A comparison of reagent strips and the refractometer for measurement of urine specific gravity in hospitalized children

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Reagent strips (Miles Laboratory, 1994) compared with a refractometer (Kernco Instruments, 1995) for testing urine specific gravity.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The study population was children at an inpatient paediatric unit (neonatal intensive care or haematology-oncology-general paediatrics) requiring measurement of urine specific gravity.

Setting
The study setting was Tertiary care.

Dates to which data relate
The dates to which data related were not stated.

Source of effectiveness data
Effectiveness data were derived from a single study.

Link between effectiveness and cost data
Costing was retrospective and was based on the same sample as that used for the effectiveness analysis.

Study sample
The authors determined that "a convenience sample of at least 100 was necessary, based on a power analysis with a small effect size for a p<0.005 (sic)". There were no explicit requirements for sample selection, other than patients requiring urine specific gravity measurement. The sample was appropriate for the study question.

A total of 157 specimens were obtained over a 5-week period and tested with both reagent strips and a refractometer. All samples were from children aged between 1 day and 16 years. In the case of three observations, nurses reported difficulty in distinguishing between two colours on the reagent strip. These samples were discarded.
Study design
The study was an uncontrolled, case series trial based at a single centre (the location was not stated).

Analysis of effectiveness
It is unclear whether or not the analysis was based on the intention to treat principle. The outcome assessed was the degree of agreement between the two methods assessed.

Effectiveness results
There was a high degree of agreement between the two methods of urine analysis for a wide range of values of specific gravity. A linear regression scatterplot confirmed that readings from the two methods were highly correlated, and that the reagent strip read significantly higher than the refractometer, \(p<0.0001\). The raw results were not reported.

Clinical conclusions
The refractometer and reagent strips provided comparable results in testing for urine specific gravity in paediatric patients. The reagent strips recorded a significantly higher value of specific gravity than the refractometer.

Measure of benefits used in the economic analysis
As the effectiveness results showed no difference in effectiveness or clinical benefit between the two methods of urine testing, the economic analysis was based on cost differences only (cost-minimisation).

Direct costs
Resource quantities and costs were not reported separately. Direct cost categories included were relevant to a hospital. Costs included were the cost of a refractometer and a bottle of reagent strips. The source of cost data was not stated. Discounting was not relevant as the costs considered were incurred immediately. The study reported marginal costs (i.e. the annual cost of refractometer use and a single bottle of reagent strips). Neither the date nor price-year to which costs referred was stated.

Indirect Costs
No indirect costs were included.

Currency
The currency used was not stated. As the authors are based in the USA, it can be assumed that US dollars ($) were used.

Sensitivity analysis
No sensitivity analysis was performed.

Estimated benefits used in the economic analysis
The reader is referred to the effectiveness results reported above.

Cost results
The authors did not assign costs to each intervention arm, but stated that, in cases where a child needed only urine specific gravity measured, the refractometer was "faster and less costly". The cost of multiple additional refractometers "could be as much as $1,200 per year", and the cost of a bottle of reagent strips was $35.
Synthesis of costs and benefits
Not applicable.

Authors' conclusions
The authors did not draw any economic conclusions. They stated that the two methods produced comparable results. The reagent strips produced significantly higher values for specific gravity. Staff at the authors’ setting decided to use the reagent strip for urine specific gravity when other urine tests were required, and the refractometer when only a specific gravity test was required.

CRD COMMENTARY - Selection of comparators
Although no explicit justification was given for the comparator used, it would appear to represent current practice in the authors’ setting. You, as a user of the database, should decide if the comparator represents current practice in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on an uncontrolled, case series trial, which was appropriate for the study question. The study sample was representative of the study population. As samples from each patient were tested by both means (reagent strips and refractometer), the patient groups were, by definition, comparable at analysis. Appropriate statistical analysis of the results was performed.

Validity of estimate of measure of benefit
It was not appropriate to derive a measure of benefit in this study. The economic analysis therefore included only costs.

Validity of estimate of costs
The cost analysis was too inadequate to allow economic conclusions to be drawn. Whilst the majority of costs were common to both arms, the study did not attempt to identify any differences in cost between each arm. Costs and quantities were not reported separately. Resource use was not quantified. A sensitivity analysis of prices was not conducted. The date to which prices relate was not stated.

Other issues
The authors did not make an explicit comparison of their results with others, however they commented that their review of the literature suggested that reagent and refractometer readings were closely related. The issue of generalisability to settings other than paediatrics was not addressed. The authors presented their results in the form of the Bland-Altman plot, rather than tabular form. The study conclusions reflected the scope of the analysis. The authors reported a number of limitations, which may hinder the internal validity of their study, namely, that information about the source of the urine sample (diaper, free void, or urinary catheter) was not recorded, neither was the time between voiding and sample testing. This study was not designed to be an economic evaluation, and as such, has a very limited interpretation of costs. With more detailed costings, this study could be incorporated into a useful economic evaluation.

Implications of the study
Reagent strips were adopted by the staff in the authors’ setting as they produced a higher reading than refractometers, and therefore will over-estimate a patient's urine specific gravity. This results in a more conservative decision in determining patient hydration status. Additionally, reagent strips are used where other urine tests are required in addition to specific gravity. Where only the specific gravity test is required, a refractometer is used.

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