predictor of the weight that some experts believe should be used for drug dosage calculation in the ED (49, 65, 66, 86).

This argument hinges on their assumption that IBW and the 50th centile of weight-for-length coincide: this was based on work done by Traub and Kichen in 1983 where, for their study, they *defined* IBW as the 50th centile of weight-for-length (52). More recent work has shown that the determination of IBW in children is controversial and that the different methods provide widely divergent estimates of IBW especially in older children, those tall-for-age and short-for-age. IBW also varies with age and cannot be predicted by length or weight exclusively and is actually probably best estimated by using BMI-for-age (171-177). It is also imperative that IBW should not be used in emaciated children or in children with a lower than average weight-for-length as this might result in a dangerous overdosing of medications.

There is no work that has been published on weight estimation techniques or emergency medication dosaging based on IBW in children. The selection of the best form of weight to use for the determination of drug doses in the ED is, however, a critical issue that may affect weight estimation techniques. It is unknown whether we should be using TBW, IBW, LBW or ABW for drug and fluid dosaging in normal, overweight or obese children.

The proposition that certain drugs should preferentially be dosed according to IBW (or even LBW) rather than TBW is possibly true, but for the most part unproven and varies from drug to drug (133). Much is unknown about the pharmacology of

many drugs in normal children, let alone those with critical illness or injuries, the obese child or the underweight child (164, 166, 167, 178-183).

- Hydrophilic drugs (such as adrenaline and sodium bicarbonate) should probably be dosed according to IBW or ABW in the obese patient (>95th weight-for-length centile), but according to TBW in a child that falls within the weight-for-length centiles. Again, it is uncertain whether or not the volume of distribution is important in the pharmacology of the initial and immediate effects of intravenous or intraosseus resuscitation medications (133).
- The initial doses of lipophilic drugs (such as benzodiazepines and amiodarone) should be dosed according to TBW, with only subsequent doses or infusions reduced. Increased vigilance and monitoring are essential in the obese child whenever medications are administered: to assess the need for further drug administration and to observe for side effects if inadvertently overdosed.

Children within the weight-for-length centiles should almost certainly be dosed according to TBW until evidence to the contrary emerges. There is very little evidence about how we should manage the emergency drug dosaging strategy in obese children (those above the 95th centile of weight-for-length). This means that, until new evidence emerges, weight estimation systems should continue to use TBW as their primary endpoint. In children with exceptionally high or low percentages of body fat, the resulting drug dose calculation may require a dose adjustment which should be left to the discretion of the emergency physician.

Other techniques such as bioelectrical impedance (173, 176, 177, 184-188) may still prove useful to provide some quantification of body composition and improve weight estimation in children with extreme body types. Future work will also need to determine which form of weight (TBW / IBW / LBW) best represents the "pharmacokinetic mass" of the critically ill or injured child that requires resuscitation (133).

2.6 A summary of paediatric weight estimation in the emergency department

In the practice of paediatric emergency medicine the ideal weight estimation system is a user-friendly method that reliably predicts weight within 10% of measured weight across a wide spectrum of populations, age groups and body habitus types. While none of the currently available weight estimation systems are perfect, the length-based systems are considerably better than the others (see Figure 2-1 which shows the advantageous characteristics of each of the currently available methods). The ideal system, in 2009, needs to satisfy as many of the requirements of a resuscitation aid as possible, and although no weight estimation system is complete in its own right - including the Broselow tape (6, 65) - a tape can be used to estimate the child's weight and another reference source can be used to provide comprehensive drug dosaging and equipment guidelines according to appropriate local standards and protocols.

Emergency weight estimation is likely to develop along two lines: firstly with the use of a measure of habitus included in the length-based estimation technique (two authors have already suggested this need (65, 133) and it has already proved

its worth in the DWEM methodology); and secondly with the addition of a rapid assessment of body composition by methods such as bioelectrical impedance.

Chapter 3 MATERIALS AND METHODS

3.1 Ethics

This research was approved by the Human Research Ethics Committee of the Faculty of Health Sciences of the University of the Witwatersrand (protocol approval number M080413 - see Appendix 4). Informed consent was obtained from either a parent or legal guardian of all children enrolled in the study and, in addition, assent was obtained from all children over the age of 7 years.

3.2 Study Design

This was a prospective, observational, hospital-based study of a convenience sample of 453 children over an 8-week period from September 2008 to October 2008.

3.3 Study Setting and Population

The study was conducted in the Emergency Department at Netcare Union Hospital and Netcare Garden City Hospital, two private hospitals in the greater

Johannesburg area.[17] These departments together receive more than 8 000 infants and children per year for emergency treatment of minor and major medical and traumatic conditions.

Inclusion criteria: children of all race and ethnic groups, aged 1 month to 12 years presenting to the Emergency Department who did not require any form of emergent management of any condition.

Exclusion criteria: failure to obtain consent; or when informed consent could not be reasonably obtained because of a child's medical condition; or when the child's medical condition was too serious to allow them to be weighed; or if emergency medical treatment precluded participation in the study; or children too short (<46cm); or too tall (>150cm) to fit within the limits of the Broselow and PAWPER tapes.

3.4 Study Protocol

3.4.1 Data collection

Data was collected on a pro forma data collection form by doctors or professional nurses in the ED who were trained in the use of the tape devices (see section 3.4.3):

[17] In South Africa, private hospitals cater for clients whose medical expenses are covered either by some form of medical insurance or by direct payment by the client. This population, while ethnically diverse, is therefore likely to be of a higher socioeconomic status than that which will be found attending the ED at a public hospital.

- Gender and age in years and months were recorded.
- The Broselow tape-predicted weights (from the Broselow Paediatric Emergency Tape 2007 Edition A) were determined, according to the directions on the tape (see section 3.4.2.1).
- The PAWPER tape-predicted weights (using the PAWPER tape version 1.1) were obtained similarly, according to directions on the tape (see section 3.4.2.2).
- The child's approximate length (in cm) was later estimated from the centre of their weight division as determined by the tape.
- The child, with heavy outer clothing and shoes removed[18], was then weighed on a digital scale to the nearest 0.1kg. The scale was calibrated according to the manufacturer's specifications.

3.4.2 The execution of the tape weight estimation techniques

3.4.2.1 The Broselow tape

The Broselow tape was used to estimate weight with the child lying supine by measuring their length with the tape. The head was kept neutral with no pillow in place. The end of the tape marked, "MEASURE FROM THIS END" was positioned

[18] This technique has been standard for most studies evaluating the accuracy of weight estimation techniques in the ED. The children were undressed to their underwear or underwear plus a light shirt / blouse and pants before being weighed. Infants with wet nappies had the nappy removed completely or a dry nappy put on. Infants able to sit were encouraged to sit on the scale without their feet touching the floor. Infants unable or unwilling to sit were weighed on an attachment that allowed them to lie on the scale.

at the vertex and the tape stretched to the child's heel with the hip and knee straight and the ankle flexed at 90°. The child's weight was read off the tape at the point where it crossed the child's heel.

3.4.2.2 The PAWPER tape

(See Appendix 1 for a full description of the use of the PAWPER tape.)
In much the same manner as the Broselow tape was used, the PAWPER tape was used to estimate weight with the child lying supine by measuring their length with the tape. The end of the tape marked, "MEASURE FROM THIS LINE" was positioned at the vertex and the tape stretched to the child's heel with the ankle flexed at 90°. The child's weight was read off the tape at the point where it crossed the child's heel.

Once this primary weight estimation was acquired, a secondary modified weight estimation was obtained through use of the habitus score technique:

- The observer executing the tape measurement performed a general visual inspection of the child in order to assign a habitus score based on their frame size and body habitus. No anthropometric techniques or specific morphological features were used for this assessment: just a general visual impression of habitus. The observer then assigned the child a habitus score from 1 to 5:

  1 – Very thin, somewhat wasted, or tiny frame (XS).

  2 – Thin, petite, slim, or small frame (S).

3 – Average body fat and frame size (M).

4 – Heavy, chubby, overweight, or large frame (L).

5 – Fat, significantly overweight or obese (XL).

- The modified weight was then read off the PAWPER tape: every weight division displays weight values that correspond to each of the 5 habitus scores.

3.4.3 Data collector training

The doctors and professional nurses who collected data for this study underwent a brief 20 minute training session on the use of the tapes. This training comprised of firstly familiarising the observers with the correct method of using both tapes and, secondly, training on how to assess body habitus.

Instruction on the assessment of body habitus was conducted by the principal investigator or other data collectors who had some experience with the techniques.

Rather than using an intensive training method using pictures of children with different body types, this training focused on the development of the practical application of cognitive image analysis[19] in the following three-step process:

[19] Cognitive image analysis refers to the method of automatic cognition that translates perceptions (images) into meaning, thoughts or ideas. The end result of image analysis is the assignment of previously stipulated terms to unknown patterns. It is essentially a three step process beginning with the perception of the image (the data acquisition), continuing with the data modelling or

- The evaluation by visual inspection of both frame size and degree of adiposity.
- The identification of each child as being of average habitus (habitus score 3) or greater than average weight-for-length (habitus score 4 or 5) or less than average weight-for-length (habitus score 1 or 2).
- The determination of whether any deviation from average was moderate (habitus score 2 or 4) or more extreme (habitus score 1 or 5) and the assignment of the appropriate habitus score value.

Observers were directed to assign habitus score values based on their perception of any deviation of the child's habitus from the average. To this end they were advised to also make use of any mental "label" evoked during the inspection to match the child to a specific habitus score, eg:

HS 1 Very thin, wasted, tiny, diminutive, little, minute, cachexic, bony, emaciated.

HS 2 Thin, skinny, slight, slender, petite, slim, small, lean, undersized.

HS 3 Average, normal, regular, standard, ordinary, typical.

HS 4 Heavy, chubby, plump, stout, hefty, overweight, large, strong, oversized.

HS 5 Fat, rotund, huge, bulky, corpulent, chunky, obese.

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analysis (the objective of this step is to assign or match terms to the acquired data) and finally the yield of a higher level of knowledge or specific contextual meaning. This analysis is made more powerful by the incorporation or fusion of semantics into the system: an unknown feature is transformed into the known by giving it a name. In this study the practise of the evaluation of body habitus was designed and taught in a manner to be as close to the process of cognitive image analysis as possible. The observer inspects the child and acquires the "image" or perception; they then match this image with respect to body habitus to semantic terms (equivalent to well below average, below average, average, above average, well above average) and finally derive the desired meaning in the conclusion of a habitus score that best matches the semantic descriptors evoked by the image.

The assessment of body habitus by general inspection has been used and validated in previous studies in experienced (4, 12) and inexperienced (12) personnel.

3.4.4 Inter-observer reliability

Fifty random[20] patients were measured by two data collectors to determine inter-observer reliability. The patient characteristics of these patients were not significantly different to that of the entire population,

3.5 Outcome Measures

The performance of the Broselow tape and the PAWPER tape (with and without modification by means of the habitus score) were compared against the actual weight (reference weight) and against each other to validate the performance of the PAWPER tape. There were a number of key outcome measures that were used for this assessment:

- The difference between the tape-predicted weights and the reference weight – a measure of estimation bias.
- The standard deviation of the residual values (the difference between the tape-predicted weight and the actual reference weight) derived from each tape – a measure of estimation precision.

[20] A random number generator was used to prospectively select 50 case numbers from the first 300 patients. These patients were used for the assessment of inter-observer reliability.

- The number of cases in which the predicted weight fell within specific estimation error categories – within 5%, 10%, 15%, 20% and 30% of actual reference weight – a measure of tape accuracy.

3.6 Sample Size Estimation

Weight categories for subgroup analysis were selected to roughly correspond to infants aged 2 years and below (≤12kg), children from 2 to 6 years of age (12.1kg to 20kg) and children over 6 years of age (>20kg). These categories fall between different ranges used in previous studies:

- ≤10kg, 10.1kg to 20kg, >20kg (118).
- ≤10kg, 10.1kg to 25kg, >25kg (12, 116).
- ≤10kg, 10.1kg to 18kg, >18kg (10).
- ≤20kg, >20kg (142).
- ≤15kg, >15kg (130).

To detect a 5% difference between the Broselow-predicted weight and the PAWPER-predicted weight a minimum sample size of 118 children was required in each subgroup to produce a power of >0.9, with a minimum aggregate of 354 children.

3.7 Data Analysis

The following descriptive statistics were used in the reporting of the data: mean with standard deviation and 95% confidence intervals for parametric and interval data; median with interquartile range for ordinal and nonparametric interval data.

The data was analysed in four basic forms to show differences between the weight predictions by each of the three techniques:

3.7.1 Correlation

Agreement between the weights predicted by the Broselow tape, the PAWPER tape, the PAWPER tape employing the habitus score modification (PAWPER + HS) and the actual measured weight was determined using Spearman correlation analysis.

3.7.2 Bias and limits of agreement

The difference between the estimated weights and the actual measured weight (the residual) was calculated for each of the three methods tested:

$$Residual\ (kg) = \ predicted\ weight - \ reference\ weight$$

Equation 3-1 Calculation of the residual value.

These residuals were used to generate Bland-Altman graphs (189-192), using a modified technique to plot the residuals against the actual measured weight (a reference value), rather than the mean of the estimated and measured weights (193). The Bland-Altman technique is a standardised analysis that is used for comparing two measurement or analysis methodologies to provide a measure of bias and precision. Using this technique, “accuracy” or “bias” is determined from the mean of the difference between the two values (predicted weight minus measured weight), while precision is determined from the standard deviation of those differences. It has been used in all previous studies that have assessed the Broselow tape.

3.7.3 Percentage error

The percentage difference (MPE) between weights predicted by the Broselow tape, the PAWPER tape, the PAWPER + HS and the reference weight were calculated:

$$Error\ \% = 100\ \times \frac{predicted\ weight\ -\ reference\ weight}{reference\ weight}$$

Equation 3-2 Calculation of the percentage error of weight estimation.

For some of the analyses an absolute value of percentage difference (AMPE) was used (this is also known as the root mean square error):

$$Absolute\ error\ \% = 100\ \times \frac{\sqrt{(predicted\ weight\ -\ reference\ weight)^2}}{reference\ weight}$$

Equation 3-3 Calculation of the absolute percentage error of weight estimation.

The difference between measured weight and that derived from the tape-predictions methods was calculated and expressed as a percentage of the actual weight more often than an absolute kilogram value. This was because a weight difference in kilograms would differ markedly from young to older age groups as weight increases with age. The percentage weight difference gave comparability across all age groups.

These percentage errors were compared and analysed using the t-test for dependent samples, both for the entire sample as well as the different genders, weight categories and habitus score values.

3.7.4 Categorical error analysis

The percentage error values of each of the measurement techniques were categorised:

- Within 5% of actual weight.
- Within 5 to 10%.

- 10 to 15%.
- 15 to 20%.
- 20 to 30.
- >30% error.

The proportion of cases falling within each error category was determined for each measurement technique for the entire population, and for subgroups of gender, weight division and habitus score value. These were then analysed using the χ^2 test.

3.8 Body Mass Index

The body mass index was calculated according to the standard formula from height and weight.[21] The centile corresponding to the BMI-for-age was determined from the NCHS 2000 growth charts for each child.

$$BMI = \frac{\text{weight (kg)}}{\text{height (m)}^2}$$

Equation 3-4 The calculation of body mass index (BMI).

Each child's BMI was evaluated according to the method of Cole et al (194) to determine whether they should be classified as overweight by comparing the actual BMI to a table of age- and gender-specific BMI limits. These limits were

[21] In this study *length* was used instead of *height*. Length was determined from the child's position on the PAWPER tape rather than by a direct measurement. This is not as accurate as an anthropometrically correct measurement of length, but introduces only a very small error (of the order of 2 to 5%) into the estimation of BMI.

produced to correspond to a BMI of 25kg/m^2 (overweight) or 30kg/m^2 (obese) at adulthood (age 18) (see Figure 3-1).

	Body mass index 25 kg/m^2		Body mass index 30 kg/m^2	
Age (years)	Males	Females	Males	Females
2	18.41	18.02	20.09	19.81
2.5	18.13	17.76	19.80	19.55
3	17.89	17.56	19.57	19.36
3.5	17.69	17.40	19.39	19.23

Figure 3-1 An excerpt of the table to determine overweight or obese state from age-related BMI. This table, which was constructed by Cole (194), shows the age- and gender-specific BMIs cut-off limits which indicate the overweight or obese child.

3.9 Reliability

The inter-observer reliability was analysed using the percent agreement method and the κ-statistic, which removes some of the bias from the percent agreement method (a value > 0.4 was considered to indicate acceptable agreement; 0.4 to 0.74 good agreement and a value >0.75 excellent agreement).

3.10 Significance level

A $p < 0.05$ was considered to be significant for all statistical tests. For convenience, all very small p values were represented as $p < 0.0001$ (rather than, for example, $p<0.00000001$ or $p = 0.00000000003$).

3.11 Software

All data was entered and stored in a Microsoft Excel® (Microsoft Office 2007, Microsoft Corporation) spreadsheet. All analysis was conducted using StatSoft, Inc. (2008) STATISTICA® (data analysis software system), version 8.0. www.statsoft.com.

3.12 Methodological limitations of this study

1. This patient population was a convenience sample derived from private hospital clientele. This might introduce bias because this patient population might not be representative of any broader population group in South Africa.
2. The study was conducted with children not requiring emergency medical treatment. Sick children were excluded, which might introduce some bias, and the emotional and cognitive stressors associated with paediatric resuscitation were not present during the performance of the tape measurements. These techniques might be more difficult and less accurate under these more challenging circumstances.
3. Ethnic origin, race, socio-economic status and gender were deliberately not included in any aspect of the PAWPER tape design or use and therefore subgroup analyses by ethnic origin and race were not performed. It is

possible that the system may perform vastly differently in different race or ethnic groups.

4. The principal investigator has previous experience in body habitus assessment – the ability to assign a condition score may not be as easy or as accurate for personnel not experienced in this field.
5. The training given to the main data collectors by the principal investigator may not be reproducible in other EDs or with other personnel.
6. The length component of the calculation of BMI was determined from the child's position on the tape, rather than a direct measurement. This potentially could have resulted in up to a 5% error (but with no bias) in the BMI.

Chapter 4 RESULTS

4.1 Basic demographic data

During the study period, 453 children were enrolled into the study, 120 in the ≤12kg group, 193 in the 12.1kg to 20kg group and 140 in the >20kg group. Consent was refused in a single case (the accompanying parent requested reimbursement for the child to participate). There were 255 (56.3%) males and 198 (43.7%) females representing a diverse spectrum of ethnic groups.

A wide range of ages (1 month to 156 months) and weights (3.1kg to 50kg) were represented. The overall mean ± standard deviation for age was 4.2 ± 3.0 years (median age 3.8 years, interquartile range 1.8 to 6.0 years). The mean ± standard deviation for measured weight was 17.9 ± 8.5kg (median weight 16.2kg, interquartile range 12.0 to 22.2kg). The age, gender and population characteristic data are summarised in Table 4-1.

Table 4-1 Population characteristics by weight subgroups.

	Weight groups based on measured weight		
	≤12kg	12.1 – 20kg	>20kg
Number	120	193	140
Age range (months)	1 to 41	12 to 97	42 to 156
Age (months) mean ±SD	13 ± 8.4	43 ± 17.9	93 ± 25
Age (months) median	11	41	90
Gender male (%)	58 (48)	114 (59)	83 (59)

4.2 Inter-observer reliability

The inter-observer agreement data on weight determination using the tape techniques and the assessment of body habitus are shown in Table 4-2. There was excellent agreement in the determination of weight using the tapes as well as the assessment of body habitus using the habitus score.

Table 4-2 Inter-observer reliability statistics for the determination of weight using the tape-based methods and the assessment of body habitus.
The percent agreement, the κ-coefficient and the 95% CI for the κ-coefficient are shown.

	PA (%)	κ-coefficient (95% CI)
Broselow tape weight	48/50 (96)	0.96 (0.89 – 1.0)
PAWPER tape weight	49/50 (98)	0.98 (0.91 – 1.0)
Habitus score	45/50 (90)	0.83 (0.65 – 1.0)
PAWPER + HS weight	47/50 (94)	0.93 (0.85 – 1.0)

The majority of the data for this study was collected by three individuals – the principal investigator and two professional nurses who did regular shifts in the ED. They collected data on over 70% of children enrolled in the study. The remainder of the data was collected by 15 other doctors or professional nurses on duty in the ED during the course of the study. The number of cases enrolled by each data collector ranged from 2 to 21. Table 4-3 shows the results of the comparative analyses between the major and minor data collectors with respect to the performance of the weight estimation systems.

Table 4-3 Comparisons in bias and precision of the PAWPER + HS technique between the major and minor data collectors.

Data for the Broselow tape is shown in blue, for the PAWPER tape in red and for the PAWPER + HS technique in green.

