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
Urinary tract cancer screening through analysis of urinary red blood cell volume distribution curves (RDC) compared with conventional screening, which evaluates all patients with microhematuria for urological disorders.

Type of intervention
Screening.

Economic study type
Cost-effectiveness analysis.

Study population
The study population was males and females aged between 20 and 79 who had a positive urine dipstick test indicating the presence of occult hematuria.

Setting
The study was set in Japan, in five secondary care hospitals. The economic study was performed retrospectively on the patients within this Japanese setting.

Dates to which data relate
The identification of patients with positive dipstick results was undertaken from 1989 to 1990. Although not explicitly stated, it was implicit that the RDC screening was performed at the time of positive identification.

The year of resource use was presumed to be the same as the year when the effectiveness data was gathered. The price year was not stated.

Source of effectiveness data
Evidence for final outcomes was derived from a single study.

Link between effectiveness and cost data
Costing was undertaken on the same patient sample as that used in the effectiveness study. Data on the resources used during screening were collected prospectively.

Study sample
21,307 adults participating in a health screening programme at the hospital were enrolled. Patients were excluded if they did not have a positive dipstick test over +1 (which would indicate the presence of occult hematuria), had gross
hematuria, diagnosed urological diseases, were undergoing treatment or were women during their menstrual period. It is not stated how the initial population was selected for the health screening programme. The sample size was not designed to assure a particular power.

912 adults were eligible for the study and had an RDC test. This study population was appropriate, as they would normally have undergone further tests if they had asymptomatic microhematuria. Five of the 912 patients were unable to provide a detailed enough RDC result and were excluded. 38 of the 907 were classified as high risk (Group 1), defined as having a normocytic or mixed pattern result, and underwent a full urological examination (standard conventional screening). 869 were low risk (Group 2), defined as having a microcytic pattern result, and underwent no further tests.

**Study design**
This was a five site, multi-centre study. The design of the study was a non-randomised, prospective study. Patients were followed up for three years from the RDC test. No patients in Group 1 and 4.1% in group 2 were lost to follow-up.

**Analysis of effectiveness**
Intention to treat analysis was carried out on all patients who were not lost to follow-up.

The primary health outcomes used in the analysis were:

- Number of urological malignancies detected;
- Number of gross hematurias detected;
- Number with microhematuria;
- Number of Group 2 patients who reported they were alive and well and without serious disease at the follow up point at three years.

The comparability of groups at baseline was not assessed.

**Effectiveness results**
On further examination of Group 1, 52.6% had no abnormal findings, 39.5% had benign disease and 2.6% had bladder cancer.

For Group 2, 95.6% reported that they were alive and well at the three-year follow-up. Of these, 1.7% had had gross hematuria, which was subsequently diagnosed as either simple cystitis or urolithiasis. 0.2% of Group 2 patients had died from non-urological related reasons.

**Clinical conclusions**
Patients requiring a complete urological evaluation could be safely selected on the basis of urinary RDC from the general population who have asymptomatic microhematuria. Normocytic or mixed patterns from RDC tests led to 43% of this group having a diagnosed urological problem.

**Measure of benefits used in the economic analysis**
The authors concluded that the RDC test was sufficient to identify safely and effectively those patients who needed further examination and those who did not. Consequently, a cost-minimisation analysis was performed.

**Direct costs**
All the costs of tests were assumed to occur in year one. The costs of any urological-related treatments other than
screening were not included. Discounting was not performed.

The authors assumed that each patient received one of each appropriate test. The RDC test also included the cost of a urinalysis. Group 1 patients also received a urine cytology, blood count, blood biochemistry, ultrasound sonography, drip infusion urography and a cystoscopy. The authors reported that the costs did not include consultant fees.

Unit prices, taken from the approved rates given by the Japanese Health Insurance System (JHIS) were given for each test. The RDC cost is not yet approved by the JHIS.

The cost perspective was the cost to the JHIS of screening and diagnosing patients.

The year for price data and any possible inflation rates used were not stated.