	Major data collectors (3)	Minor data collectors (15)	Significance
Cases (%)	324 (72%)	129 (28%)	
Residual	-1.0kg	-0.5kg	NS
	-0.5kg	-0.3kg	NS
	-0.18kg	0.06kg	NS
MPE	-4.2%	-2.6%	NS
	-1.0%	-1.0%	NS
	-0.3%	0.6%	NS
AMPE	9.0%	9.5%	NS
	7.6%	8.5%	NS
	4.1%	5.4%	p<0.01
≤10% error	65%	60%	NS
	73%	66%	NS
	91%	85%	NS

Although the AMPE of the PAWPER + HS technique was significantly different between the major and minor data collectors, the quality of the weight estimation was generally very similar. While the experienced data collectors trended towards a marginally greater bias to underestimate weight with the Broselow tape, they also trended towards a higher precision and accuracy with each of the three tape techniques.

4.3 Correlation analysis

The correlation between each of the three weight estimation methods and actual weight was excellent, with the r^2 values for the Broselow tape 0.89, for the PAWPER tape 0.90 and for the PAWPER + HS 0.97. Correlation was generally best in infants and least impressive in older children. Figures 4-1, 4-2 and 4-3 show the correlation between actual measured weight and the Broselow tape, the PAWPER tape and the PAWPER + HS technique, with Tables 4-4, 4-5 and 4-6 showing the correlation coefficients for each of the age divisions.

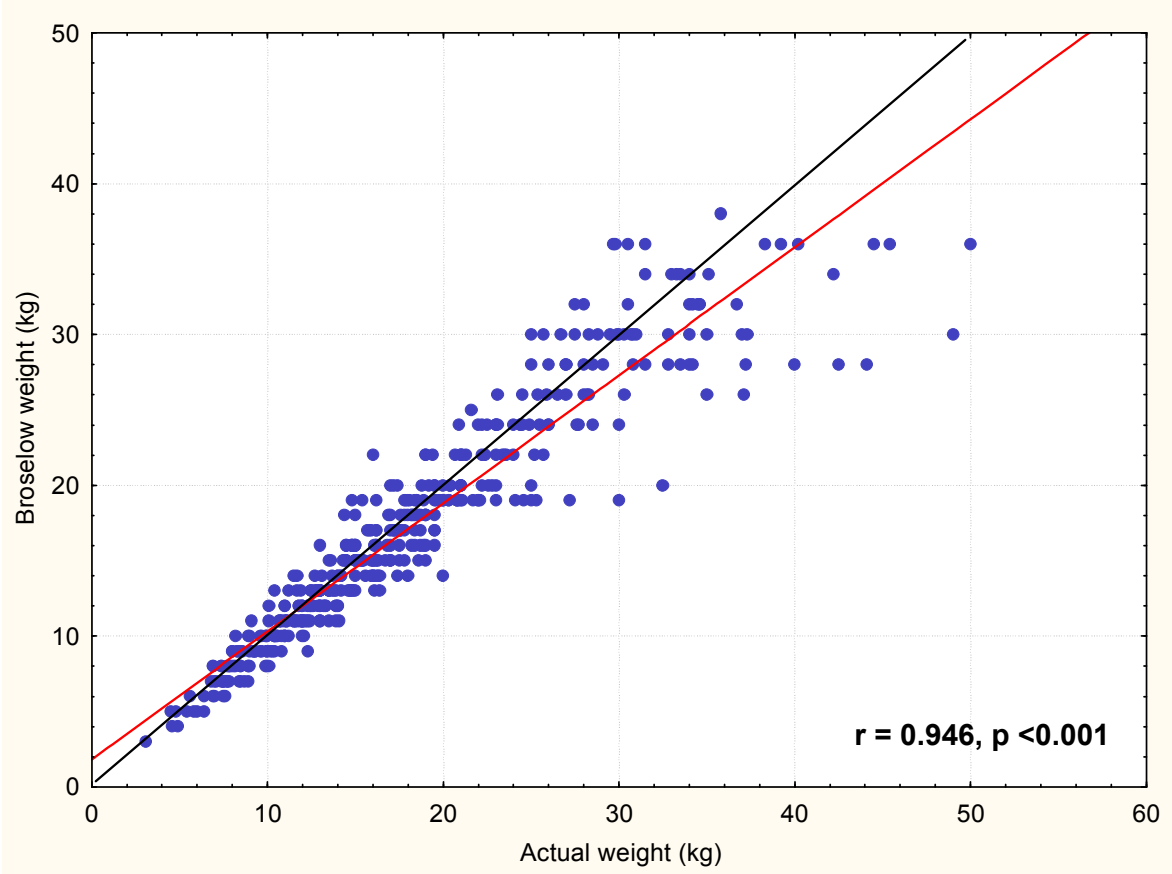

Figure 4-1 Correlation between actual measured weight and weight predicted by the Broselow tape. The black line represents equal predicted and actual weights (a correlation coefficient of 1); the red line represents a linear regression line based on the study population; the degree of divergence between the two is an indication of error in the predictive method.

Table 4-4 Correlation coefficients (r) of the agreement between measured weight and weight predicted by the Broselow tape for each weight subgroup.

	Measured weight groups			
	All	≤12kg	12-20kg	>20kg
Correlation coefficient	0.946	0.900	0.797	0.752
Significance level	p<0.001	p<0.001	p<0.001	p<0.001

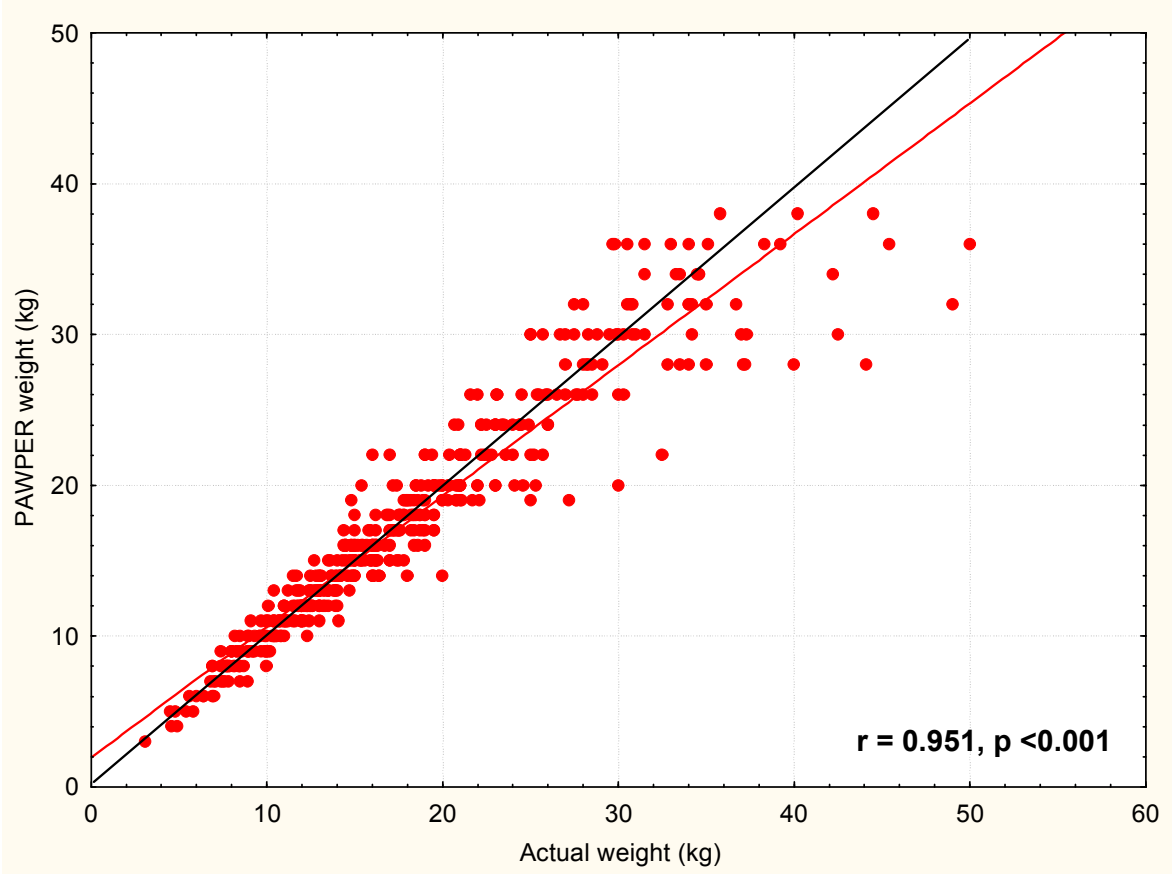

Figure 4-2 Correlation between actual measured weight and weight predicted by the PAWPER tape.

The black line represents equal predicted and actual weights (a correlation coefficient of 1); the red line represents a linear regression line based on the study population; the degree of divergence between the two is an indication of error in the predictive method.

Table 4-5 Correlation coefficients (r) of the agreement between measured weight and weight predicted by the PAWPER tape for each weight subgroup.

	Measured weight groups			
	All	≤12kg	12-20kg	>20kg
Correlation coefficient	0.951	0.921	0.821	0.769
Significance level	p<0.001	p<0.001	p<0.001	p<0.001

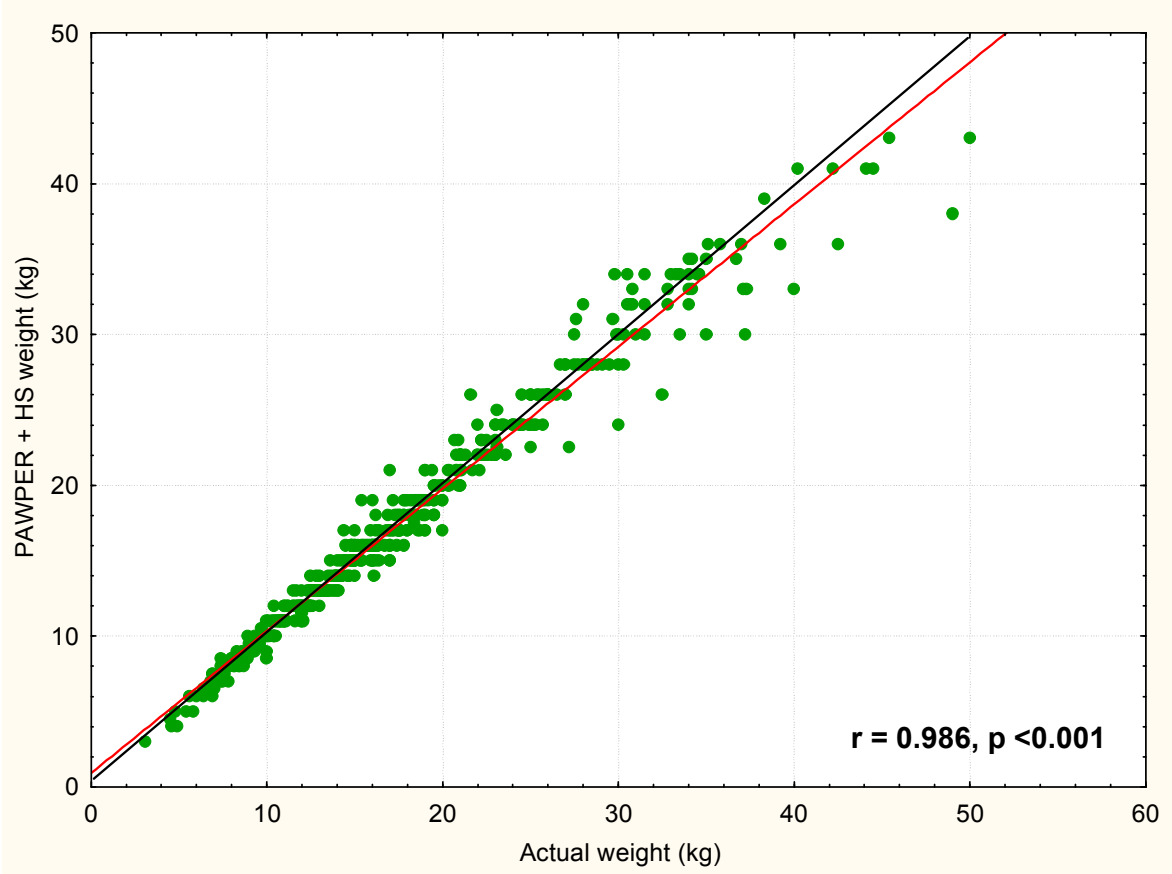

Figure 4-3 Correlation between actual measured weight and weight predicted by the PAWPER + HS technique.

The black line represents equal predicted and actual weights (a correlation coefficient of 1); the red line represents a linear regression line based on the study population; the degree of divergence between the two is an indication of error in the predictive method.

Table 4-6 Correlation coefficients (r) of the agreement between measured weight and weight predicted by the PAWPER + HS technique for each weight subgroup.

	Measured weight groups			
	All	≤12kg	12-20kg	>20kg
Correlation coefficient	0.986	0.970	0.915	0.941
Significance level	p<0.001	p<0.001	p<0.001	p<0.001

4.4 Analyses of tape performances in the entire population and in the weight sub-categories

4.4.1 Parametric analyses of tape bias and precision

4.4.1.1 Bland-Altman analysis

The overall bias of each of the weight estimation methods, as demonstrated by the Bland-Altman methodology, was an underestimation of weight by 0.9kg, 0.4kg and 0.1kg for the Broselow tape, the PAWPER tape and the PAWPER + HS technique respectively ($p<0.0001$ for each comparison). The precision, reflected by the 95% confidence limits of the Bland-Altman methodology was -6.3kg to 4.5kg, -5.6kg to 4.7kg and -2.9kg to 2.7kg for the Broselow tape, the PAWPER tape and the PAWPER + HS technique respectively ($p<0.0001$ for each comparison). Figures 4-4, 4-5, 4-6 and 4-7 show Bland-Altman plots for each of the three weight estimation techniques for the entire study population and for each of the three weight categories. The Bland-Altman plots are positioned on the same page to allow for comparison between the three techniques.

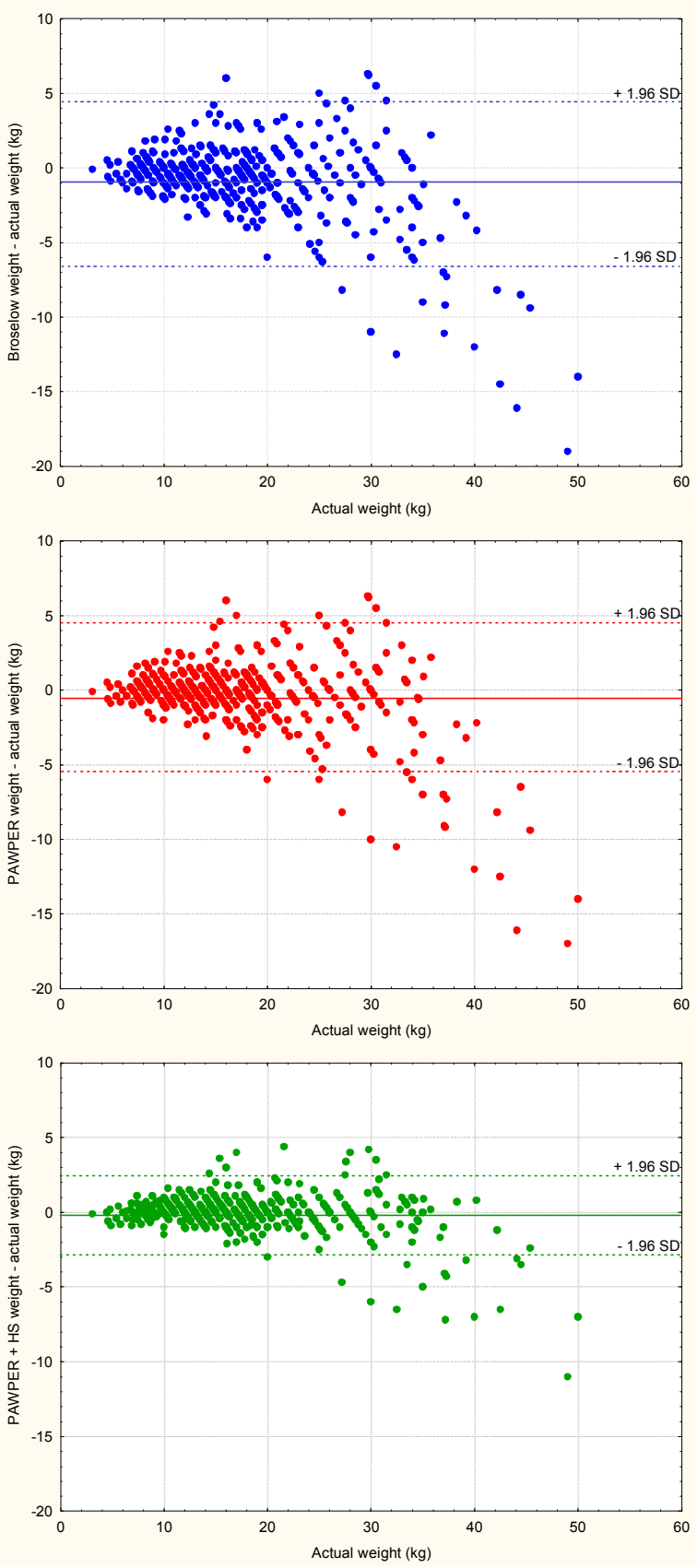

Figure 4-4 Bland-Altman plot illustrating the bias and limits of agreement for the entire study population.

The chart displays the difference between the actual measured weight and the weight predicted by the Broselow tape (top graph with blue markers), the PAWPER tape (middle graph with red markers) and the PAWPER + HS technique (bottom graph with green markers). These graphs plot the residual (predicted weight - actual weight) against actual weight. The solid line represents the bias and the dashed lines represent the 95% confidence intervals for the prediction (the limits of agreement or precision).

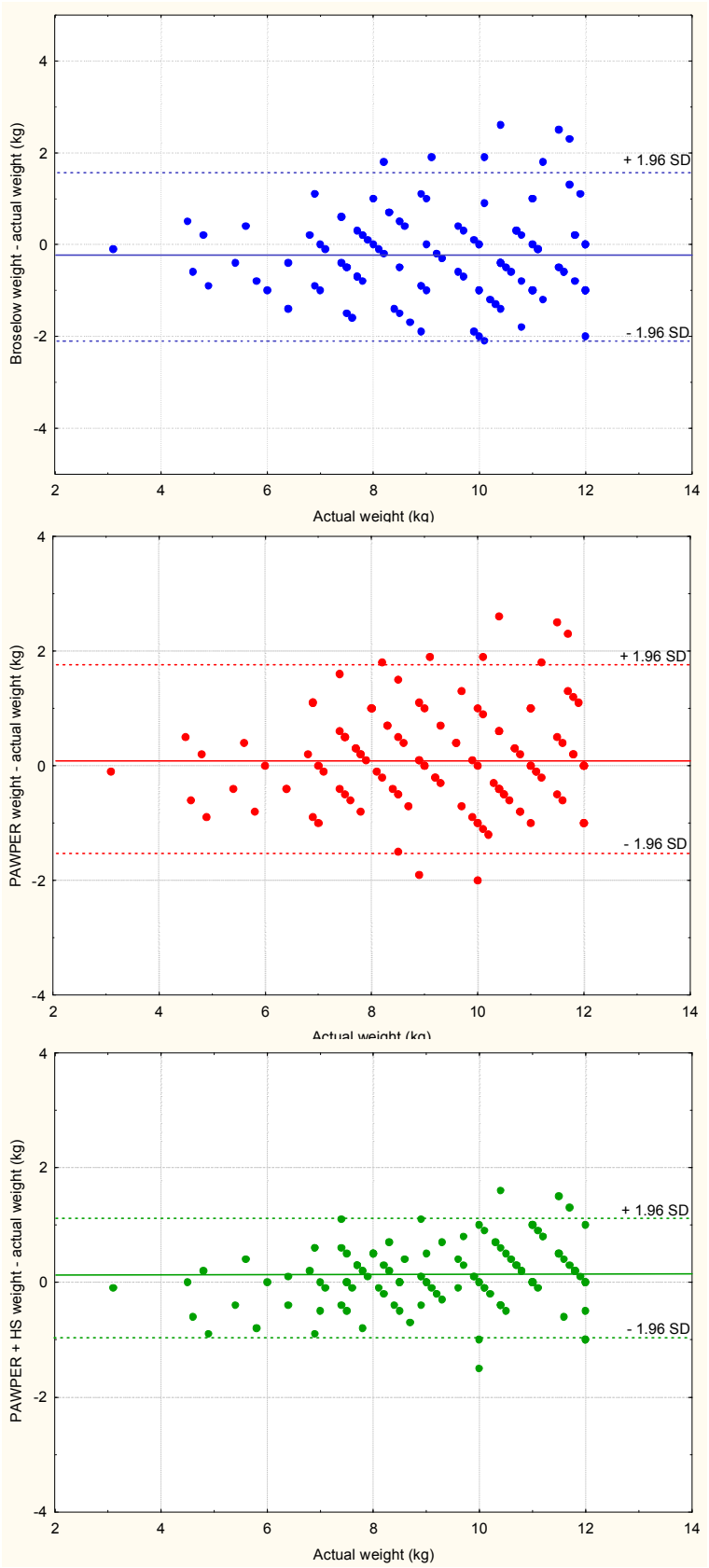

Figure 4-5 Bland-Altman plot illustrating the bias and limits of agreement for the cohort of patients with a body weight of ≤12kg.

The chart displays the difference between the actual measured weight and the weight predicted by the Broselow tape (top graph with blue markers), the PAWPER tape (middle graph with red markers) and the PAWPER + HS technique (bottom graph with green markers). These graphs plot the residual (predicted weight - actual weight) against actual weight. The solid line represents the bias and the dashed lines represent the 95% confidence intervals for the prediction (the limits of agreement or precision).

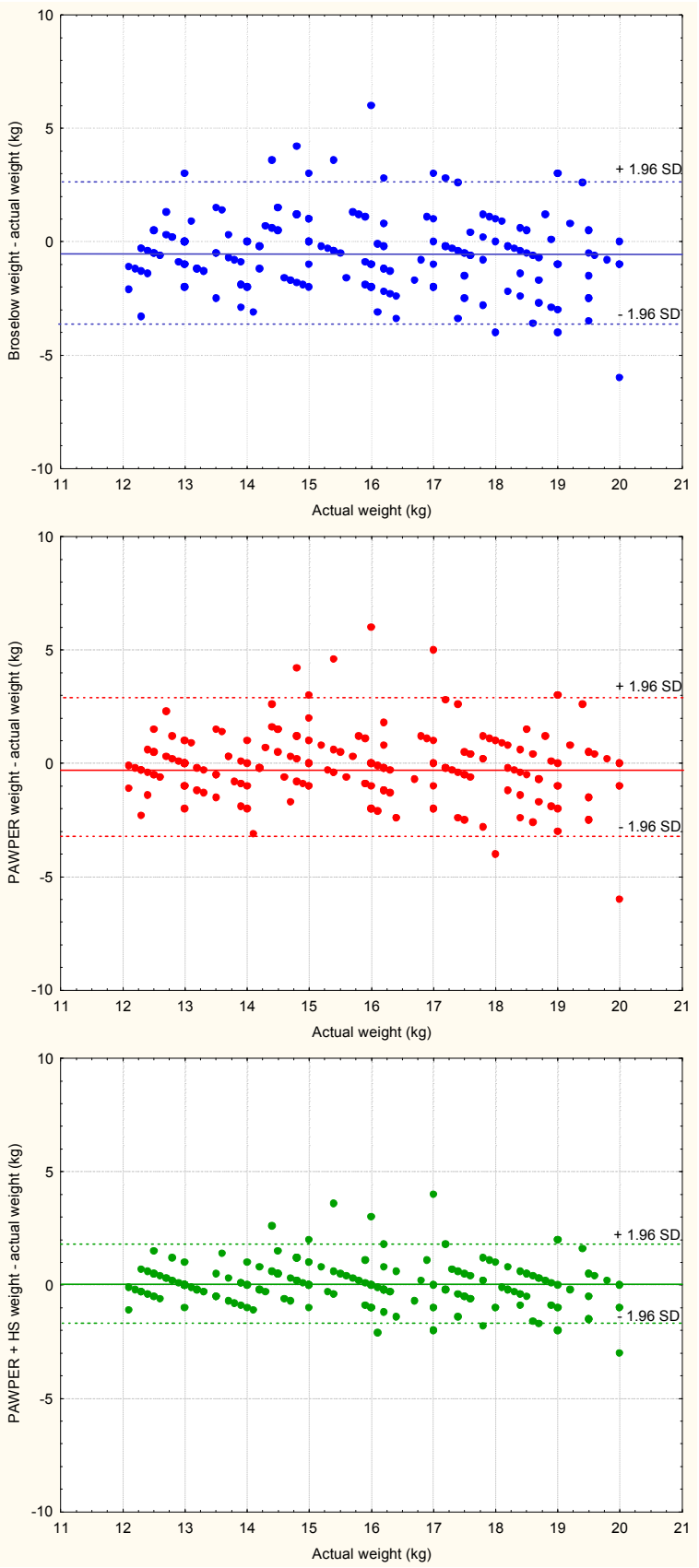

Figure 4-6 Bland-Altman plot illustrating the bias and limits of agreement for the cohort of patients with a body weight of 12.1 to 20kg.

The chart displays the difference between the actual measured weight and the weight predicted by the Broselow tape (top graph with blue markers), the PAWPER tape (middle graph with red markers) and the PAWPER + HS technique (bottom graph with green markers). These graphs plot the residual (predicted weight – actual weight) against actual weight. The solid line represents the bias and the dashed lines represent the 95% confidence intervals for the prediction (the limits of agreement or precision).

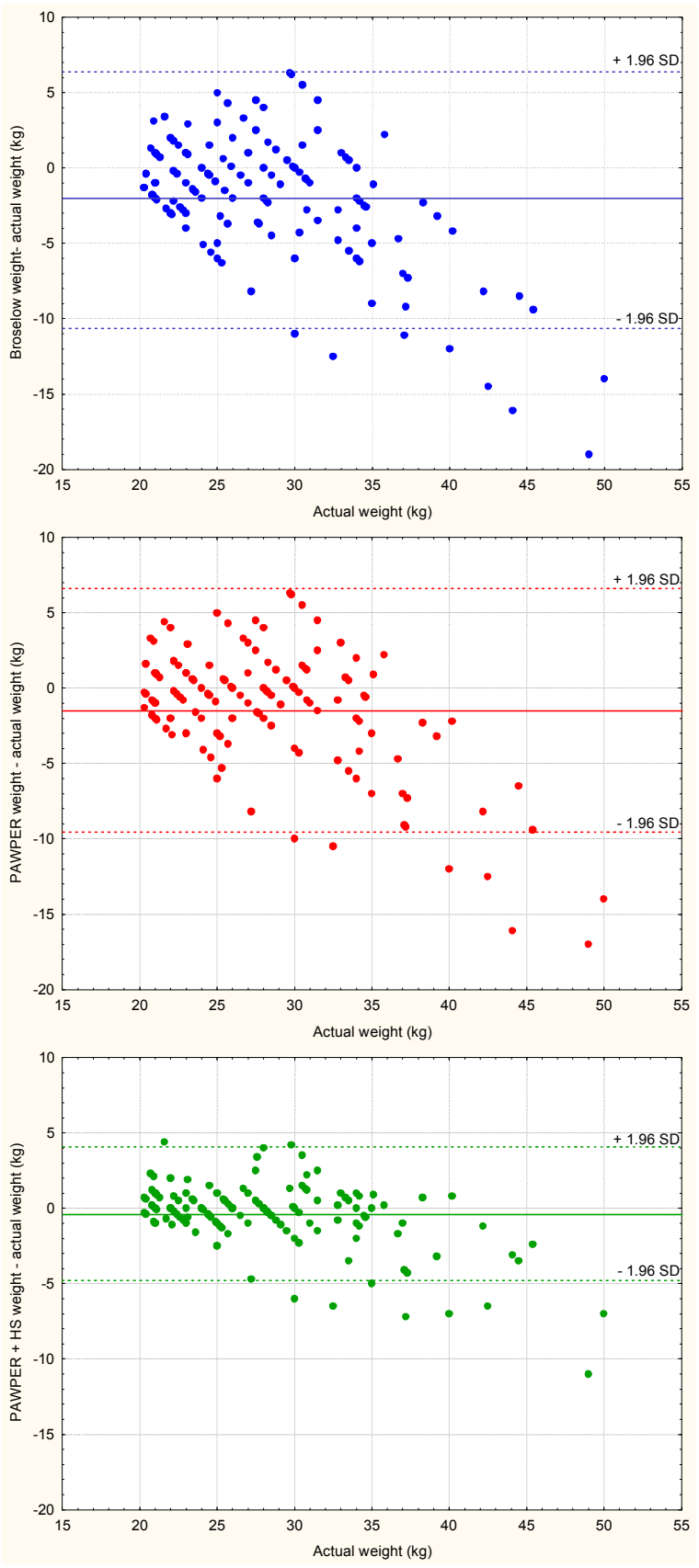

Figure 4-7 Bland-Altman plot illustrating the bias and limits of agreement for the cohort of patients with a body weight of >20kg.

The chart displays the difference between the actual measured weight and the weight predicted by the Broselow tape (top graph with blue markers), the PAWPER tape (middle graph with red markers) and the PAWPER + HS technique (bottom graph with green markers). These graphs plot the residual (predicted weight - actual weight) against actual weight. The solid line represents the bias and the dashed lines represent the 95% confidence intervals for the prediction (the limits of agreement or precision).

4.4.1.2 Other measures of bias and precision

The other major indicator of bias, the mean percentage error (MPE), showed an underestimation of 3.8%, 1.0% and 0% for the Broselow tape, the PAWPER tape and the PAWPER + HS technique respectively ($p<0.0001$ for each comparison).

Table 4-7 contains a summary of the data for the measures of bias and precision for each of the three weight estimation techniques, including the Bland-Altman limits of agreement. The data is represented for the entire study population as well as for each of the weight division cohorts.

Table 4-7 Indicators of bias and precision in weight estimation by the Broselow tape, the PAWPER tape and the PAWPER + HS technique.

		Measured weight groups			
		All	≤12kg	12-20kg	>20kg
Bias	**Mean difference (residual)**				
	Broselow tape (kg)	-0.9	-0.2	-0.5	-2.0
	PAWPER tape (kg)	-0.4	0.1	-0.1	-1.4
	PAWPER + HS (kg)	-0.1	0.1	0	-0.4
	MPE				
	Broselow tape (%)	-3.8	-2.4	-3.0	-6.0
	PAWPER tape (%)	-1.0	1.2	-0.6	-3.6
	PAWPER + HS (%)	0	0.9	0	-0.9
Precision	**AMPE**				
	Broselow tape (%)	9.1	8.6	8.2	10.9
	PAWPER tape (%)	7.9	7.4	6.8	9.8
	PAWPER + HS (%)	4.5	4.5	4.2	4.8
	SD of difference (residual)				
	Broselow tape (kg)	2.8	1.0	1.6	4.3
	PAWPER tape (kg)	2.6	0.9	1.5	4.2
	PAWPER + HS (kg)	1.4	0.5	1.0	2.2
	SD of MPE				
	Broselow tape (%)	11.2	10.5	10.2	12.6
	PAWPER tape (%)	10.5	9.5	9.3	12.4
	PAWPER + HS (%)	6.2	6.1	5.9	6.8
	SD of AMPE				
	Broselow tape (%)	7.4	6.4	6.8	8.7
	PAWPER tape (%)	7.1	6.0	6.4	8.4
	PAWPER + HS (%)	4.4	4.1	4.1	4.9
	Bland-Altman limits				
	Broselow tape (kg)	-6.3, 4.5	-2.1, 1.7	-3.7, 2.7	-10.5, 6.3
	PAWPER tape (kg)	-5.6, 4.7	-1.6, 1.8	-3.1, 2.9	-9.5, 6.8
	PAWPER + HS (kg)	-2.9, 2.7	-1.0, 1.2	-1.9, 1.9	-4.8, 4.0

The MPE and mean absolute percentage error (AMPE) of weight estimation for the entire study population is shown in Table 4-8. The PAWPER + HS technique was statistically significantly better than both the Broselow and PAWPER tapes (MPE $p<0.0001$ and $p=0.002$ respectively, AMPE $p<0.0001$ and $p<0.0001$ respectively). The PAWPER tape itself performed statistically significantly better than the Broselow tape (MPE $p<0.0001$, AMPE $p<0.0001$).

4.4.1.2.1 Analysis by gender

There was no significant difference between the performances (by any statistical measure) of each of the tape techniques when males and females were compared directly. However, the difference in bias of the PAWPER and PAWPER + HS techniques, as indicated by the MPE, was significantly different in males ($p=0.0004$). This reflects a slight trend towards a decreased bias in underestimation of weight in females by each of the three techniques and was greatest with the Broselow and PAWPER methods.

Table 4-8 shows the percentage error and absolute percentage error of weight estimation by each of the three study techniques for male and female children.

4.4.1.2.2 Analysis by weight category

In the analysis of the weight categories, the MPE of the PAWPER + HS system was significantly better than the Broselow tape in each of the three weight categories ($p<0.0001$), but significantly better than the PAWPER tape only in the group >20kg ($p<0.0001$). The AMPE was significantly higher with the Broselow tape than both the PAWPER tape and the PAWPER + HS system for each weight category ($p<0.01$ to 0.0001). The PAWPER + HS system AMPE was significantly better than the PAWPER tape in all three weight categories as well ($p<0.0001$ for each). Table 4-8 shows the MPE and AMPE of weight estimation by each of the three study techniques for children in each of the weight category subgroups.

Table 4-8 MPE and AMPE by weight category, gender and body habitus.

The mean ± SEM is shown for the Broselow tape in blue, the PAWPER tape in red and the PAWPER + HS system in green. The MPE is an indicator of bias and the AMPE of precision or accuracy. The p values for the paired t-test are shown.

			Instrument			Statistical significance		
			Broselow tape	PAWPER tape	PAWPER + HS	BT vs PT	BT vs PTHS	PT vs PTHS
All patients		MPE	-3.8±0.5	-1.0±0.5	-0.0±0.3	0.0001	0.0001	0.002
		AMPE	9.1±0.4	7.9±0.3	4.5±0.2	0.0001	0.0001	0.0001
Weight categories	≤12kg	MPE	-2.3±1.0	1.2±0.9	0.87±0.6	0.0001	0.0001	NS
		AMPE	8.6±0.6	7.4±0.6	4.5±0.4	0.01	0.0001	0.0001
	12.1 to 20kg	MPE	-3.0±0.7	-0.6±0.7	0.0±0.4	0.0001	0.0001	NS
		APME	8.2±0.5	6.8±0.5	4.2±0.3	0.0001	0.0001	0.0001
	>20kg	MPE	-6.0±1.1	-3.6±1.1	-0.9±0.6	0.0001	0.0001	0.0001
		AMPE	10.9±0.7	9.8±0.7	4.8±0.4	0.0004	0.0001	0.0001
Gender	Female	MPE	-2.7±0.8	-0.2±0.8	0.2±0.5	0.0001	0.0001	NS
		AMPE	9.1±0.5	8.0±0.5	4.5±0.3	0.0002	0.0001	0.0001
	Male	MPE	-4.6±0.7	-1.7±0.7	-0.2±0.4	0.0001	0.0004	0.002
		APME	9.2±0.5	7.8±0.4	4.6±0.3	0.0001	0.0001	0.0001
Body habitus	HS<3	MPE	8.8±0.9	11.7±0.8	3.5±0.6	0.0001	0.0001	0.0001
		AMPE	10.0±0.8	11.7±0.8	5.0±0.5	0.0002	0.0001	0.0001
	HS=3	MPE	-2.6±0.4	0.0±0.4	0.0±0.4	0.0001	0.0001	-
		AMPE	5.6±0.3	4.0±0.2	4.0±0.2	0.0001	0.0001	-
	HS>3	MPE	-15±0.7	-12±0.7	-2.7±0.6	0.0001	0.0001	0.0001
		APME	15±0.7	12±0.7	4.9±0.4	0.0001	0.0001	0.0001

4.4.2 Non-parametric analysis of tape performance

4.4.2.1 Analysis in the entire population and in the weight sub-categories

Figure 4-8 illustrates the percentage of cases falling within each percentage error category for each of the three weight estimation techniques. Table 4-9 shows the results of the Chi-squared test applied to observed and expected frequencies within each error category.

Figure 4-9 shows the categorical data of absolute percentage error for each of the tape estimation techniques. Table 4-10 shows the results of the Chi-squared test applied to observed and expected frequencies within each error category.

When comparing the performance of the three systems by error category, the Broselow tape performed significantly worse than the other two methods ($p<0.005$ to 0.0001), with 63.6% of cases predicted within 10% of actual weight, 81.0% within 15% and 91.6% within 20%, compared to the PAWPER tape with 71.3% within 10% of actual weight, 86.1% within 15% and 93.6% within 20% and the PAWPER + HS system with 89.2% within 10% of actual weight, 96.9% within 15% and 99.1% within 20%. The prediction accuracy of the PAWPER + HS was significantly better than the PAWPER tape ($p<0.0001$).

The analysis of categorical data of absolute percentage error for each of the tape estimation techniques for each of the three weight subgroups showed a significantly better performance by the PAWPER + HS system compared to the

other two methods, across all weight categories ($p<0.0001$). The PAWPER tape was significantly better than the Broselow tape only in the 12.1kg to 20kg weight category, with a trend to improved performance in the other categories. These results are illustrated in Figures 4-10, 4-11 and 4-12. Tables 4-11, 4-12 and 4-13 show the results of the Chi-squared test applied to observed and expected frequencies within each error category.

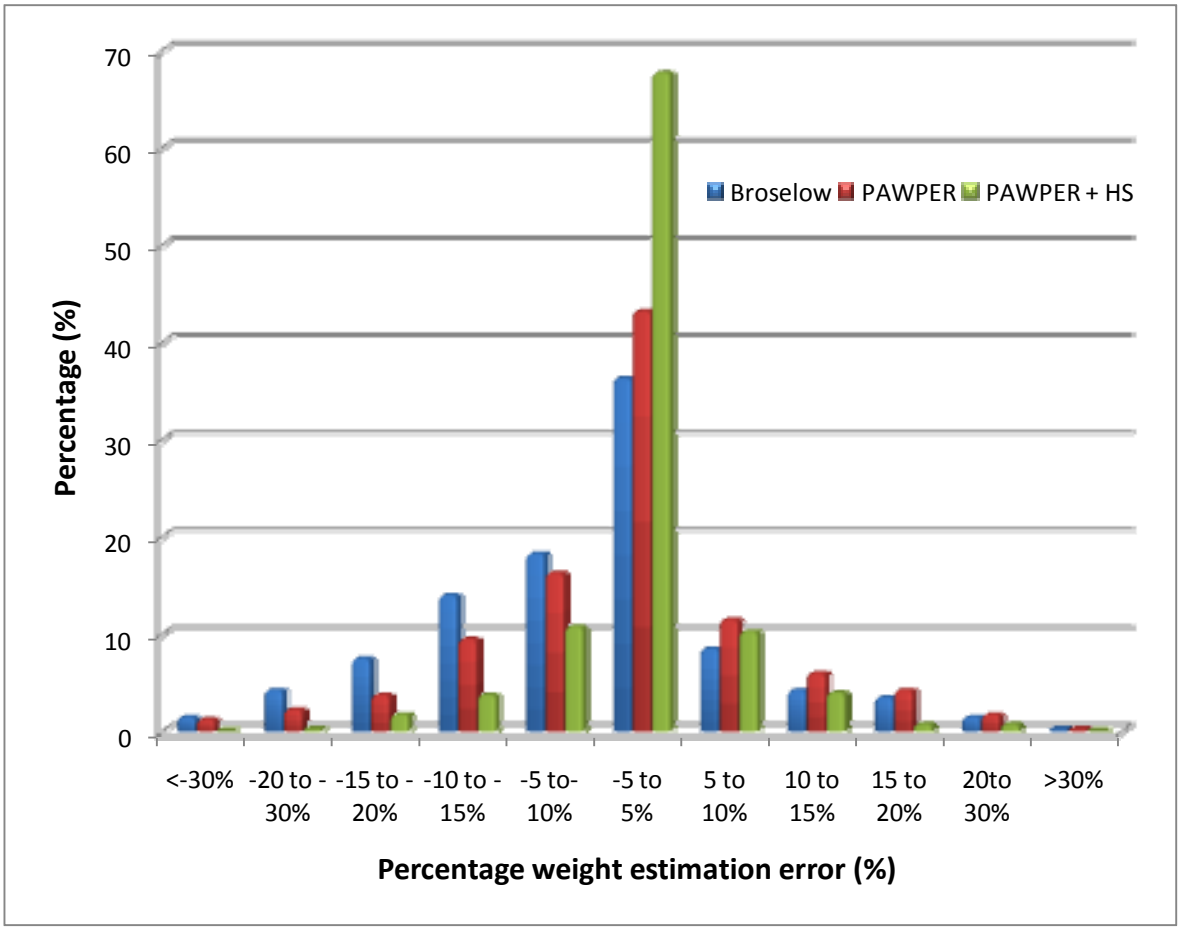

Figure 4-8 Categorised percentage error data for the entire study population.
The proportion of cases falling into each percentage error category is demonstrated for each of the three estimation methods. A negative percentage indicates an underestimation of weight.