**Indirect Costs**
Indirect costs were not included in the analysis.

**Currency**
Japanese Yen (Y). No conversions were undertaken.

**Sensitivity analysis**
A sensitivity analysis was not undertaken.

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

**Cost results**
By only doing a full urological examination on those patients identified as high risk in the RDC test, a saving of Y 40,790,860 for 907 patients was achieved. This represented an average saving of Y 44,973 per patient.

**Synthesis of costs and benefits**
A synthesis of costs and benefits was not relevant as a cost-minimisation analysis was undertaken.

**Authors’ conclusions**
Compared with conventional screening, the RDC method is both safe and cost saving. A complete urological work-up is only necessary for the small group of patients with normocytic or mixed hematuria RDC results.

**CRD COMMENTARY - Selection of comparators**
The RDC test prevents patients undergoing a full urological examination. The tests involved in this full examination are reported earlier in this abstract and were assumed to occur if the RDC test were not performed. The user of the database should decide if this particular patient group would normally undergo such tests in their own setting.

**Validity of estimate of measure of effectiveness**
This non-randomised study had a study sample taken from a large sample of patients undergoing health screening. The paper did not report how these people were initially selected, although it seems they were part of a mass health screening programme. If mass screening of this nature is not current practice in your own setting, you must consider how you would select people for RDC testing. Patients were not randomly selected and it is unclear how they were
selected into the mass screening programme initially. Consequently, the sample in this study may be biased and this should be taken into account when interpreting the effectiveness and cost results.

Validity of estimate of measure of benefit
The analysis of benefits was based upon the therapeutic equivalence of treatment (screening) alternatives. Consequently, the economic analysis only included costs. Therapeutic equivalence was defined as not undergoing urological treatment for microhematuria during the past three years, and being alive and well without serious illness at the three year follow-up point. If the reader expects that a full urological examination would detect problems not covered by these two definitions of therapeutic benefit, the benefits of RDC testing would be reduced.

Validity of estimate of costs
The implicit perspective of the Japanese Health Insurance System included direct costs. However, these costs were only for screening and excluded the cost of treatment of those patients requiring it during the follow-up period. It is likely that this would not adversely affect the overall result of the study, particularly if a full examination would have led to the same treatment experienced by those patients just receiving an RDC test. In other words, such costs would be common to both treatment (screening) arms. The reader should decide if this is the case in his or her own setting. Implicit in the paper is that patients receive one of each appropriate test dependent upon their risk categorisation. Consequently, quantities and costs were reported separately.

No statistical analysis of quantities of resources was performed, although this would seem reasonable given that each patient only receives one of each test.

Prices were taken from a published source, and represented the rates approved by the Japanese Health Insurance System. The price year was not stated and a sensitivity analysis of prices was not conducted. No discounting was performed as all costs were incurred in year one. If costs incurred in other years, such as treatment costs, were to be included then discounting should be taken into consideration.

Other issues
The authors made appropriate comparisons of their findings with those from other studies. Although they did not explicitly address the generalisability of the results, they did conclude that the RDC screening test was both safe and cost saving.

The authors’ conclusions answer the study question and they have presented their results in a non-selective manner. They reported the strengths of the RDC test but did not comment on the limitations of the study itself. In particular, there was no discussion of the accuracy of selecting people identified as having a positive urine dipstick test result, the specificity and sensitivity of both this urine test and the RDC. The cost of detecting urological problems using the RDC test presented in this study is therefore relevant only for those patients who have had a positive dipstick test.

The reader should decide if the three year time span in this study is appropriate to his or her own setting. If follow-up screening would normally occur within three years the results are more generalisable. If, however, screening should occur after three years, the authors offer no evidence or conclusions on the accuracy of the RDC test after three years.

Implications of the study
The authors concluded that RDC is safe and cost saving for screening patients with asymptomatic microhematuria when compared against conventional, full screening practice. Consequently, they argue that complete urological work-up for asymptomatic microhematuria should be restricted to those patients with normocytic or mixed hematuria, as identified by the RDC. Those identified with microcytic hematuria are safe from urological cancer.

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