Table 4-9 Results of the Chi-squared tests comparing the percentage error of estimation of the three weight estimation techniques for the entire study population.

	x^2 value	df	Significance
Broselow vs PAWPER	43.6	11	p<0.0001
Broselow vs PAWPER + HS	571.7	11	p<0.0001
PAWPER vs PAWPER + HS	232.2	11	p<0.0001

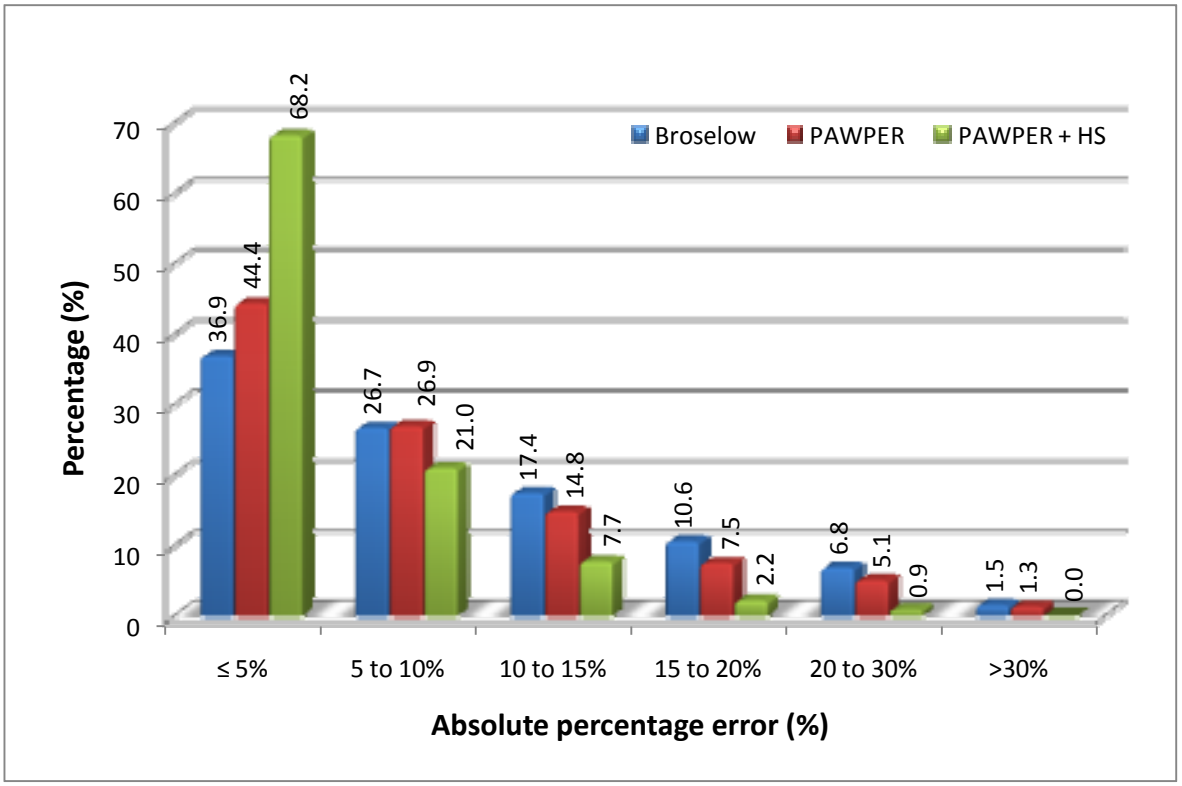

Figure 4-9 Categorised absolute percentage error data for the entire study population.
The proportion of cases falling into each percentage error category is demonstrated for each of the three estimation methods. The Broselow tape estimated weight to within 10% of actual weight in 63.6% of the population, the PAWPER tape 71.3% and the PAWPER + HS technique 89.2%.

Table 4-10 Results of the Chi-squared tests comparing absolute percentage error in each of the three weight estimation techniques for the entire study population.
There was no significant difference in the performance of the techniques between male and female children.

	x^2 value	df	Significance
Broselow vs PAWPER	16.6	5	p=0.005
Broselow vs PAWPER + HS	454.3	5	p<0.0001
PAWPER vs PAWPER + HS	222.5	5	p<0.0001

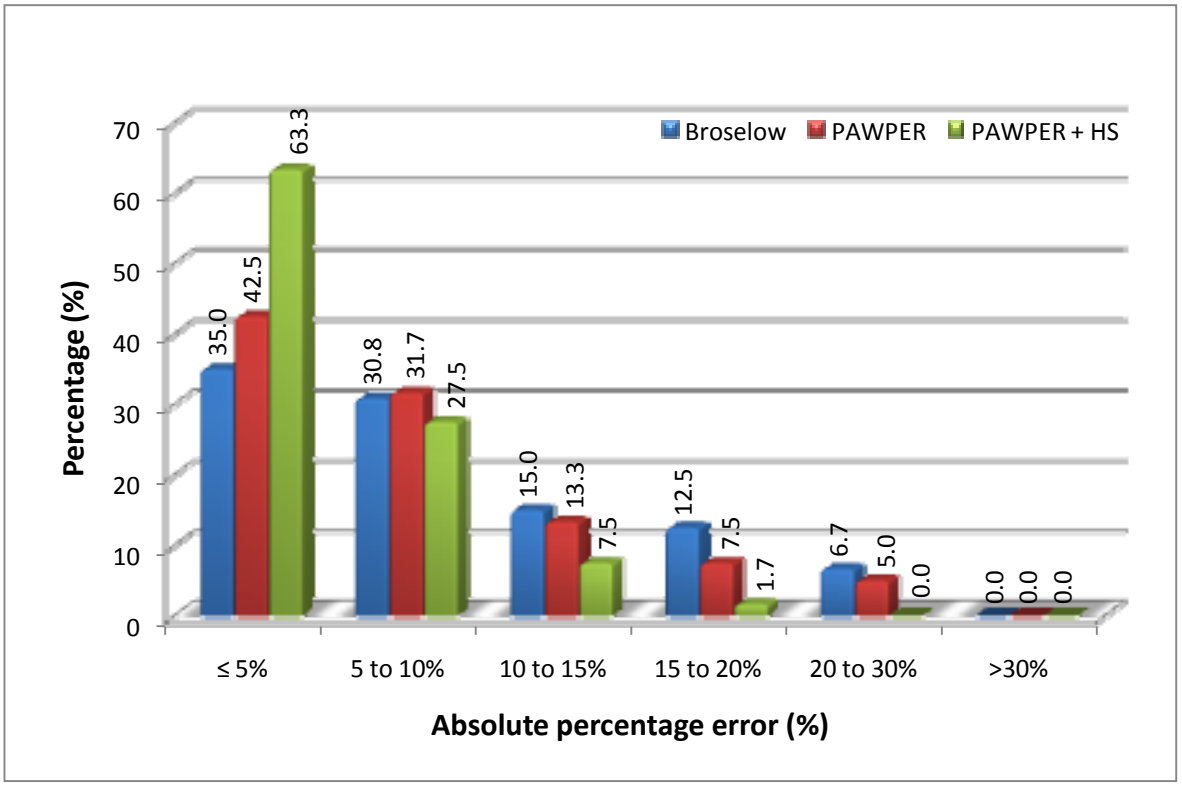

Figure 4-10 Categorised absolute percentage error data for children in the ≤12kg weight subgroup. The proportion of cases falling into each percentage error category is demonstrated for each of the three estimation methods. The Broselow tape estimated weight to within 10% of actual weight in 65.8% of the population, the PAWPER tape 74.2% and the PAWPER + HS technique 90.8%.

Table 4-11 Results of the Chi-squared tests comparing each of the three weight estimation techniques in children in the ≤12kg subgroup.

	x^2 value	df	Significance
Broselow vs PAWPER	6.5	5	NS
Broselow vs PAWPER + HS	109.2	5	p<0.0001
PAWPER vs PAWPER + HS	38.9	5	p<0.0001

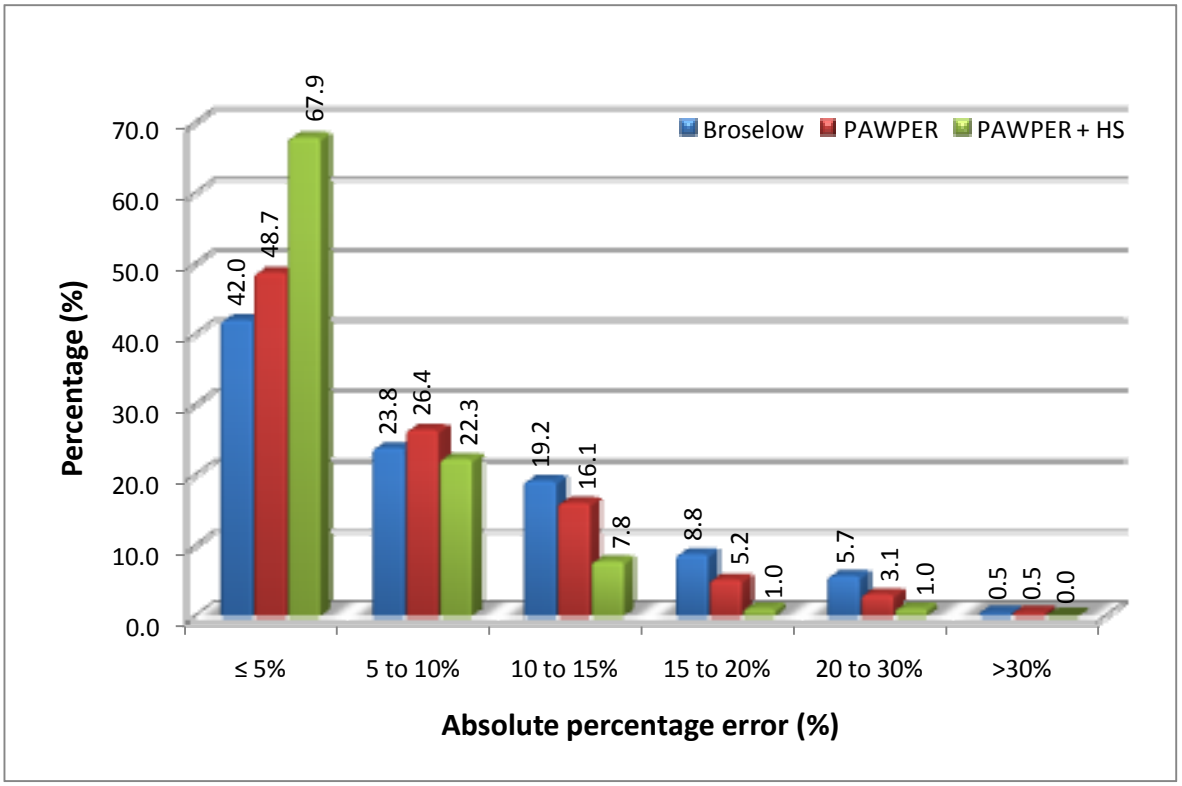

Figure 4-11 Categorised absolute percentage error data for children in the 12.1 to 20kg weight subgroup.

The proportion of cases falling into each percentage error category is demonstrated for each of the three estimation methods. The Broselow tape estimated weight to within 10% of actual weight in 65.8% of the population, the PAWPER tape 75.1% and the PAWPER + HS technique 90.2%.

Table 4-12 Results of the Chi-squared tests comparing each of the three weight estimation techniques in children in the 12.1 to 20kg subgroup.

	X^2 value	df	Significance
Broselow vs PAWPER	12.5	5	p = 0.03
Broselow vs PAWPER + HS	204.6	5	p<0.0001
PAWPER vs PAWPER + HS	69.0	5	p<0.0001

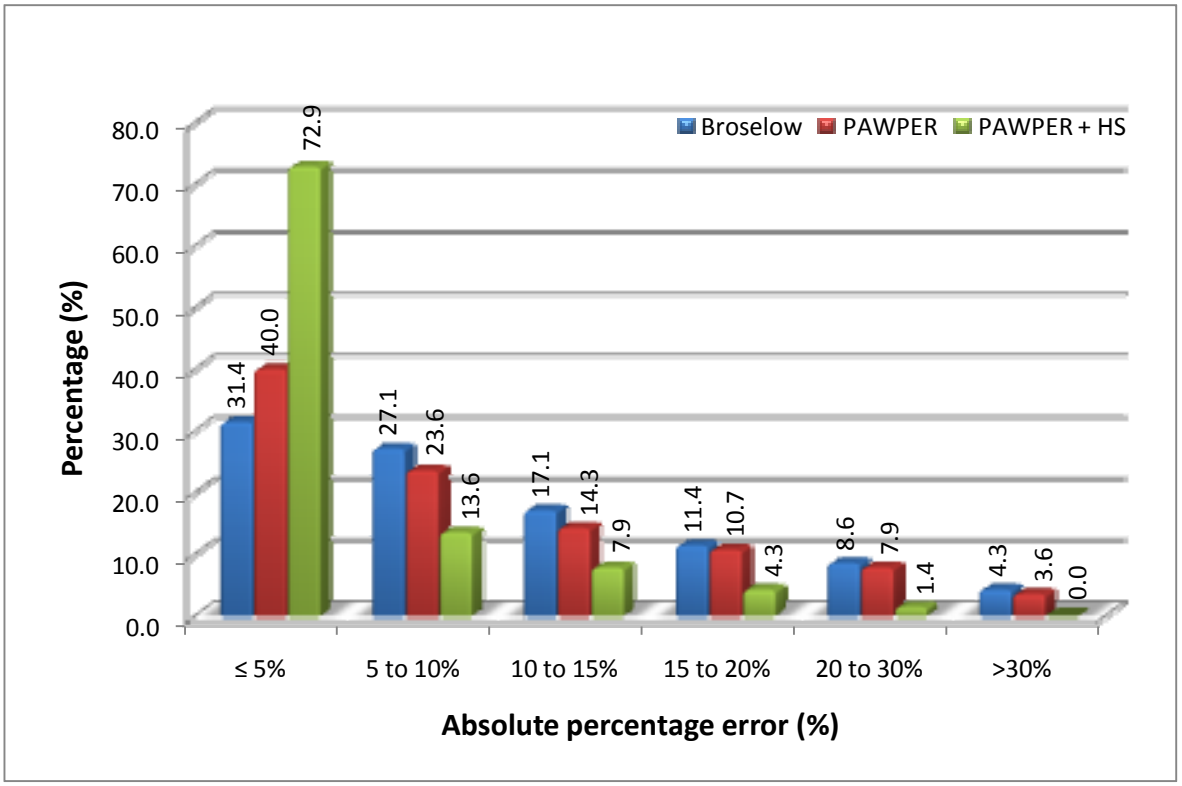

Figure 4-12 Categorised absolute percentage error data for children in the >20kg weight subgroup. The proportion of cases falling into each percentage error category is demonstrated for each of the three estimation methods. The Broselow tape estimated weight to within 10% of actual weight in 58.6% of the population, the PAWPER tape 63.6% and the PAWPER + HS technique 86.4%.

Table 4-13 Results of the Chi-squared tests comparing each of the three weight estimation techniques in children in the >20kg subgroup.

	x^2 value	df	Significance
Broselow vs PAWPER	4.5	5	NS
Broselow vs PAWPER + HS	134.0	5	p<0.0001
PAWPER vs PAWPER + HS	92.4	5	p<0.0001

4.5 Analysis of the habitus score

4.5.1 Demographic data relating to the habitus score

The percentage of children that were assigned to each habitus score (HS) is demonstrated in Figure 4-13. Table 4-14 contains a summary of the population characteristics of children in each habitus score. The children with a HS of 3 and 4 were significantly younger than the children in the other HS categories ($p<0.05$), but the groups had otherwise similar population characteristics.

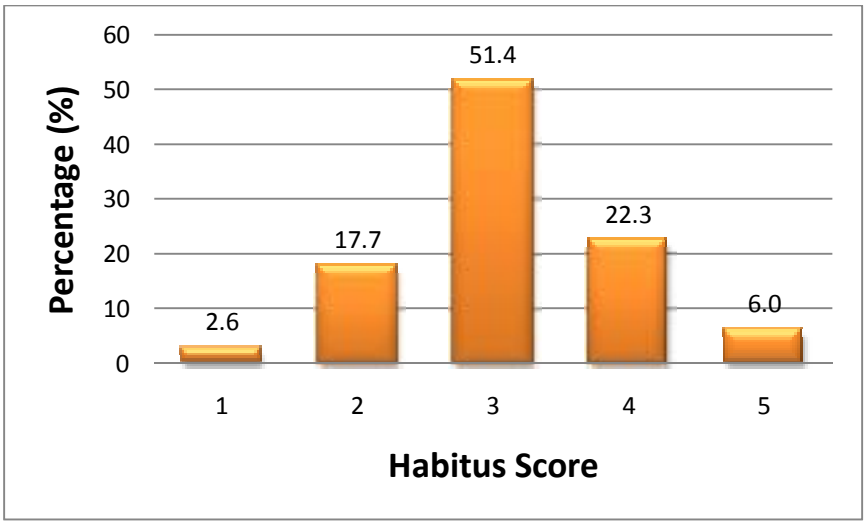

Figure 4-13 Percentage of cases falling within each habitus score category.
A total of 20.3% of children were below average weight-for-length, and 28.3% were above average.

Table 4-14 Population characteristics of the children in each of the habitus score categories.

	Assigned habitus score				
	1	**2**	**3**	**4**	**5**
Number (%)	12(2.6)	80 (17.7)	233(51.4)	101(22.3)	27(6.0)
Gender male (%)	7(58.3)	36(45.0)	137(58.8)	55(54.5)	20 (74.1)
Age mean ± SD	6.1±4.3	5.0±3.2	3.9±2.8	4.0±2.9	5.4±3.4
Age median	5.4	4.7	3.4	3.1	5.3
Weight mean ± SD	16.6±7.4	17.3±7.6	16.4±7.2	19.6±8.2	27.4±12.7
Weight median	14.9	17	15.3	17.8	27.2

4.5.2 Analysis of habitus score and body mass index

Body mass index (BMI) and the BMI centile (from the NCHS 2000 BMI-for-age charts) were strongly correlated with HS (r = 0.78 and r = 0.79 respectively). There was a significant difference between the BMI and BMI-for-age centile for each of the HS categories (p=0.0002 or less). The BMI and BMI-for-age-centile are shown for each HS category in Figure 4-14.

The BMI for the entire population was (mean ± SD) 16.4 ± 2.0 (median 16.2) and the BMI-for-age centile was (mean ± SD) 48.4 ± 30.8 (median 50.0). There are fewer children in the BMI-for-age centile groups because there is no reliable data on BMI-for-age for infants under 2 years and these cases were therefore excluded. This data is summarised in Table 4-15.

The results of the Cole method (194) of identifying children who are overweight or obese is shown in Table 4-16. Some older studies make use of a different methodology and terminology based on the NCHS 2000 BMI-for-age charts:

- BMI% 85 to 94.9% - *at risk for being overweight* (equivalent to Cole *overweight*);
- BMI% ≥ 95% - *overweight* (equivalent to Cole *obese*)

This information is shown for comparison with other older studies. Children less than 2 years of age were again excluded because there is no reference data for this age group.

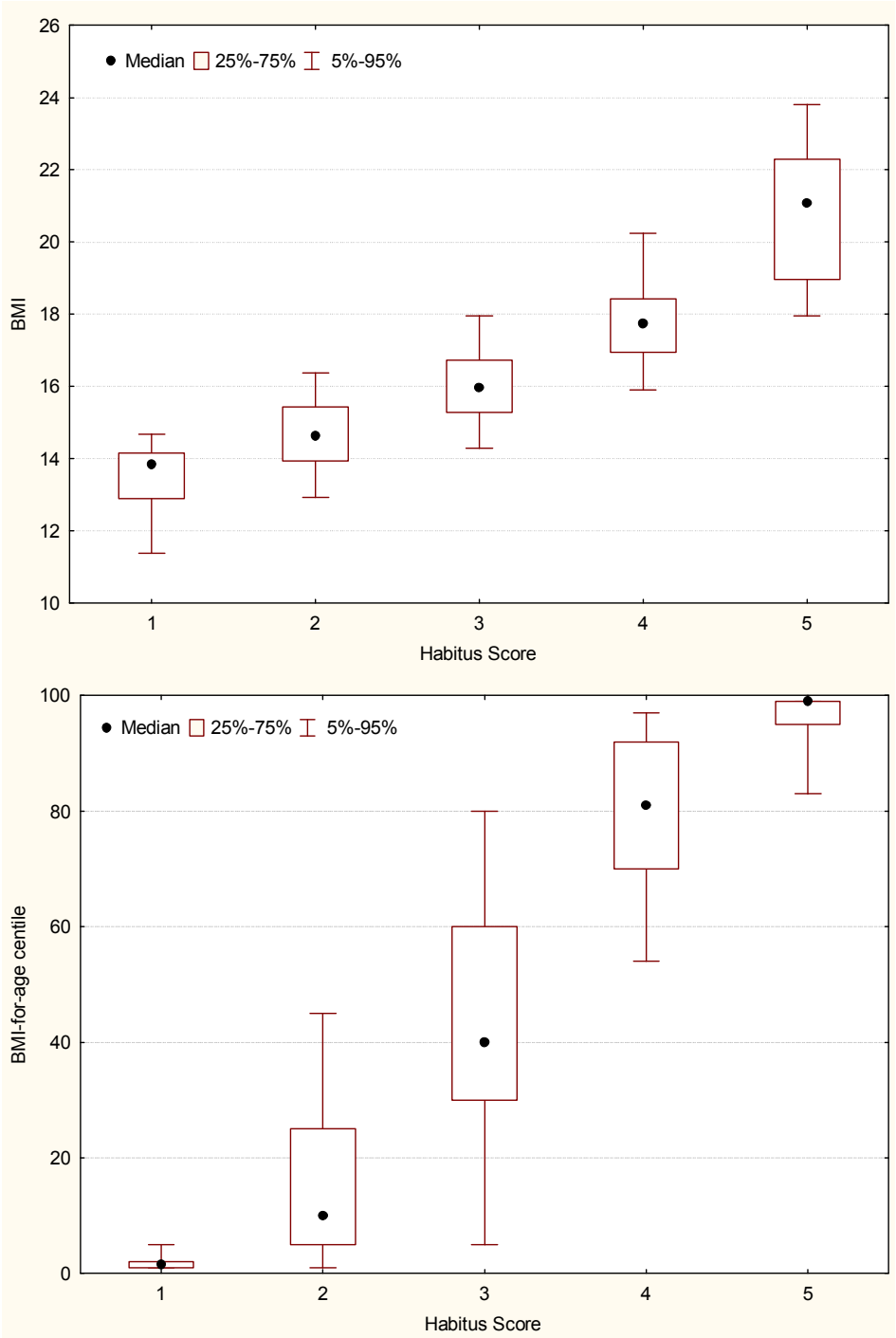

Figure 4-14 Box-and-whisker plot of BMI and BMI-for-age centiles (NCHS 2000 charts) for each category of habitus score.

Non-parametric measures of central tendency (median) and distribution (interquartile range and 5th and 95th centiles) were used because the data was not normally distributed.

Table 4-15 Body mass index (BMI) and NCHS 2000 growth chart BMI-for-age centile (based on the NCHS 2000 charts) for each category of habitus score.

	Assigned habitus score				
	1	**2**	**3**	**4**	**5**
N	12	80	233	101	27
BMI mean ± SD	13.4 ± 1.0	14.7 ± 1.0	16.0 ± 1.1	17.9 ± 1.4	20.8 ± 2.1
BMI median	13.8	14.6	16.0	17.7	21.1
N	10	69	183	80	22
BMI-for-age % mean ± SD	2 ± 1.4	17 ± 15.8	44 ± 22.4	79 ± 14.5	96 ± 6.2
BMI-for-age % median	1.5	10	40	81	99

Table 4-16 BMI-for-age centiles (BMI%) for each weight group and the proportion of children classified as overweight or obese according to the centile method and the Cole method.

Weight	N	Median BMI%	BMI% 85 - 95% (Overweight*)	BMI% ≥ 95% (Obese*)
≤12kg	35	25	2.8% (0%)	0 (0%)
12.1 – 20kg	189	40	9.5% (4.8%)	3.2% (1.6%)
>20kg	140	65	11.4% (14.3%)	16.4% (7.1%)
Total	364	50	9.6% (9.3%)	8.0% (3.6%)

4.5.3 Analysis of reliability and accuracy of habitus score

A *post hoc* review of the HS data showed that, in theory, weight estimation might have been improved in 30 cases (6.6%) if a different HS had been assigned. Twelve of these cases were extreme body-types (very thin or very fat). This meant that there was a 423/453 (93.4%) agreement (κ 0.89 p<0.0001) between the actual HS assigned by data collectors during the study and an "optimum" HS assigned after looking at the child's weight (see Table 4-17).

Table 4-17 Actual HS compared with a theoretical possible HS (assigned *post hoc* based on measured body weight).
For example: of the 80 children assigned an HS of 2 during the study 10 children would have had a better weight estimation if they had been assessed as an HS of 1. There was agreement in 70 (the italicised figure) of the 80 cases.

		Actual Habitus Score assigned					
		1	**2**	**3**	**4**	**5**	
Possible Habitus Score assigned	**1**	*12*	10	2			**24**
	2		*70*	6			**76**
	3			*218*			**218**
	4			6	*96*		**102**
	5			1	5	*27*	**33**
TOTALS		**12**	**80**	**233**	**101**	**27**	**453**

The use of the HS system improved the weight estimation of the PAWPER tape in 196 cases (43.2%); it was unchanged in 241 cases (53.2%) (an assigned HS of 3); and it worsened the weight estimation in 16 cases (3.5%). In these cases the resulting AMPE was 6.4% with a PE range of -8% to 12%.

4.6 Analysis of tape performance by HS (BMI) category

4.6.1 Analysis of bias and precision with parametric data

In children with a lower than average weight-for-length, the PAWPER + HS technique showed a significantly smaller bias of weight overestimation (as reflected by the MPE) and a significantly higher precision (as reflected by the AMPE) than the Broselow or PAWPER tapes ($p<0.0001$). The PAWPER tape performed significantly less well in both bias and precision than the Broselow tape in this subgroup of patients ($p=0.0002$ or less).

In children with an average weight-for-length, the PAWPER tape and PAWPER + HS technique (which produce the same result in children classified with an HS of 3) were significantly less biased and more precise than the Broselow tape ($p<0.0001$).

In children with a greater than average weight-for-length, the PAWPER + HS technique performed better than both the Broselow and PAWPER tapes ($p<0.0001$) and the PAWPER tape performed significantly better than the Broselow tape ($p<0.0001$).

Table 4-8 shows the MPE and AMPE in the weight estimation by each of the three tape techniques for children who have a lower than average weight-for-length, an average weight-for-length and a greater than average weight-for-length.

Figures 4-15, 4-16 and 4-17 are Bland-Altman plots showing the bias and limits of agreement for each of the weight estimation techniques analysed for subgroups of HS.

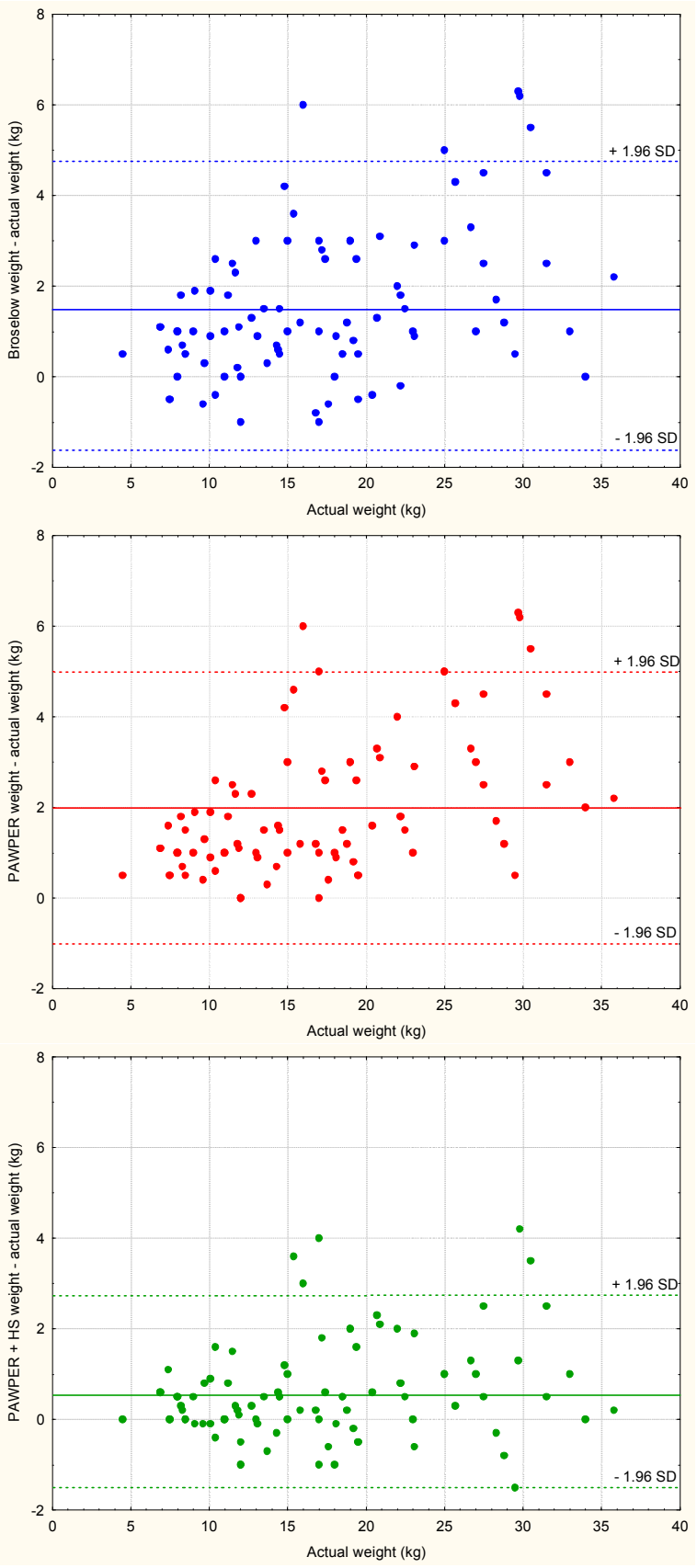

Figure 4-15 Bland-Altman plot illustrating the bias and limits of agreement for the cohort of patients with a habitus score of <3 (lower than average weight-for-length).

The chart displays the difference between the actual measured weight and the weight predicted by the Broselow tape (top graph with blue markers), the PAWPER tape (middle graph with red markers) and the PAWPER + HS technique (bottom graph with green markers). These graphs plot the residual (predicted weight – actual weight) against actual weight. The solid line represents the bias and the dashed lines represent the 95% confidence intervals for the prediction (the limits of agreement or precision).

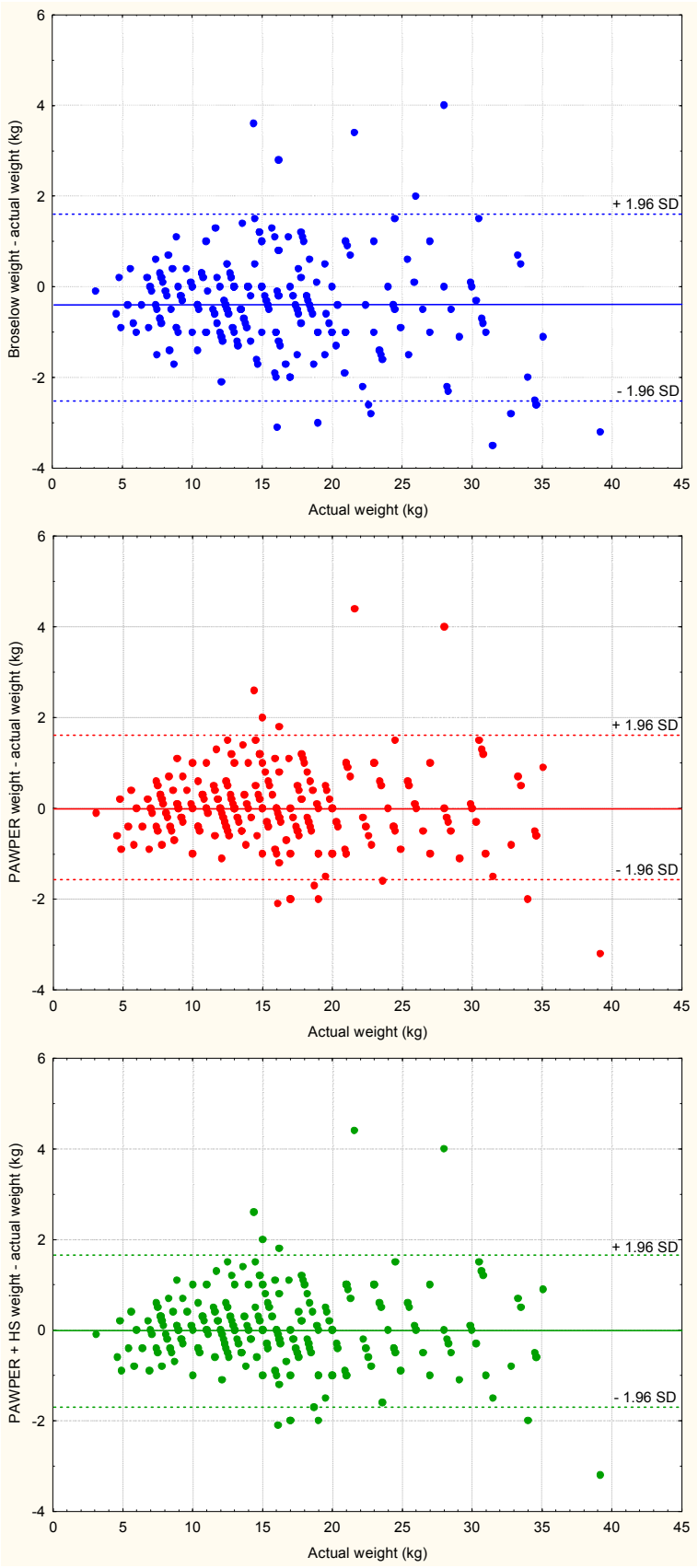

Figure 4-16 Bland-Altman plot illustrating the bias and limits of agreement for the cohort of patients with a habitus score of 3 (an average weight-for-length).

The chart displays the difference between the actual measured weight and the weight predicted by the Broselow tape (top graph with blue markers), the PAWPER tape (middle graph with red markers) and the PAWPER + HS technique (bottom graph with green markers). These graphs plot the residual (predicted weight – actual weight) against actual weight. The solid line represents the bias and the dashed lines represent the 95% confidence intervals for the prediction (the limits of agreement or precision).

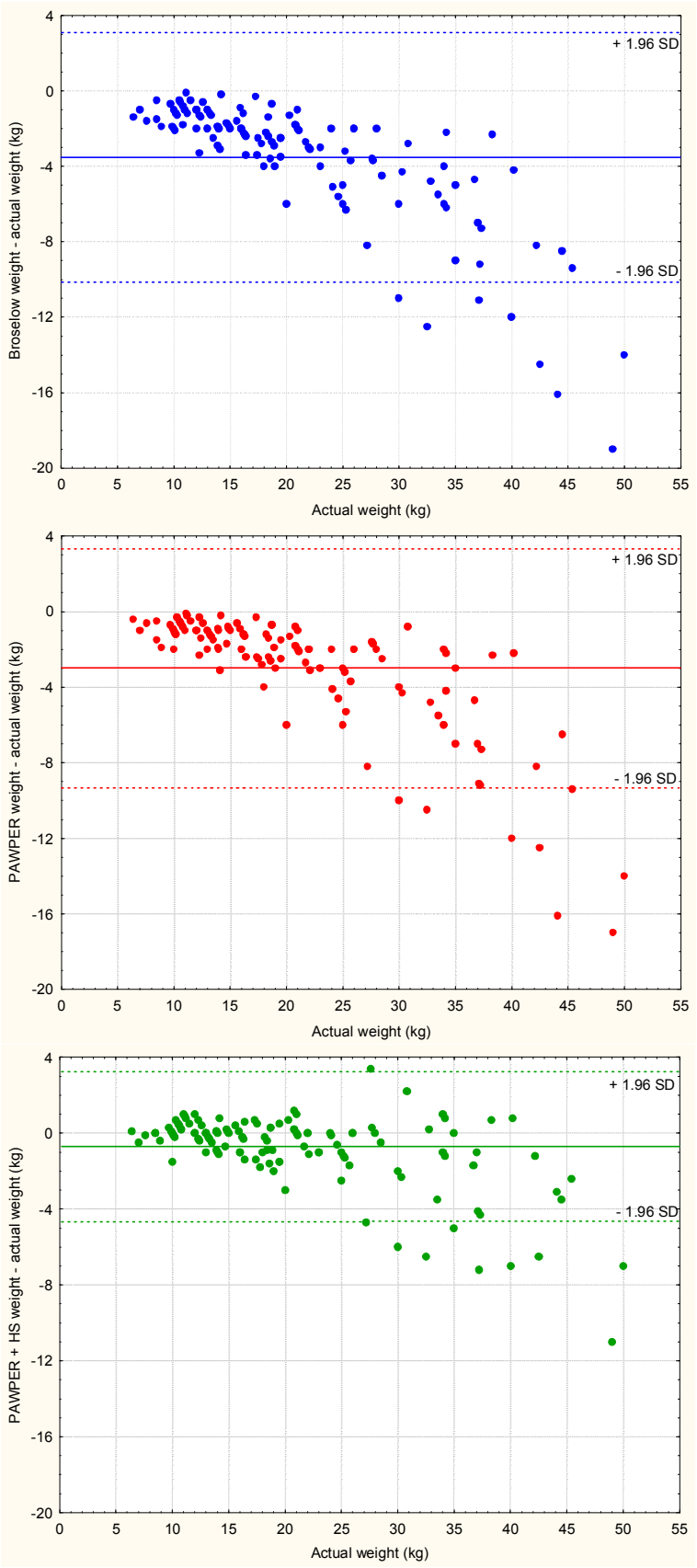

Figure 4-17 Bland-Altman plot illustrating the bias and limits of agreement for the cohort of patients with a habitus score of >3 (greater than average weight-for-length).

The chart displays the difference between the actual measured weight and the weight predicted by the Broselow tape (top graph with blue markers), the PAWPER tape (middle graph with red markers) and the PAWPER + HS technique (bottom graph with green markers). These graphs plot the residual (predicted weight – actual weight) against actual weight. The solid line represents the bias and the dashed lines represent the 95% confidence intervals for the prediction (the limits of agreement or precision).

4.6.2 Analysis by weight estimation error categories

When comparing the performance of the three systems in children with an HS of 1 and 2, the PAWPER + HS system performed significantly better than the other two methods ($p<0.0001$), with 85.9% of cases predicted within 10% of actual weight, 95.7% within 15% and 97.8% within 20%, compared to the Broselow tape with 58.7% within 10% of actual weight, 73.9% within 15% and 89.1% within 20% and the PAWPER tape with 47.8% within 10% of actual weight, 68.5% within 15% and 88.0% within 20%. The prediction accuracy of the PAWPER + HS was significantly better than the PAWPER and Broselow ($p<0.0001$) tapes and the prediction accuracy of the Broselow tape was significantly better than the PAWPER tape ($p=0.007$).

For children with an HS of 3, the Broselow tape performed significantly less well than the PAWPER tape ($p<0.0001$) with 91.8%, 98.7% and 99.6% of cases within 10%, 15% and 20% error respectively compared to the Broselow tape with 85.0%, 95.3% and 99.6% respectively. The PAWPER + HS system predicts the same weight as the PAWPER tape in these children.

For children with an HS of 4 and 5, the PAWPER + HS system again performed significantly better than both the Broselow tape and the PAWPER tape ($p<0.0001$) with 86.7%, 94.5% and 99.2% of cases within 10%, 15% and 20% error respectively compared to the Broselow tape with 28.1%, 60.2% and 78.9% respectively and the PAWPER tape with 50.8%, 75.8% and 86.7% respectively.

The PAWPER tape's performance was significantly better than that of the Broselow tape ($p<0.0001$) in this subset of children.

Figures 4-18, 4-19 and 4-20 show the categorised percentage error of weight estimation by each of the three tape techniques for children with lower than average weight-for-length, average weight-for-length and greater than average weight-for-length.

Tables 4-18, 4-19 and 4-20 contain the results of the Chi-squared tests comparing the observed and expected frequencies within the error categories.

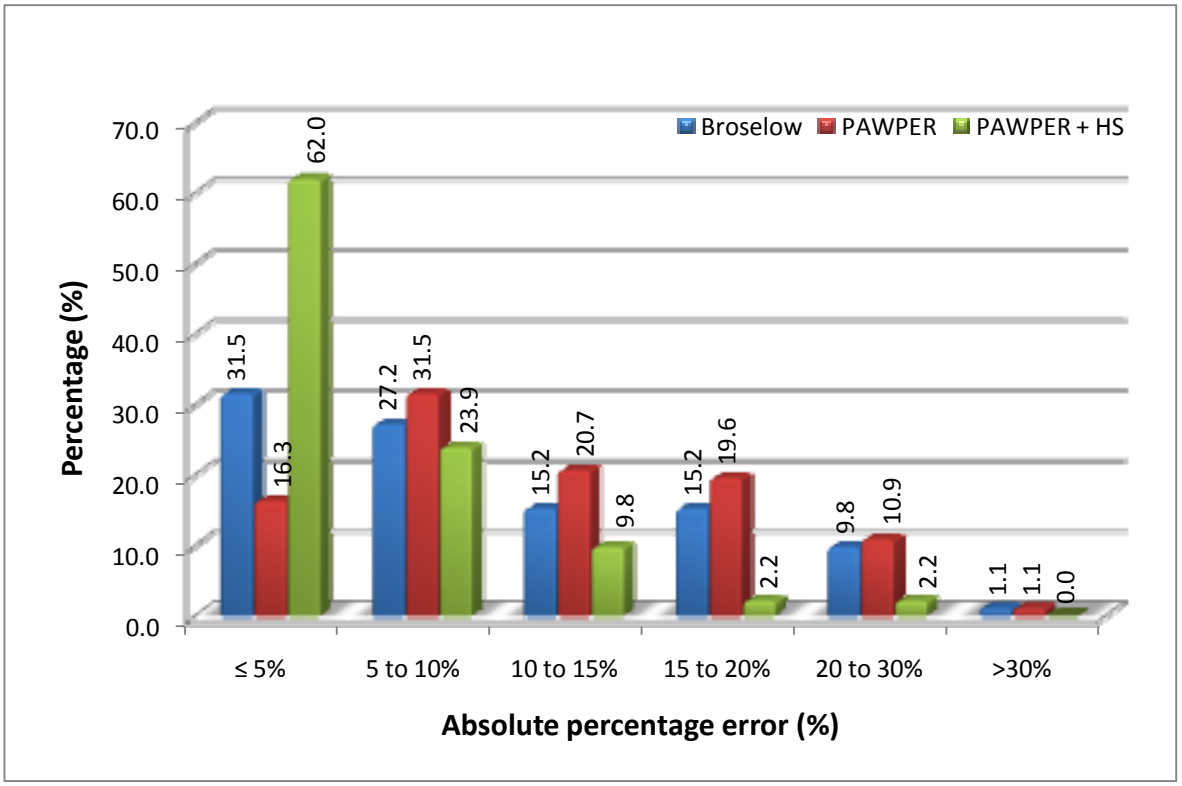

Figure 4-18 Categorised absolute percentage error data for children with a lower than average weight-for-length (habitus scores of 1 and 2).

The proportion of cases falling into each percentage error category is demonstrated for each of the three estimation methods. The Broselow tape estimated weight to within 10% of actual weight in 58.7% of the population, the PAWPER tape 47.8% and the PAWPER + HS technique 85.9%.

Table 4-18 Results of the Chi-squared tests comparing each of the three weight estimation techniques in children with a low weight-for-length.

	x^2 value	df	Significance
Broselow vs PAWPER	15.9	5	p = 0.007
Broselow vs PAWPER + HS	113.4	5	p<0.0001
PAWPER vs PAWPER + HS	204.3	5	p<0.0001

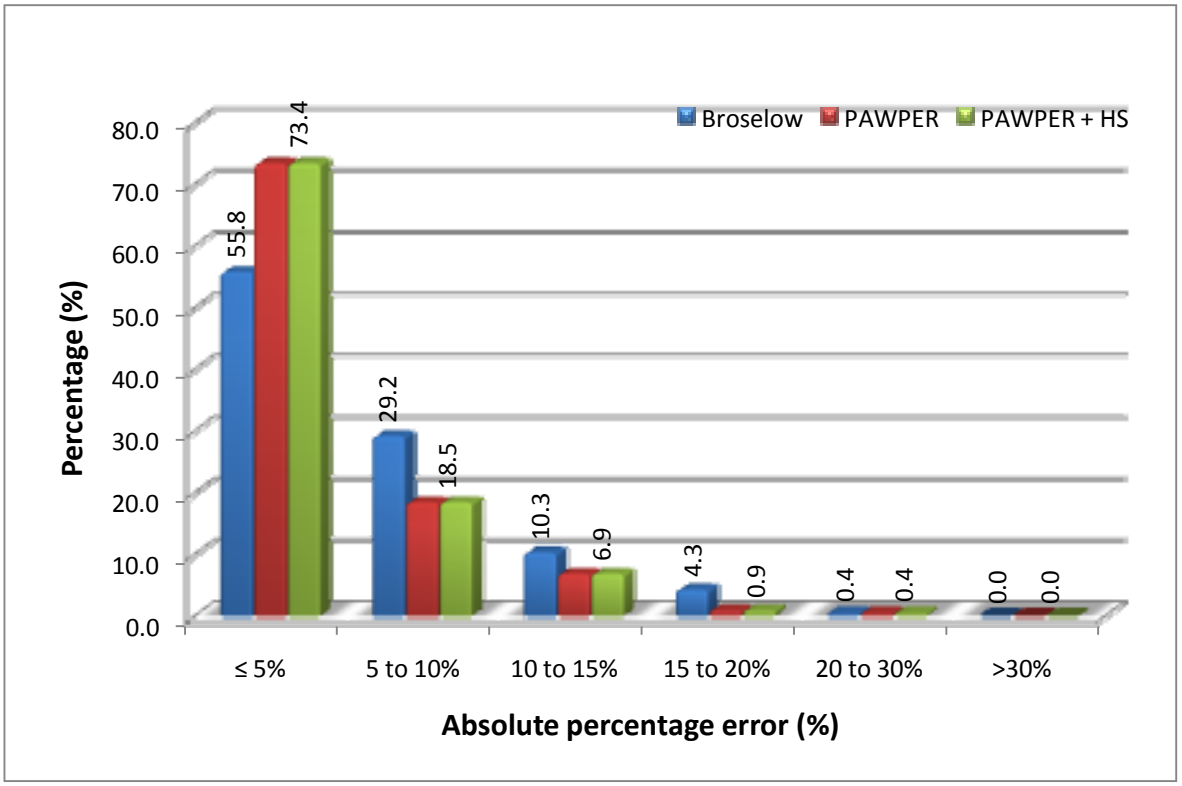

Figure 4-19 Categorised absolute percentage error data for children with an average weight-for-length (habitus score of 3).

The proportion of cases falling into each percentage error category is demonstrated for each of the three estimation methods. The Broselow tape estimated weight to within 10% of actual weight in 85.0% of the population, the PAWPER tape 91.8% and the PAWPER + HS technique 91.8%.

Table 4-19 Results of the Chi-squared tests for comparing each of the weight estimation techniques in children with an average weight-for-length.

There is no modification to the PAWPER estimated weight with children with a habitus score of 3; the PAWPER + HS estimated weight is the same as the PAWPER estimated weight.

	x^2 value	df	Significance
Broselow vs PAWPER	60.4	5	p<0.0001

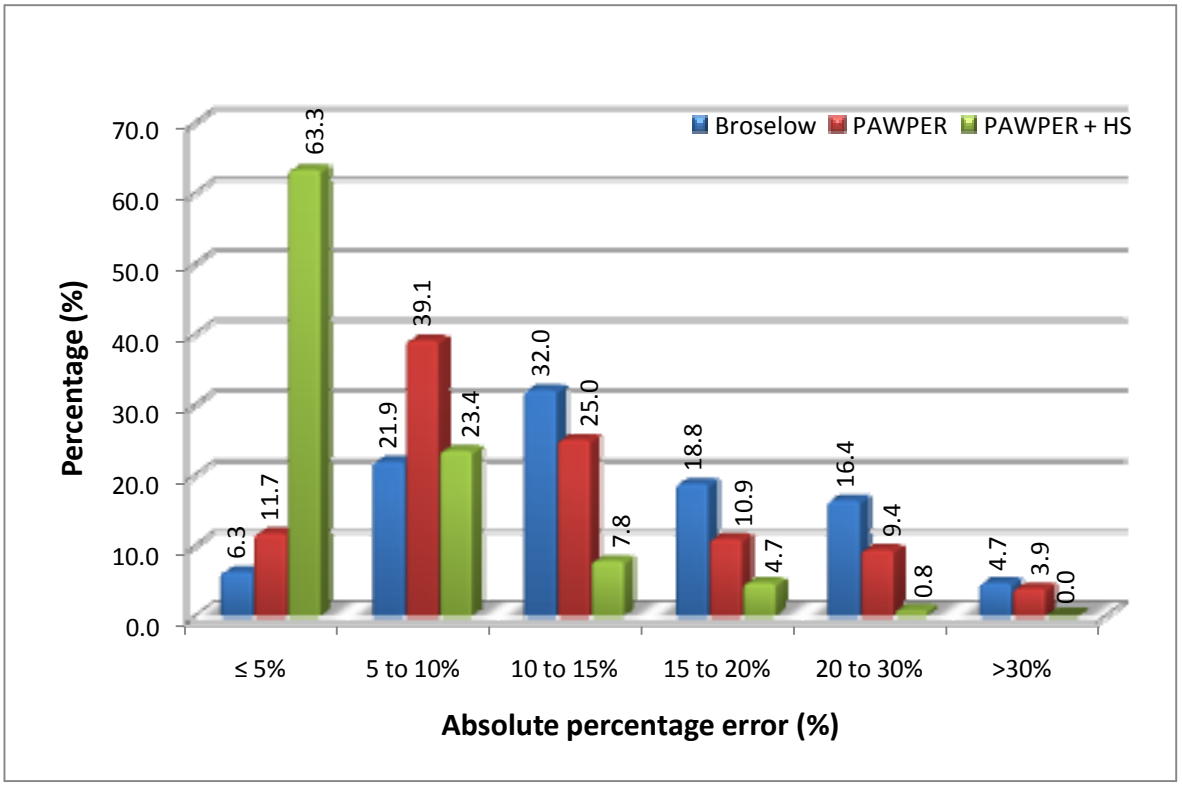

Figure 4-20 Categorised absolute percentage error data for children with a higher than average weight-for-length (habitus scores of 4 and 5).

The proportion of cases falling into each percentage error category is demonstrated for each of the three estimation methods. The Broselow tape estimated weight to within 10% of actual weight in 28.1% of the population, the PAWPER tape 50.8% and the PAWPER + HS technique 86.7%.

Table 4-20 Results of the Chi-squared tests for comparing each of the three weight estimation techniques in children with a large weight-for-length.

	X^2 value	df	Significance
Broselow vs PAWPER	29.6	5	p<0.0001
Broselow vs PAWPER + HS	616.0	5	p<0.0001
PAWPER vs PAWPER + HS	247.2	5	p<0.0001

Chapter 5 DISCUSSION

5.1 Medication errors and resuscitation aids

Patient safety and the reduction of errors are contemporary issues in medicine in general (195) and paediatric emergency medicine specifically (5, 47, 133). The ED has been identified as the most error-prone area of the hospital, with drug dosaging the main cause of errors, and young children the most common patients involved (13, 196).

During the emergency management of critically ill or injured children, the inability to obtain a measured weight is a common impediment to the determination of accurate drug dosages and so an accurate and reliable method of estimating weight is needed (133). The end-point of a weight estimation system, however, should be more than just the weight itself: sick children are best served by the incorporation of evidence-based resuscitation aids into the team protocol, to remove the clinician's (and the team's) distraction from issues not crucial to the medical management of the patient. Instead of requiring the emergency physician's full attention, the determination of drug doses and equipment sizes (which are also crucial) can be relegated to a process of looking them up on a chart or computer which does not require *active* or *non-automatic* thinking or memory. Critical, non-automatic thinking is better utilised on the specific medical issues relating to the patient's condition and medical care (6, 7, 65, 66, 94, 133). For this reason a *complete* system is ideal for use during the paediatric

resuscitation so that one or more devices can be used *automatically* to predict weight, to guide on equipment size selection and to provide drug dosaging, dilution and delivery information. Other issues that are important in the selection or development of a resuscitation aid include cost, availability, ease of use, disposability and transportability.

The desirable aspects of the first component of a resuscitation aid, the weight estimation system, are best embodied in a length-based tape system: most other commonly used forms of weight estimation have either not exhibited the desired degree of accuracy[22] (eg. age-based formulas, "guesstimations") or require calculations which can be prone to error (eg. age- or length-based formulas). Even tape-based systems can be vulnerable to error, however, as the measurement of the child may be performed incorrectly or the tape may predict the child's weight inaccurately (eg. in children whose weight is not close to the 50th centile of weight-for-length of the growth charts used for the development of the tape).

The second component of the resuscitation aid is the part that provides critical information to the resuscitation team on drug dosaging and equipment sizes that should not be trusted to memory (6, 7, 65, 133). It may take the form of the tape itself, a chart, a booklet or a point-of-care computer and it should be specifically designed (or positioned) to provide relevant information to the entire team, not just the doctor, to minimise the possibility of errors during a time of high cognitive load and emotional stress. This aspect of the resuscitation aid has not been addressed in any way in this study other than to emphasise its importance and the critical

[22] A weight estimation system should estimate weight to within 10% of actual weight in > 60% of children.

relationship and interaction between the weight-estimation system and the drug dosaging system.

Two currently used systems have incorporated both elements of the resuscitation aid into a single device: the Broselow tape and the Sandell tape. The Sandell tape contains useful supplementary information on drug dosaging and drug preparation, but is untested by clinical trials. The Broselow tape itself contains information on equipment sizing and basic drug dosaging (with pre-calculated drug doses presented in each colour zone), with additional information on drug dilution and volume administration contained in the companion book (the *Broselow paediatric resuscitation medication/Infusion guide* (2)) which must be purchased separately.

The PAWPER tape was designed to be the weight-estimation component of a resuscitation aid in concert with the *Emergency drug dosing in children* booklet (3). It is a cheap, disposable device that was designed to increase the accuracy of weight estimation in children across a broader range of body types than can be achieved without taking body habitus into account. The PREM system (which was designed in the UK based on local growth charts) makes use of a similar concept: a disposable tape which was designed only to estimate weight and an accompanying book which may be used to provide information on drug dosaging and equipment sizing. Two-part systems are generally more complete than one-component resuscitation aids, but are less resilient as there is twice the risk of one of the items going missing or malfunctioning.

The discussion of the concept of resuscitation aids is important because the design of a weight estimation system should be determined largely by its ability to improve patient care and not just provide an estimate of weight. This also applies to a clinician's planning of which system to use in his or her ED. Thus weight-estimation is a less desirable end-point than accurate drug dosaging and the selection of the correct equipment size.

In this study the PAWPER tape has proved to be an accurate system when used by a spectrum of healthcare workers (see below) and has produced weight estimations that are on a par or better than the Broselow tape and the reported accuracies of other systems (eg. parental estimates of their children's weights accurate to with a 10% error in 80% of cases (48)). The assessment of habitus score was designed to be as easy and instinctive as possible, to correspond with the cognitive image analysis process, but it might well contribute in a small way to increasing the cognitive burden of weight estimation. While tape-based weight estimation should be completely automatic the system of modification according to an assigned habitus score might not be, especially in individuals not experienced in the use of the system. This potentially troublesome aspect needs to be explored in further studies. The use of more specific criteria[23] to make a habitus assessment would amplify the complexity of the system and the consequent cognitive load. This would increase the possible delays in initiating treatment due to indecision as well as the time needed for the assessment. This would defeat the objectives of a resuscitation aid which should be "cognitively neutral" and able to be rapidly employed. The PAWPER tape was designed with this in mind and, in

[23] eg. prominence of the ribs or iliac crests; truncal or limb obesity etc.

this preliminary testing, has shown promise to produce accurate weight estimations and to conform to the advantageous aspects of a resuscitation aid. If the operator is uncertain about how to apply the habitus modification technique there is a degree of inbuilt resilience in the system: the unmodified PAWPER tape predicted-weight may be used because it is as accurate (or more accurate) than the Broselow tape. This study also showed that the use of the habitus score modification often improved but very seldom worsened the final estimate of weight: this could potentially reassure the end-user of the resilience of the system and increase their confidence in their own ability to use the technique.

The ergonomics of the PAWPER tape was also carefully considered: it is small but self-contained, displaying only information pertaining to weight estimation. The size of any tape system constrains the information it contains (1) and for a system to be a complete resuscitation aid, it would need to be very large.

This study has not evaluated any drug dosage referencing system in any way whatsoever.

5.2 Endpoints in weight estimation

It seems realistic to use a target weight estimation error of within 10% as acceptable for drug dose calculation, and this has become the most common practice in weight estimation studies (115). Only two recent studies have regarded a weight-estimation error of within 20% as acceptable (61, 128).

There are other latent, unavoidable and undetectable errors that make a target error of <10% impractical: as an example, the amount of adrenaline contained within a 1mg ampoule may vary from 0.9mg to 1.15mg (90% to 115%) according to statutory compendial requirements (165). It seems unreasonable to expect weight estimation to be more precise than the drug dose error that is already possible because of drug concentration variability (10% underdose to 15% overdose); while this occult error is concerning, it is completely unavoidable and cannot be taken into account during clinical management.

Errors related to the rounding-off of body weight may also introduce a significant extra degree of variability that cannot easily be determined.[24] Since weight-prediction tapes and resuscitation aids usually reflect weight as an integer, an error of 1kg in weight estimation will yield a percentage error of only 3% in a 35kg child, but a 25% error in a 4kg infant (116). Unfortunately it is also the smallest patients who are at most risk of harm from medication-related errors and for this reason the PAWPER + HS system makes use of intermediate half-kilogram values to limit the effects of rounding errors in infants. Dosage recommendations in resuscitation aids should take this into account.

Another important consideration is whether to prefer a slight under- or overestimation of weight, and therefore drug dose, in the emergency or

[24] The average potential rounding error over the weight ranges of the Broselow and PAWPER tapes is just over 5% eg. A child who actually weighs 3.5kg may have a drug dose calculated based on 3kg (17% error) or 4kg (13% error); similarly a child weighing 35kg may have a drug dose calculated based on 34kg or 36kg (3% error).

resuscitation setting.[25] There is no conclusive evidence-based answer to this question as yet (115, 133, 170) and there is probably not enough evidence to adequately support a valid conclusion without "splitting scientific hairs" (133) but both positions have been argued:

- **Avoid ineffective drug doses.** Almost all drugs that might be used in emergencies (for airway management, seizures, anaphylaxis, and cardiac arrest) should be used in a dosage that is definitely adequate to be effective as repeated doses (re-dosing) may lengthen the time of the resuscitation with a resultant adverse outcome. An error with a *slight* overdose would be preferable to the risk of ineffective treatment (115). The dose ranges for most medications allow for a substantial margin for error in any event. This does *not* apply to less emergent situations, such as procedural sedation, when drug doses must be based on a measured weight because the risk of overdose may be associated with increased morbidity because of the different drugs used and the different clinical scenario.[26]
- **Avoid overdosing potentially harmful drugs.** A drug dose that definitely falls on or below the recommended dosage should be administered initially. Since resuscitation drugs are often titrated to response, re-dosing can be safely performed if the initial dose failed to achieve the desired effect (65,

[25] This is reflected by the overall bias towards under- or over-estimation of the weight-estimation system, and is important in the design of a new system: the Broselow tape has been shown to have a bias towards underestimating weight in most populations (except in Asian populations) and the position of the weight divisions on the PAWPER tape was therefore designed differently to avoid this overall bias.

[26] A slight overdose of a sedative agent administered for procedural sedation may have more significant consequences than a slight overdose of the same agent used for a rapid sequence intubation.

66). In this way the potentially harmful effects of inadvertent overdose can be avoided.

These issues highlight the importance of actual measuring body weight, and possibly body composition, whenever possible. Future developments in resuscitation aid technology may well focus on a scale incorporated into the resuscitation trolley which can be linked to a computer-based system to automatically provide comprehensive information on drug dosaging.

Notwithstanding this, length, and therefore also weight predicted by length, is a better predictive variable for equipment size (especially endotracheal tube size) than weight itself (1, 74, 86, 87, 142, 144, 147, 148, 197-199). This impacts on the PAWPER tape because it is not known whether equipment size will correlate better to the unmodified estimated weight (length on the 50th centile) or the estimated weight modified by the habitus score assessment. It would complicate the process of equipment selection to the use the unmodified weight to predict size and the modified weight for drug dosaging. This will still need to be evaluated in further studies.

The most important piece of equipment that commonly needs urgent sizing recommendation is the ETT. There are few recent studies to show whether ETT prediction using length has changed with the changing growth and body composition characteristics of children. The increasing use of cuffed ETTs has also somewhat diminished the importance of exact tube sizing prior to the first intubation attempt. It is possible that children with increased weight-for-length as a

result of a large frame may have a different ETT requirement than a child with increased weight-for-length as a result of obesity. The former child might have an ETT size better predicted by a modified weight and the latter by an unmodified weight; this is unknown and will need elucidation from further scientific evaluation.

5.3 The performance of the Broselow tape

In this study population the Broselow tape did not perform quite as well as in the original study (49), but the overall performance was very good. The number of children in this study with a weight estimation of ≤10% error was higher, but the number of our children with a weight estimation error of >25% was also greater. These findings are also better than some of the more recent studies that have concluded with negative findings about the Broselow tape (10, 12, 114, 116, 130, 142). Nearly 64% of children had a weight estimate within 10% of their actual weight. This varied from 65% in smaller children to 58% in children >20kg. The corollary of this is, however, that about one-third of all children had a weight estimate with an error exceeding 10%. The overall bias was a 0.9kg underestimation of weight, with most of the variability noted in children >20kg where the mean underestimation was 2kg. The upper quartile of the AMPE was 13% reflecting that three-quarters of the study population had a weight estimation error of <13%. With a breakdown of performance by body habitus, the Broselow tape performed poorest in children of above average weight-for-length (only 28% were within 10% of actual weight), poorly in children of less than average weight-

for-length (just under 60% were within 10% of actual weight), and best in children of average body habitus (85% were within 10% of actual weight).

5.4 The performance of the PAWPER tape without habitus modification

The PAWPER tape performed adequately in this study, with just over 70% of children receiving a weight estimate within 10% of actual weight (varying from 64% to 75% by weight category and from 48% to 92% by body habitus category). The overall bias was very small in children ≤20kg, but with a mean bias of underestimation of 1.4kg in children >20kg. The upper quartile of AMPE was 11%, indicating that three-quarters of the children in the study population had a weight estimate error <11%. The PAWPER tape performed adequately across the three weight categories (>60% within 10% weight error in each category) but performed poorly in children above and below average weight for length (51% and 48% within 10% error respectively).

The performance of the PAWPER tape in the group of children <20kg was sufficiently accurate that the habitus score modification could be omitted in these children. This would result in a simpler, although somewhat less accurate, system. Further studies would be needed to determine the benefit of simplifying the system for this weight category.

5.5 The performance of the PAWPER tape with habitus modification

The PAWPER + HS technique performed well in this study. Nearly 90% of children had a weight estimate of within 10% of their actual weight. This ranged from 90.8% in children ≤12kg to 86.4% in children >20kg. The overall bias was virtually zero in children ≤20kg, with a mean bias of underestimation of 0.4kg in children >20kg. The upper quartile of the AMPE was 6.5% which indicates that three-quarters of the study population had a weight estimation error of <6.5%. The PAWPER + HS technique also performed well in children across the spectrum of body habitus: in children with above average weight-for-length, 86.7% were within 10% of actual weight; in children of less than average weight-for-length, 85.9% were within 10% of actual weight; and in children of average body habitus, nearly 92% were within 10% of actual weight.

5.6 Gender differences

There was no significant difference in the performance of any of the weight estimation systems when male and female children were compared. Although the precision was identical between genders for all three tape systems, the bias towards weight underestimation in the Broselow and unmodified PAWPER system was slightly less in females than in males. This is worthy of note because the weight divisions on the PAWPER tape were developed from the growth charts for boys. It is possible to conclude then, that this does not result in unacceptable weight estimation accuracy in girls.

The PAWPER + HS system estimated weight equally well in boys and girls with virtually no bias and equal precision.

5.7 The PAWPER tape vs the Broselow tape

Although the Broselow tape performed well in this study population, the PAWPER tape (without the use of the habitus modification) performed as well or better:

- The correlation with actual weight was better overall and in each weight category.
- Both measures of tape bias (MPE, Bland-Altman residual) were significantly more neutral in the PAWPER than the Broselow tape, and showed a 50% reduction in bias across all weight categories.
- Each measure of tape precision (AMPE, SD of residual and MPE, Bland-Altman 95% CI limits) was significantly better in the PAWPER tape than the Broselow tape, amounting to a 10% improvement in precision, both in the entire population and in each weight category.
- The PAWPER tape predicted weight to within 10% of actual weight more often than the Broselow tape: 71% vs 64% for the entire population and 74% vs 66%, 75% vs 66%, and 64% vs 59% for each weight category, respectively. This was statistically significant except in the comparison for children ≤12kg, which showed a trend to better performance.

In cases when the weight estimation was >10% of actual weight, the PAWPER tape was slightly more likely to overestimate rather than underestimate children's weight when compared with the Broselow tape, which most often underestimated weight. For the PAWPER tape, of the 28.7% of cases in which the weight estimation error was >10%, 16.5% were overestimations and 12.3% were underestimations. For the Broselow tape, on the other hand, of the 36.4% of cases in which the weight estimation error was >10%, 9.5% were overestimations and 26.9% were underestimations.

The PAWPER tape performed somewhat better than the Broselow tape at predicting weight in children who were above average weight-for-length (51% vs 28% were estimated to within 10% of actual weight) and who were of average weight-for-length (92% vs 85% were estimated to within 10% of actual weight). The PAWPER tape was less accurate than the Broselow tape in children with a lower than average weight-for-length (48% vs 59% were within 10% of actual weight).

The difference in performance of the PAWPER and Broselow tapes in children who had an average or an above-average weight-for-length was the main determinant of the overall slightly better weight-estimation performance of the PAWPER tape. The better performance of the PAWPER tape in these children compensated for the poorer performance in children with a below average weight-for-length.

There are two main reasons to explain the slightly improved performance of the PAWPER tape compared to the Broselow tape. The first is the selection of the WHO 2006 weight-for-length growth charts as the basis for the PAWPER tape as opposed to the NCHS 2000 charts upon which the Broselow tape is based. While the difference between the 50th centiles of these charts is fairly modest, with the WHO 2006 50th centile only between 3.7% lower to 0.7% higher than the NCHS 2000 50th centile over the comparable weight ranges from 3kg to 20kg (140), it may be enough to enhance the accuracy of weight estimation in a heterogeneous population. The second, and more substantial, reason for the improved performance is the positioning of the weight divisions of the PAWPER tape relative to the 50th centile of the weight-for-length chart (see Figure A1-1). The divisions of the Broselow tape occupy the area below the 50th centile[27] while those of the PAWPER tape straddle the 50th centile: this made it less likely to underestimate the weight of children with an average habitus, and decreased the underestimation of weight in larger children. It also explains why the PAWPER tape was less accurate in children with a low body mass index.

This data has shown that the unmodified PAWPER tape is at least equivalent to the Broselow tape in terms of weight estimation in this study population.

[27] There is no published information from the developers of the Broselow tape about the rationale behind the statistical construction of the tape. It is therefore only possible to speculate about the reasons underlying the positioning of the weight divisions.

5.8 The PAWPER + HS vs the Broselow tape

The inclusion of a measure of body habitus considerably improved the accuracy of weight estimation. The PAWPER + HS technique appreciably, and statistically significantly, outperformed both the Broselow tape and the PAWPER tape (without the modification) in the study cohort, in each weight group and each body type: every measure of bias and precision was substantially improved (see especially Tables 4-7 and 4-8). This methodology showed virtually zero bias with at least double the precision of the other two tape estimation methods. This difference was most pronounced in children >20kg and in children both above and below average weight-for-length. In every subgroup analysis no fewer than 85% to 90% of children had a weight estimation that fell within 10% of actual weight. Only 49 children (10.8%) in the entire study population had a weight estimation error exceeding 10%, of which half were overestimations (median 12.3% error) and half were underestimations (median 13.8% error). Of the children whose weight was underestimated, 17 of the 25 would be classified as obese (>95th centile of the BMI-for-age NCHS 2000 chart).

Inasmuch as the PAWPER tape performed somewhat better than the Broselow tape, the PAWPER + HS technique outperformed them both substantially. The difference in weight prediction accuracy was most notable in the areas of weak performance of the Broselow and unmodified PAWPER tape methods: children >20kg and children with BMI greater or less than average (above or below average weight-for-length). For instance, children with a high BMI had a weight prediction within 10% of their actual weight as follows:

- Broselow tape – 28% of children.
- PAWPER tape – 51% of children.
- PAWPER + HS technique – 87% of children.

The use of the habitus score in this form thus proved crucial to the overall improvement of performance of weight estimation.

Recent studies have demonstrated poor performance of both the Broselow tape and DWEM system in children >20kg (118) possibly because of the increased effect of differences in body habitus on weight estimation in bigger children as well as the change in the “average” child over the last 2 decades rendering the older growth charts inaccurate. It is likely that weight estimation systems will need to be regularly updated to keep pace with the changing body composition of children in today’s (and tomorrow’s) society.

5.8.1 The habitus score

The addition of a measure of body habitus (by means of the habitus score) to the length-based weight estimation by the PAWPER tape improved its predictive accuracy tremendously, with only a slightly increased intellectual demand on the person performing the measurement.

The use of an assessment of body habitus to improve the accuracy of length-based weight estimation has been suggested by several authors (48, 115, 128,

133) and is currently under investigation by the developers of the Broselow tape for inclusion into their system (65). Body habitus appraisal has already been described and developed into a weight estimation system, the devised weight-estimating method (DWEM) (4) which made use of three habitus categories: slim, average and heavy. This method has been externally validated in subsequent studies (4, 12, 118).

Body habitus can be readily and reliably assessed by visual inspection at the same time that length is measured using a tape or tape-based weight estimation system (4, 12), but some authors have suggested that the need for special training might preclude the use of body habitus assessment in a busy multidisciplinary ED with a rapid turnover of junior doctors and nurses (114). In the only two studies that have evaluated the DWEM (12, 118), both had positive findings with respect to the accuracy of the system but the assessment of body habitus was performed only by the principal investigator in each group. Habitus assessment has been proven to be able to improve weight prediction, but it might be difficult to implement in clinical practice if accurate body habitus assessment is beyond the abilities of doctors and professional nurses outside of an academic setting. The ability of both senior and junior ED personnel to assess body habitus accurately using pictures of children has been demonstrated (12), but whether this can be reproduced in clinical practice still needs to be fully established.

In this study body habitus was gauged purely by general visual inspection at the same time that the tape measurements were obtained and a habitus score from 1 to 5 was assigned (see Appendix 1 for a full description of the method used). The

child's habitus was assessed to fall into one of five categories: average weight and frame size (a score of 3); below average weight and/or frame size (a score of 1 for very thin/small children or 2 for thin/small children); and above average weight and/or frame size (a score of 4 for large/overweight children or 5 for very large/overweight children).

No anthropometry or specific physical characteristics were used to assist with the body habitus assessment; the assessors were instructed to use an immediate overall impression to determine the HS. While a more directed or focused protocol would probably increase the accuracy of the assignment of a body habitus score, it would also increase the complexity of the system and therefore the potential for errors and waste of critical thinking time. The need for a rapid method of habitus assessment in an emergency setting is paramount.

A goal-directed and reproducible method of training individuals to assess body habitus, such as a web- or software-based system, might be needed to develop the desired degree of competence and confidence that is required for this system to be reliably used in clinical practice.

The inter-observer reliability of body habitus score determination using this method was excellent with a 90% agreement of scores (κ-coefficient of 0.83), showing that it is a reliable and repeatable adjunct to length-based weight estimation. The comparisons between the "experienced" data collectors who collected the majority of the data and the "inexperienced" minor data collectors showed only a single statistically significant difference between the groups: the AMPE of the PAWPER +

HS technique was just over 1% better in the major data collector group. The trends in this data suggest that the experienced collectors were better at wielding the tapes themselves as well as in their ability to accurately assess body habitus. Even in the group of inexperienced data collectors the use of the habitus score still improved the overall accuracy of weight estimation impressively. So while it is correct that experience and training improve the ability to assess habitus, as can be seen by the increased precision of estimation in the experienced assessors, it is also true that the system can be employed by relatively inexperienced personnel to good effect.

It was interesting that only about half of the total population of children were assessed as having an average habitus (habitus score of 3), with roughly one quarter above average (28%) and roughly one fifth below average (20%) weight-for-length. This highlights the importance of the inclusion of a measure of body habitus in tape-based weight estimation: both the Broselow and the PAWPER tapes performed extremely well in children with an average body build, but less well as soon as the body habitus deviated from the norm. The use of the PAWPER + HS technique allowed the accurate prediction of weight in these children whose weight is normally over- or underestimated using other methods. In this study the weight estimation was improved in over 43% of cases by modifying the tape weight with the HS. There were 16 children (3.5%), however, in whom the weight estimation was worse after the modification with the HS but this change was small (a nett AMPE of 6.4%) and only 1 case (0.2%) had a subsequent AMPE of >10%.

There was an excellent agreement between the HS assigned during the study and a theoretical optimum HS assigned *post hoc*. In only 6.6% of cases could a different HS have produced a better weight prediction at the measured length; an additional 2.6% of children would have required an HS of less than 1 or greater than 5, however, as they had extreme body habitus types. During the study we noticed a small number of children who had a large discrepancy between the PAWPER + HS estimated weight and measured weight, but when we re-examined them we agreed with the initial HS assessment. There is little doubt that although body habitus and length have been identified by multiple regression techniques as the variables accounting for the majority of variation in body weight (4) there are still other factors influencing weight.

5.8.2 The habitus score and body mass index

The habitus score was strongly correlated with body mass index (BMI) and the NCHS 2000 BMI-for-age centile (BMI%). There was also a significant difference in the BMI and BMI% between each of the HS groups. This substantiates the premise that the HS methodology would accurately and reliably separate children into groups according to BMI (or body habitus). This is advantageous because other studies have shown BMI or BMI% to be better at predicting malnutrition and obesity than variables derived from weight-for-length only (157, 172, 200). An indirect measurement, such as the HS, that correlates well with BMI therefore promises to add a proven element of discrimination between undernourished and obese children into the weight estimation process.

In this study population, the children who were assigned an HS of 3 (average) were indeed average (BMI 16.0 vs 16.4 for the entire population) although the median BMI% was below average (40 vs 50 for the entire population). This raises the question, then, of what is *average*? This becomes important if this technique is used outside of the reference population: it may then underestimate weight in a population where *average* constitutes a higher average BMI; or it may overestimate weight in a population where the *average* patient has a lower BMI. It may be necessary to specifically train individuals using the system (or create a more objective process) in how to accurately assess body habitus: this question was beyond the scope of this study and requires further investigation.

5.9 The epidemics of obesity and malnutrition in South Africa

An escalating prevalence of obesity has been identified by many authors as one of the primary reasons for the documented diminished accuracy of length-based weight estimation systems (11, 115, 118, 127, 133, 135, 147). The epidemic of obesity is beginning to penetrate even the poorest developing countries in the world, although it is most significant in the developed world, and especially in the USA. It affects not only the affluent portions of the population but also those from the semi-urban and rural sectors, mostly as a result of an increasing dietary fat content (201). This is true in South Africa and other parts of Africa as well (160, 202-204), but there are still large numbers of children who are undernourished with a low weight-for-length and weight-for-age (61, 129, 205) resulting in a

population with many children at both extremes of body type. There is also evidence that length-based weight-estimation systems may overestimate weight in children from a population where malnutrition is common (10, 61, 129). Thus a population of children in South Africa faces a "double jeopardy" of potential over- or underestimation of weight unless a measure of body habitus is used to modify weight prediction methodologies, as has been suggested previously (48, 114, 115).

The population of this study had a mean BMI of 16.4 which was similar to that of comparable age-groups across a wide range of socio-economic groups of South African children reported previously (15.5 to 16.7) (160) and straddles the 50th centile of the NCHS 2000 BMI-for-age growth charts (15.5 to 16.5 for this age range). It was a little higher than 2002 figures from Ethiopia (14.2 to 14.5), Zimbabwe (15.3 to 15.4) and other figures from South Africa (13.8 to 14.0) (202). The number of overweight and obese children (9.3% and 3.6% respectively) in this study population was also similar to that reported in a recent large South African study (13.9% and 3.4% respectively) (160). These percentages are about half of what might be expected in the USA, but reasonably similar to figures from the rest of the world (160). There was also a reasonable representation of small-for-length children in the study population (7.1% of children were below the 5th centile of the NCHS 2000 BMI-for-age charts). The fact that the PAWPER + HS technique was able to accurately predict weight in both the over- and underweight child through the use of habitus assessment was encouraging. The strong association between the HS and BMI shown in this study further supports the benefits of using a habitus assessment in a heterogeneous population such as found in South Africa.

5.10 The potential use of the PAWPER tape with habitus modification in clinical practice in South Africa and internationally

The current study was conducted in children attending an ED attached to a private hospital which raises a concern that the sample may be biased towards a more affluent, urban population. Authors from India have suggested that the growth and development of children in their affluent population is very similar to that of children in Europe, but that children from their poor community are notably smaller-for-age than expected (10, 130).

The BMI data from this study population, however, is comparable to published data obtained from a local South African population with a broad range of race, ethnicity, geographical location and socio-economic status (160, 202-204). It is also similar to data from other European and Asian nations. This data also suggests that this technique might be accurate in other parts of South Africa, in Europe and Australasia to estimate the weight of children within the centiles of the weight-for-length charts. The prediction of weight in obese children was much better with this technique than with any other method described to date, but is still prone to underestimate weight in this group of patients. If this device is used in a population with a very high prevalence of obesity (such as in the USA), this should be taken into account.

The PAWPER + HS methodology has shown acceptable predictive value in children with a low BMI, a moderately high BMI as well as an average body type. The use of this system with a resuscitation aid containing drug dosage information

should, therefore, assist to ensure that as many as possible children receive an appropriate dose of medication or fluid (sufficient drug administered) and that as few as possible children are overdosed or over-resuscitated (which in itself may be dangerous). The inclusion of the habitus assessment into a weight-estimation system has been shown in this study in a heterogeneous population to be superior to a system that is based on length alone.

5.11 Limitations of this study

The primary investigator in this study to validate the PAWPER tape was the inventor and developer of the tape. This raises the potential for bias in the study and is therefore a limitation.

The principal investigator of this study (MW) has had previous training and experience in anthropometry, other aspects of body composition assessment as well as in human growth and development. This experience and the training given to the members of the nursing staff who collected much of the data may be different to that available in a general ED and our observations and assessments of body habitus might not be comparable to those obtained elsewhere. Other clinicians may potentially be less accurate in their assessment of body habitus without a specific training programme or without using objective criteria to assist the assessment.

This patient population was a convenience sample of children attending two specific EDs. Children requiring emergency treatment were excluded and this may have introduced some bias in two respects: children with critical illness or injury may be different to ambulant paediatric patients in terms of their body composition; and the usual physical, psychological and cognitive stresses experienced by healthcare personnel during a paediatric resuscitation were not present. The patient population from this study might also not be indicative or typical of the entire population in our area or across the country.

Ethnic origin, race and socio-economic status were not recorded or used for any analysis. Gender was also not used for separate analyses and all growth chart data were taken from growth charts for boys. While in theory it may improve the accuracy of an analysis to introduce additional variables, the complexity increases exponentially. A tape-based system needs as few variables as possible to account for as much variability as possible in order to balance accuracy with expedience.

The ability of the PAWPER + HS system to accurately estimate weight in the obese patient is still limited. The addition of a 6th habitus score category (obese or XXL) may be required to further improve weight estimation in these patients or, more likely, some novel technique such as bioelectrical impedance may need to be employed to increase accuracy.

Which form of body weight to use for drug dose calculations in the emergency management of critically ill or injured children is still unresolved. Until this is clear most researchers are still using TBW, or an estimate using TBW as the standard.

5.12 Strengths of this study

This is a prospective study to validate an existing newly developed instrument: the study population was used exclusively for validation and did not contribute to the development of the instrument.[28]

The study was adequately powered to allow for accurate equivalence / superiority analysis within 3 subgroups.

The actual tapes were used to obtain measurements rather than a tape measure and children were measured in the supine position to obtain a true length rather than height.

[28] This is important from a purely technical, statistical perspective.

Chapter 6 CONCLUSIONS

The Broselow tape performed virtually as well in our population as it did in the original population in the USA. There has been no previously published validation of the Broselow tape in a South African population (to my knowledge) and this study confirms that it can be confidently used with the expectation that it will perform as well as its developers intended.

The unmodified PAWPER tape system performs as well, or a little bit better than the Broselow tape. If the operator is uncertain about the habitus modification system the tape can still be used using a length-based method only and still produce a weight estimation that is as good as any other system currently available.

The system of weight estimation used by the PAWPER tape, incorporating a weight adjustment based on body habitus to the length-based weight estimation, is simple, accurate and performed as well or better than the Broselow tape.

The habitus score, assigned by visual inspection by trained observers, was shown to accurately reflect BMI and considerably improved the accuracy of weight estimation. This system has addressed some of the issues surrounding inaccuracies in weight estimation in children who have above or below average BMI, and has performed well across the spectrum of weight ranges and body types.

The tape can be used with minimal training and removes the need to remember formulas and perform calculations to estimate weight during stressful medical management situations. It can thus potentially remove one of the common delays that hinder emergent and potentially life-saving treatment.

The PAWPER tape has thus been validated under study conditions in the ED but still needs further assessment in a number of different environments and by a number of different observers. It can potentially be used in the prehospital environment or the ICU as well, but that must also be tested. It has the potential to perform well in other local or international populations that have characteristics similar to that of this study.

The estimation of weight in the truly obese child still remains a concern. While the performance of the PAWPER tape system is better than that of the Broselow tape in this group, the end results are still somewhat unsatisfactory.

Additional research is urgently needed to establish a pharmacokinetic “target weight” which should be used for drug dose calculation, and therefore weight estimation strategies.

Recommendations

The PAWPER tape needs to be evaluated in a number of different populations to establish its accuracy across a range of socio-economic strata and ethnic and racial characteristics.

The PAWPER tape needs to be evaluated in a group of acutely and chronically ill children to establish whether the HS system improves length-based weight estimation in the same way as less ill children.

The HS system needs to be evaluated when used by a number of different people with varying degrees of training and experience in paediatrics, paediatric emergency medicine, and experience in body habitus assessment.

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APPENDIX 1 The creation of the PAWPER tape system

The best weight estimation system available at present for use in the ED is arguably the Broselow tape. There are, however, a number of recent studies that have shown that weight estimation by the Broselow tape may be inaccurate in some individuals: specifically in children in the upper centiles of weight-for-length (and obese children) (115, 142) and also in children who are in the lower centiles of the weight-for-length charts (10, 61, 143).

The PAWPER tape was devised to optimise the accuracy of emergency weight estimation in children through including a measure of body habitus into the standard length-based weight estimation process as well as the use of the WHO 2006 rather than the NCHS 2000 weight-for-length growth charts. It was inspired by the accuracy of the DWEM system and the practical usefulness of the Broselow tape, and a combination of a tape-based and a habitus/length based system was developed. While all the basic principles have been proven in previous studies, the application of these principles by means of this device is completely novel.

What is the PAWPER tape?

The PAWPER tape is, in essence, a full scale representation of the 50th centile of the WHO 2006 weight-for-length chart. Each weight division corresponds to the 50th centile of weight at that length with the 50th centile[29] falling in the centre of each weight division on the tape.

[29] The 50th centile represents the median weight at each length – half the population is above and half below this weight-for-length.

Since not every child has a weight on the 50th centile for their length, the PAWPER tape was designed to improve the accuracy of the weight estimation of children with a higher or lower than average weight-for-length. It has been shown previously that weight can be predicted more accurately when a measure of frame-size or habitus is included in the prediction methodology (4, 12, 118). For this reason a tape-based system was devised whereby the weight predicted by length could be modified by the inclusion of an assessment of body habitus. The body habitus of each child, as appropriate for their age, is scored on a five-point scale:

- Habitus score 1: very small frame and/or very thin with ribs easily visible (XS).
- Habitus score 2: slightly smaller than average frame and/or decreased adiposity ("thin" / "petite") (S).
- Habitus score 3: average frame size and body habitus (M).
- Habitus score 4: slightly larger than average frame size and/or somewhat increased adiposity ("chubby" / "well padded") (L).
- Habitus score 5: very large frame and/or significantly increased adiposity ("fat" / "overweight") (XL).

This appraisal of body habitus is obtained by visual inspection by the person performing the length measurement with the PAWPER tape. It is not based on any specific anthropometric or morphological assessment: this technique has been validated using a three-tier scale (slim, average or heavy) in previous studies (4, 12, 118). The assessment of body habitus needs to be a process that can be

rapidly employed to avoid delays in weight estimation and, consequently, emergency medical treatment.

Once an estimation of body habitus and a body habitus score has been established, the modified weight-for-length can be read off the PAWPER tape. Weights approximating the rounded-off values at the 5th, 15th, 85th and 95th weight-for-length centiles at that specific length are shown in each weight division. These weights are the predicted weights for each habitus score (i.e. 1, 2, 4 and 5) at that length. The principle of this technique of using the centiles to guide the development of a modified weight-estimation system has been proven under somewhat different circumstances previously (4, 61).

The available evidence suggests that equipment size (such as endotracheal tube size and depth of insertion) is probably best predicted using the length at the 50th centile weight (133). Whether this holds true in children below or above average weight-for-length children has not been studied. Therefore, with the PAWPER system, whether equipment size should be selected based on the unmodified weight or on the weight modified by body habitus is unknown. This needs to be addressed in a clinical trial. This does, unfortunately, potentially create a more complex system with a corresponding higher risk for error.

Salient features of the PAWPER tape system

The most important aspects of the design, development and function of the PAWPER tape can be summarised as follows:

1. The PAWPER tape is exclusively a specialised weight-estimation device. It was designed to provide as accurate an estimation of weight as can realistically be achieved with the application of currently available knowledge and techniques.
2. The PAWPER tape is based on the WHO 2006 weight-for-length growth charts.
3. The PAWPER tape is designed so that the 50th centile is in the centre of each weight division in order to avoid underestimating children's weight by emulating the process of rounding-off: eg. a weight predicted by the length as measured by the tape of 14kg would represent weights from 13.5kg to 14.49kg, rather than weights from 14.0 to 14.99kg (see Figure A1-1).
4. The PAWPER weight estimation system makes use of two important components of the variability associated with body weight in children: length and body habitus. The system produces a primary estimation of weight based on recumbent length, with a method of increasing the weight estimation accuracy in children who are large or small for length. This secondary estimation of weight is accomplished by means of the assigned habitus score (1 to 5) which corresponds to approximations of weight at the 5th, 15th, 85th and 95th centiles for length which are printed on the tape within each weight division. The habitus score is assigned by visual inspection by

the person performing the tape measurement and is a reflection of the frame-size or degree of adiposity of the patient.

5. The PAWPER tape was designed to be used in conjunction with a drug dosaging reference system (3) to provide complete information to assist the emergency physician to manage emergencies in children.
6. It is a single-use, low-cost, disposable device.

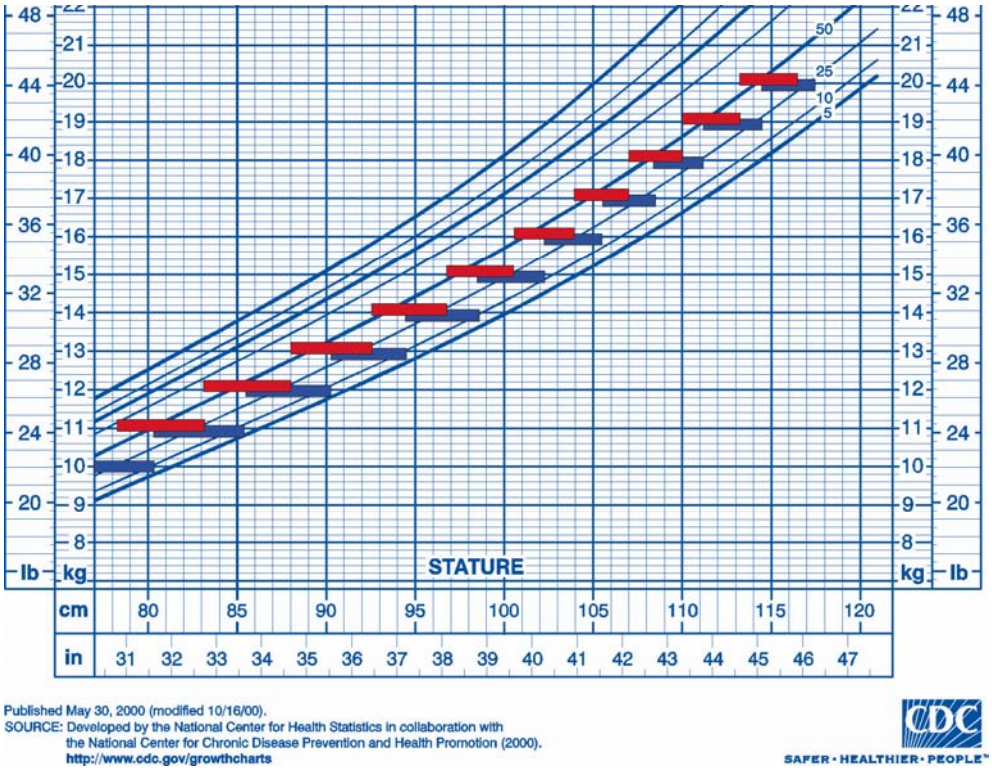
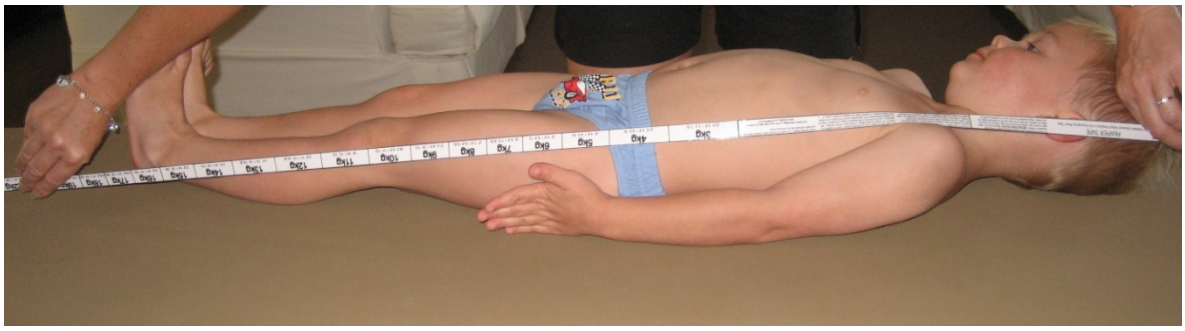


Figure A1-1 The relative positions of the PAWPER and Broselow tape weight divisions to the 50th centile of the NCHS 2000 weight-for-stature chart.

The red bars represent the PAWPER tape divisions and the blue bars show those of the Broselow tape for comparison. The blue bars of the Broselow tape divisions occupy the space between the 25th and the 50th centiles while the red bars of the PAWPER tape straddle the 50th centile. The apparent 2cm to 3cm "left-shift" of the PAWPER tape weight divisions means that the same weight as the Broselow tape is predicted at shorter statures. This difference in design philosophy was conceived to compensate for the reported underestimation errors of the Broselow tape. *Chart reproduced with permission.*

How to use the PAWPER tape

(All photos with permission by courtesy of Dr M Wells)



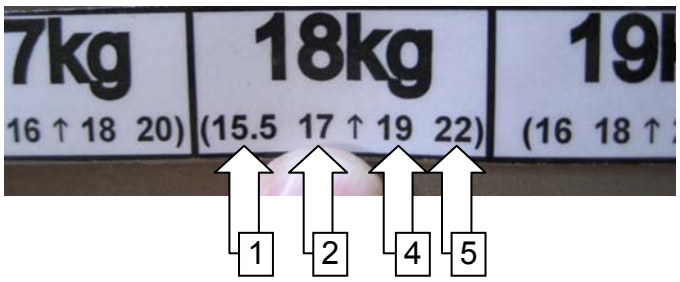
Step 1: Position the child supine on the bed or trolley. Use the PAWPER tape to measure from the child's head at the vertex (the most superior part of the head) to their heel (with the ankle flexed at 90°), starting from the end that reads "MEASURE FROM THIS LINE". Read off the primary weight estimation at the point at which the tape crosses the heel.



Step 2: This primary weight estimation at the point which represents the child's head-to-heel length is equivalent to the weight predicted by a system such as the Broselow tape and may be used for drug dose calculations.

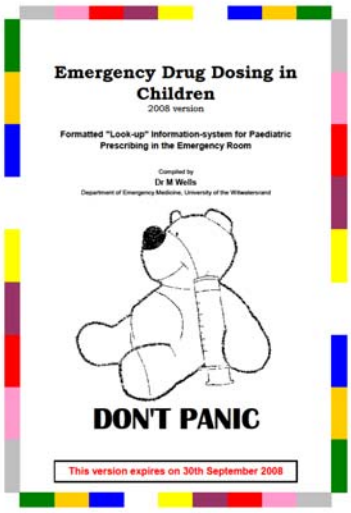
Step 3: If, however, you think that the child is heavier or lighter than average for their length, the weight estimate may be adjusted by the use of a habitus score. Assign the child a score from 1 to 5 based on the size of their frame and their degree of adiposity:

1 – Very thin, somewhat wasted, or tiny frame (XS).
2 – Thin, petite, slim, or small frame (S).
3 – Average body fat and frame size (M).
4 – Heavy, chubby, overweight, or large frame (L).
5 – Fat, significantly overweight, obese (XL).

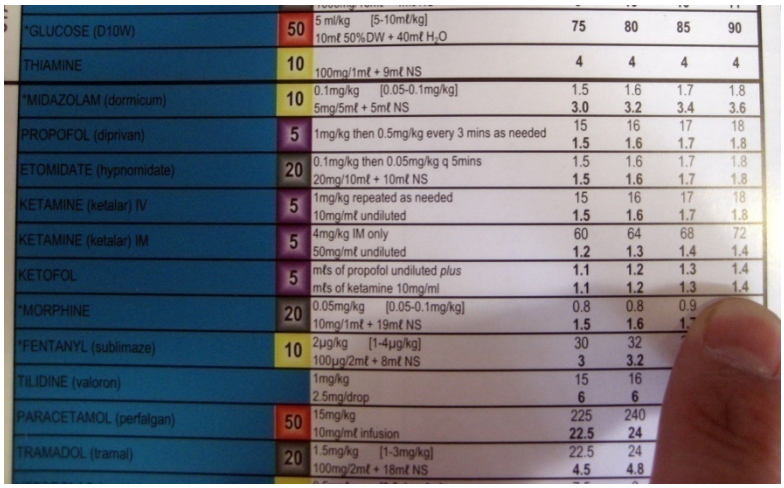


The numbers in brackets on the PAWPER tape correspond to the secondary weight estimations for each habitus score at that length, and represent approximations of the 5th, 15th, 85th and 95th centiles. For example at the indicated length a child who is slightly underweight or “petite” would have a primary weight estimation of 18kg, but since she would receive a habitus score of 2 her secondary weight estimation would be 17kg.

The weight can be estimated with a much higher degree of accuracy by using the modified secondary weight estimation in children with a higher or lower than average weight-for-length. A child with a habitus score of 3 (average) has an unchanged weight estimation (use the big number).



Step 4: Use a reference source, such as a computer-based or chart-based system, to look up the equipment size, drug dose and drug preparation information. The reference should comply with evidence-based recommendations on the presentation of drug dose information to minimise the risks of medication errors in children.



Current evidence suggest that the drug dose reference system (as an example the *Emergency drug dosing in children* booklet is shown here) should contain information on equipment sizing as well as drug dosaging. The drug dose information should include the dosage based on body weight, the total drug dose, the method of dilution and the millilitre volume of the diluted drug to administer. No calculations should be required.

APPENDIX 2 The Emergency drug dosing in children reference

Critically ill and injured children and infants that present to the ED are at considerable risk for harm following errors occurring during the delivery of drug therapy (5). Infants and smaller children, those with co-morbidities and the critically ill are more susceptible to medication errors and more vulnerable to resultant harm (21, 206-208). These errors are most likely to be related to dosaging errors of drugs or fluids as these are committed in as many as 10% of paediatric drug orders (5, 23, 159). Calculation errors in the determination of drug dosages for children (derived from a milligram per kilogram base dose) by emergency physicians are common (98, 99); similarly errors in the preparation and administration of the millilitre volume of the drug-dilution by the nurse is prone to error (72, 75). The high stress and high activity of a paediatric resuscitation further degrades the team members' ability to avoid medication errors (7).

Solutions to this problem include the creation and maintenance of a "culture of safety" relating to medication administration to children in the ED, the judicious use of technology to assist in drug dose calculation and delivery, or pre-printed dosage calculation sheets which include information on drug doses, dilution and delivery (13, 209-212). Furthermore the approach to the paediatric resuscitation should be team-based, pre-planned, standardised and simplified by the use of resuscitation aids such as the Broselow tape or the PAWPER tape *in addition* to extra material which provides complete drug dosaging information from the base dose through to the millilitre volume to administer (1, 6, 7, 65, 66, 92).

The *Emergency drug dosing in children* series was designed to do exactly this: to provide on a page all the information needed to assist the resuscitation team to accurately prepare and administer any medications that might be required in an emergency, to both remove the cognitive burden of drug dose calculation and to minimise the chances of medication errors. Furthermore, information on emergency equipment sizing, the use of emergency infusions and emergency ventilator settings is also included. The book has three major sections: oral drugs doses, IV/IO bolus drug doses and IV/IO drug infusions. The oral drug and infusion information is presented for each weight from 3kg to 36kg (as it appears on the Broselow tape). The IV/IO emergency bolus drug dosage information is grouped together by colour zone to facilitate use with the Broselow tape.

This book of dosaging information may be used with actual measured body weights, or with weights estimated by the Broselow tape, PAWPER tape or other method and includes both intravenous and oral drug dosage guidelines.

Figure A2-1 contains a section of the instruction page of the booklet which illustrates the format of the information contained for each drug.

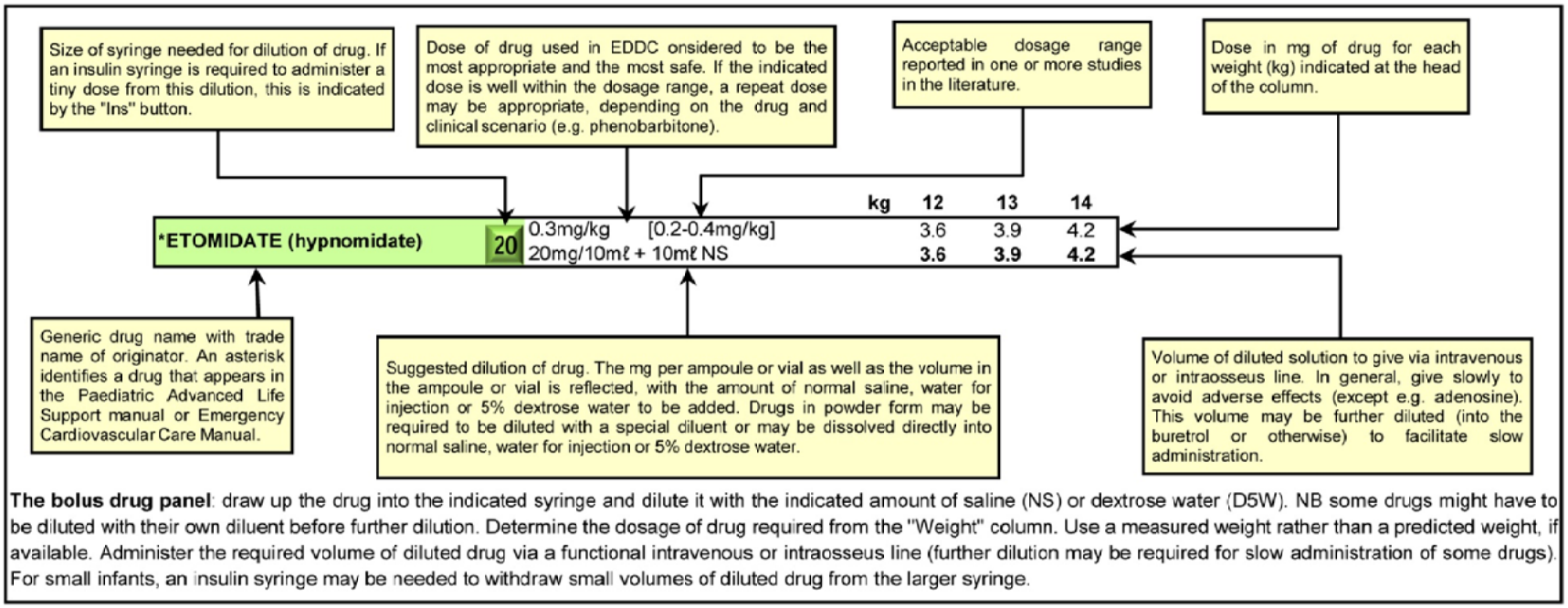


Figure A2-1 A sample panel from the instruction page of the “Emergency drug dosaging in children” reference booklet which illustrates the information provided in the device: comprehensive drug dosage and dilution information.

APPENDIX 3 Human Research Ethics Committee clearance

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Wells

CLEARANCE CERTIFICATE	**PROTOCOL NUMBER M080413**
PROJECT	Weight perdiction in children in the emergency department
INVESTIGATORS	Dr M Wells
DEPARTMENT	Emergency Medicine
DATE CONSIDERED	08.04.25
DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 08.06.11 **CHAIRPERSON** .....
(Professor P E Cleaton Jones)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : Dr A Coovadia

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES