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ORIGINAL RESEARCH ARTICLE

Cost Analysis of the Automated Examination of Urine with the Sysmex UN-Series™ in a Spanish Population

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Abstract

Background Current practice for urinalysis mainly entails different manual or semi-automated procedures that generate substantial financial costs, as well as a high and time-consuming workload for laboratory personnel.

Objective The aim of this study was to assess whether the availability of integrated and fully automated urinalysis systems such as the UN-Series™ from Sysmex could resolve such concerns.

Methods The target population was established based on 92,459 urine samples, which is the total average number of urine samples collected in the clinical and microbiology laboratory department of La Mancha Centro Hospital over a 10-year period (2008–2018). Financial data were retrieved from the eSalud database. Reference and test scenarios were defined based on clinical features found in reports from public websites. The cost and savings analyses were based on total costs over a 1-year time frame for the reference and test scenarios. The total average annual time savings for laboratory personnel were also calculated.

Results The comparison of annual costs for current practice versus the automated examination of urine samples found average cost savings of €340,003 per year. Assessment of body fluids using the automated analysis system would provide average annual savings of €1063. The use of the UN-Series™ would save 1615 h annually for laboratory personnel.

Conclusion Implementing the UN-Series™ for the automated analysis of urine samples within routine practice in clinical laboratories could minimise costs, provide substantial savings for investment and improve laboratory procedures. Furthermore, the UN-Series™ could contribute to synergy between clinical analysis and microbiology laboratories in Spain.

Key Points for Decision Makers

Inclusion of the UN system in microbiology and clinical laboratories could provide a regional hospital with an annual cost saving of €340,003.

The implementation of the UN system could contribute to optimising working time for laboratory personnel.

1 Introduction

Urinalysis is one of the most common tests carried out in clinical laboratories [1, 2]. Considering that in Spain, 232.5 urinalyses are carried out for each 1000 inhabitants [3] in primary health care alone, we find that in total, 10,800,816 urinalyses were carried out in 2014. This is because urinalysis is an essential test for clinical medicine that is used to screen, diagnose and monitor diseases that can be detected through the urinary system [1, 4, 5]. Urinary tract infections (UTIs) and kidney disease are two very significant examples of diseases that can be detected or monitored by urinalysis [6].

Moreover, it is estimated that four million people in Spain have chronic kidney disease (CKD), which is associated with four highly prevalent chronic diseases, namely diabetes mellitus, arterial hypertension, heart failure and ischaemic heart disease [7]. For this reason, early detection of CKD is very important, due to the classification of kidney damage in the

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aforementioned at-risk patients by measuring their albuminuria levels [7].

Spanish health expenditure in 2014 amounted to 95,722 million euros for a population of 46,455,123 inhabitants [8, 9]. According to the World Health Organization (WHO), chronic diseases account for 75% of total health expenditure [7]. In Spain, CKD alone accounts for up to 3% of total health expenditure [7].

Currently, urinalysis is divided into three processes that may or may not be requested depending on the requirements of the prescribing physician (Fig. 1). Most of these processes are carried out manually, are very laborious and expensive and do not provide fast results. In addition, there is high inter-observer variability, which leads to increased costs [2, 5, 10, 11].

The European Urinalysis Guidelines recommend using a combination of automatic and manual systems, as this is essential for establishing a new operating procedure for urine workflow [12]. The UN-Series™ is the new automated analysis system for urine sample screening from Sysmex, which can contribute to reducing the proportion of samples that require further manual inspection (Fig. 1).

In addition, various studies have shown that automating the evaluation of body fluids provides rapid results, which may be crucial to the prognosis of patients with certain diseases such as bacterial meningitis or peritonitis [13–15].

Several studies have pointed out important savings in working time due to the use of automated analysers for urine screening. However, few studies have reported health economic data [10, 14, 16]. Methods and procedures are often not clearly described, and the example scenarios can also be quite restricted. Therefore, our aim was to carry out a cost-minimisation analysis for the installation of UN-Series™ automated analysers in both clinical analysis and microbiology laboratories, considering a setting with broad scope that includes the routine screening of urine samples from primary care or the emergency room, microalbuminuria analysis, microbiology and body fluid scenarios.

2 Materials and Methods

2.1 Patient Population

The target population was established based on the total average number of urine/body fluid samples collected in the clinical and microbiology laboratory department of La Mancha Centro Hospital (92,459 urine samples and 94 body fluid samples) over a 10-year period (2008–2018).

2.2 Interventions

In current practice, urine samples are subjected to different procedures and pathways, simultaneously or consecutively, depending on the patient's characteristics and/or disease symptoms. First, the urine is checked for renal pathologies by the immunochemical assessment of albuminuria. If the microalbumin results are negative, the patient is then monitored on a yearly basis. Otherwise, if the urine test is positive, this must be confirmed by obtaining two positive results from a total of three tests [17, 18]. Then, due to differences in management between clinical laboratories, different procedures are followed depending on whether the sample came from the emergency room (ER) or from primary care (PC). Samples from the ER with one or more positive results for biochemical parameters (dipstick assay) are directly examined by manual microscopy, whereas samples from PC are first analysed by dipstick and then by flow cytometry using an automated system. In cases with unclear results from the automated analyser or a request for review by the physician, the urine sediment is examined by microscopy. Next, urine cultures are performed if a UTI is suspected. This is followed by the use of an antibiogram for those samples with positive cultures, to identify the pathogen.

In contrast, our proposal would be to implement the UN-Series™, which is a system that encompasses a biochemical analyser (UC-3500), a flow cytometry urine particle analyser (UF-4000/UF-5000) and a digital imaging device (UD-10). Thus, the UN-Series™ would be used as a single pathway with two final branches. Urine samples would undergo all analyses consecutively. The final procedure for urine assessment would be carried out based on the physician's specific requests. Therefore, all samples would be evaluated by dipstick (UC-3500 analyser). Only those samples with positive results from the UC-3500 analyser would be analysed by flow cytometry (UF-4000/UF-5000 analysers). Some samples would require further evaluation by digital imaging (UD-10 analyser), urine culture or both. In cases with positive cultures, an antibiogram would be conducted.

2.3 Model Description

A two-scenario comparative model was used to assess the difference in costs between the reference scenario, based on standard clinical practice using urine cultures and microscopic analysis for diagnosis, versus the test scenario, based on new clinical practice adjusted for the UN-Series™. The percentages used for the different scenarios (Fig. 1) were taken from the data obtained in two previously published studies [19, 20].

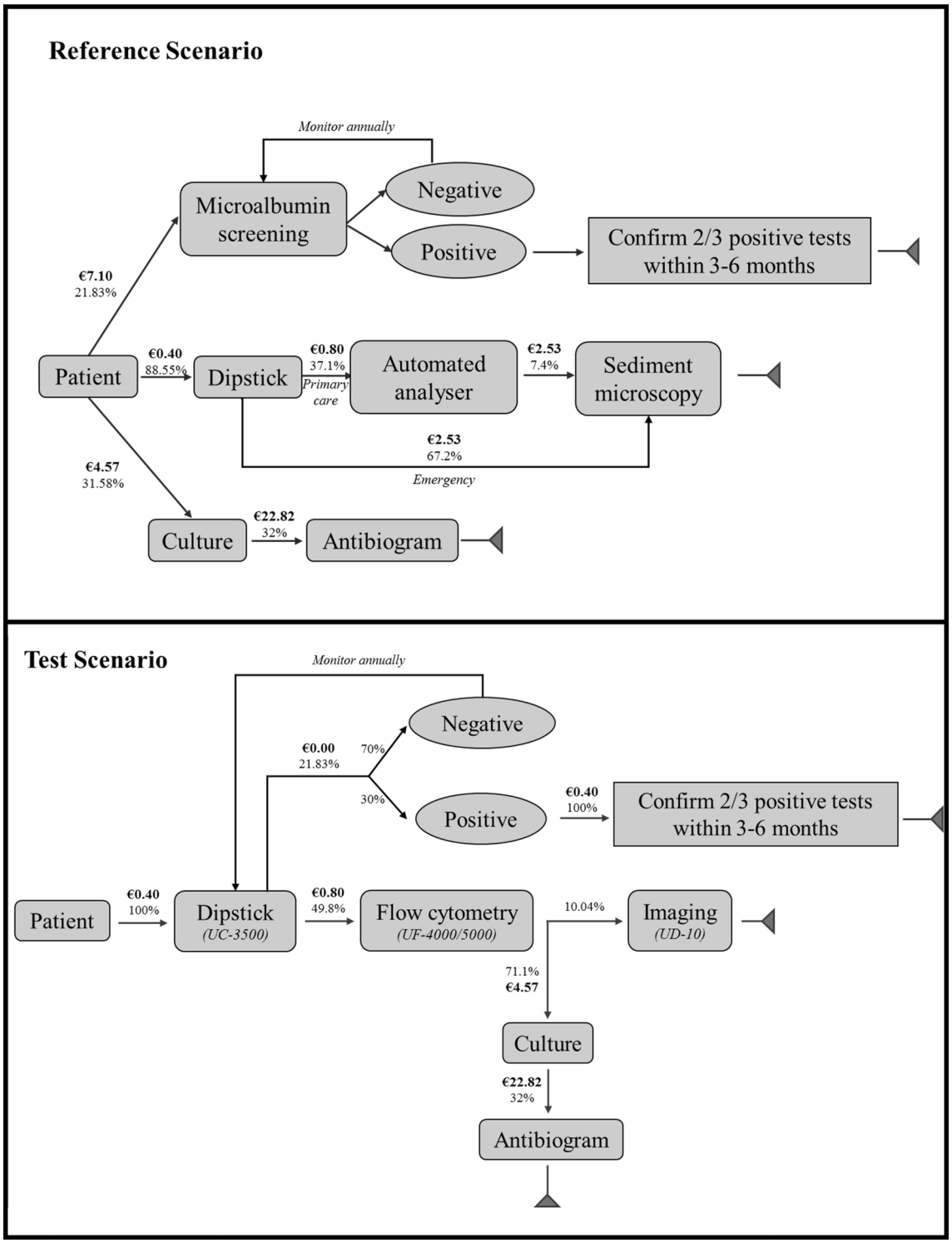

Fig. 1 Reference and test scenarios for operating procedures for urinalysis in clinical laboratories

In order to assess the difference in costs between each module of the UN-Series™ and the corresponding gold standard, a two-scenario comparative model was used: a reference scenario based on standard clinical practice using urine cultures and microscopic analysis for diagnosis, versus a test scenario based on new clinical practice adjusted for the UN-Series™. The scenarios were structured with clinical pathways for the target patients (Fig. 1).

The scenarios were structured based on the clinical guidelines that are most frequently consulted in Spain [6, 12, 18]. Of the total number of patients who required urinalysis, 21.83% had undergone microalbumin analysis, 31.58% urine culture and 88.55% dipstick analysis, and 84.24% of them had undergone sediment microscopy. In the test scenario, the UN-Series™ was applied for the analysis of microalbumin, dipstick analysis, comprehensive urine culture and sediment microscopy.

2.4 Perspective, Target Audience and Costing

A 'what-if' budget impact of introducing the UN-Series™ to screen urine samples in symptomatic patients was performed from the perspective of the Spanish National Health System (NHS). The analysis was developed using the SensIt program (a sensitivity analysis add-in for Microsoft® Excel 2007–2013; Microsoft Corporation, Redmond, WA, USA).

The Spanish NHS establishes strategies aimed at increasing the rational use of drugs [21]. Although medical procedures, tests and drugs administered in the hospital setting are fully covered by Spanish health services, patients in Spain must pay a percentage of the cost for drugs prescribed in primary care, depending on their income.

Financial data and direct costs from 2018 were retrieved from the Spanish Health Costs Database (eSalud) [22]. Indirect costs such as condition-related costs were not included in this study, in order to evaluate the relevant impact of the introduction of the UN-Series™. All cost data were expressed in euros (€).

2.5 Time Frame

The cost analysis was based on total costs over a 1-year time frame for both scenarios. Percentages and total costs were calculated for each scenario.

Table 1 Variables of operating procedures for urine sample analysis

Procedure	Variable	Inputs	Range	References
Dipsticks (reference scenario)	Samples (primary care)	72.76%	0–100%	[19, 20]
	Samples (emergency)	15.80%	0–100%	[19, 20]
	Cost	€0.40	€0–0.80	PC
	Positive rate (primary care)	37.12%	0–100%	[19, 20]
	Negative rate (primary care)	62.88%	0–100%	[19, 20]
	Positive rate (emergency)	67.22%	0–100%	[19, 20]
	Negative rate (emergency)	32.78%	0–100%	[19, 20]
UF-5000 (reference scenario)	Cost	€0.80	€0–1.6	
	Positive rate (primary care)	7.44%	0–100%	[19, 20]
	Negative rate (primary care)	92.66%	0–100%	[19, 20]
Sediment microscopy	Cost	€2.50	€2.00–3.00	[22]
Urine culture	Samples	31.58%	0–100%	[19, 20]
	Cost	€10.10	€5.19–15.00	[22]
	Positive rate	32%	0–100%	[25]
	Negative rate	68%	0–100%	[25]
Antibiogram	Cost	€20.00	€15.00–25.04	[22]
Dipstick (test scenario)	Samples (primary care, emergency and microbiology)	100%	0–100%	[19, 20]
	Cost	€0.40	€0–0.80	PC
	Positive rate (image)	28.83%	0–100%	[19, 20]
	Negative rate (image)	71.17%	0–100%	[19, 20]
	Positive rate (culture)	20.97%	0–100%	[19, 20]
	Negative rate (culture)	79.03%	0–100%	[19, 20]
UF-5000 (test scenario)	Cost	€0.80	€0–1.6	
	Imaging positive rate (test)	10.04%	0–100%	[19, 20]
	Culture positive rate (test)	71.1%	0–100%	[19, 20]
	Negative rate (test)	18.86%	0–100%	[19, 20]
Albumin analysis	Cost	€3.00	€2.00–4.00	[22]

PC Personal communication

2.6 Input Data

The parameter values for all clinical and cost data items for both scenarios are indicated in Table 1. Data sources from 2000 to 2017 were searched for in PubMed and eSalud using different combinations of keywords such as 'Urinalysis', 'Flow cytometry', 'National Health System' and 'Costs' and in personal communications from expert clinicians from La Mancha Centro Hospital. Selection criteria were applied to choose the most appropriate results from the literature, and those results that correlated well with the patient population, model structure and variables were selected. Official websites and databases of the Spanish NHS were searched and the most relevant results were evaluated. Data sources and data collection methods were confirmed. The strengths, weaknesses, possible biases and direction and magnitude of potential bias are described in Table S1 (see electronic supplementary material [ESM]).

2.7 Working Time Savings for Personnel

Annual time savings for laboratory personnel in each scenario are summarised in Table 2. In current laboratory practice, the microscopic examination of urine or blood samples and the inspection of urine or blood culture results require 1.7 min and the plating procedure takes 1 min. In contrast, in the test scenario, the time needed for analyser preparation is estimated at 0.2 min, and only samples with suspicious results require culture or plating procedures.

Table 2 Annual time savings for laboratory personnel stratified by sample source and operating procedure

	Reference scenario	Test scenario
Primary care, emergency room, body fluids		
Sample processing	613.68 h (122,304)[a]	445.30 h (122,416)[c]
Microscopic visualisation	437.75 h (14,825)[b]	78.48 h (2676)[c]
Microbiology		
Sample processing	486.64 h (29,199)	387.25 h (19,389)
Urine culture visualisation	827.29 h (29,199)	658.32 h (19,389)
Total	1051.43 h	523.78 h

Sample size is shown in brackets

[a]Calculation includes primary care (390.90 h) + emergency room (212.36 h) + body fluids (10.42 h)

[b]Calculation includes primary care (141.81 h) + emergency room (278.23 h) + body fluids (17.71 h)

[c]Calculation includes all sources and urine requirements (primary care, emergency room, body fluids and microbiology)

2.8 Sensitivity Analysis

The total costs of each scenario have been obtained according to the proportion of patients under each variable. The cost savings analysis for the UN-Series™ has been calculated using the difference between the test scenario and the reference scenario (Figs. 2, 3).

For the sensitivity analysis, both in those cases showing the percentage for each process and in those showing the price, a minimum, a maximum and a baseline have been established. For both the reference scenario and the test scenario, the baseline data were obtained from La Mancha Centro Hospital's data. Note that for the minimum and maximum percentages, in the absence of other information, minimums of 0% and maximums of 100% were established.

In order to estimate the effect of uncertainty for each variable and to be able to determine critical assumptions, a one-way sensitivity analysis (OWSA) was carried out including all variables related to the total savings calculation. Nineteen variables related to the calculation of cost savings were evaluated by verifying possible 'output transitions' calculated over maximum and minimum intervals (Fig. 2).

Furthermore, a two-way sensitivity analysis (TWSA) was carried out including the variables 'Urine Culture RS [reference scenario] vs TS [test scenario] (%)', 'Urine Culture RS vs UF-5000 (culture) TS (%)' and 'Antibiogram RS vs TS (%)' (Fig. 3).

The model used to calculate the minimum and maximum for the microalbumin pathway was established as follows:

Minimum Both scenarios establish that 100% of samples would be negative in screening and therefore it would not be necessary to conduct further tests.

Maximum Both scenarios have established that, in 30% of samples, the screening test was positive and the first follow-up test was negative, and therefore it would be necessary to conduct a third test to be sure of the patient's status. For the reference scenario, the two additional follow-up tests are carried out using the gold standard, while in the test scenario they would be carried out using strips.

3 Results

3.1 Target Urine Samples

The cost analysis was calculated using the charges of a reference laboratory that processes an average of 92,459 urine samples from primary care or emergency patients per year (Tables 1, 3). In the reference scenario, 20,184 samples were estimated to require microalbumin screening by immunohistochemical test, 81,882 by dipstick analysis and 29,199 by urine culture, whereas in the test scenario all samples (92,459) were expected to go through

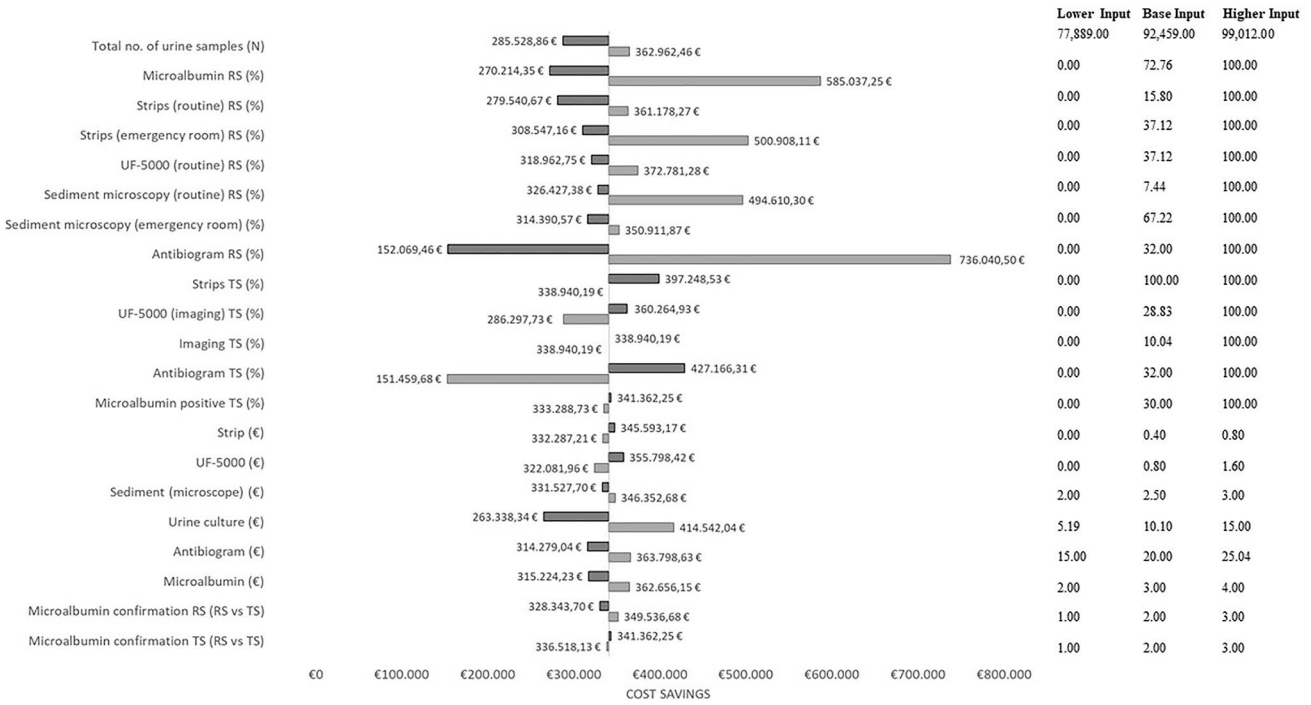

Fig. 2 Tornado diagram, one-way sensitivity analysis results. The vertical line indicates the total cost saving from the base input, and the horizontal lines reveal the shift in the range of outputs obtained by varying each input to a lower value (dark grey) and a higher value (light grey). *N* number, *RS* reference scenario, *TS* test scenario, % percentage

dipstick analysis (UC-3500). Concerning microalbumin assessment in the test scenario, albuminuria screening is included on the dipstick analysis and only the positive results (6055) were expected to be assessed by immunochemical testing to confirm abnormal albuminuria levels.

Moreover, for microscopic sediment in the reference scenario, the samples were expected to be separated into two groups depending on the urine source. Primary care samples (5005) were expected to be assessed by sediment microscopy after being screened with an automated analyser (24,972), whereas emergency room samples (9820) were expected to be directly evaluated by sediment microscopy. However, in the test scenario, 46,045 urine samples would be re-screened with the flow cytometer analyser (UF-4000/UF-5000) and, based on the UF-4000/UF-5000 results, 2676 samples were estimated to undergo digital imaging review with the UD-10 analyser and 13,785 with urine cultures.

Lastly, the positive urine culture samples were expected to undergo antibiogram analysis in both the reference scenario and the test scenario (9344 vs 4,411).

3.2 Target Body Fluid Samples

The number of patients with a body fluid analysis request within a 1-year time frame at La Mancha Centro Hospital was 625. In the reference scenario, the assessment of body fluids required manual counting in Fuchs Rosenthal chambers. According to the model of the test scenario, only 94 body fluid samples were estimated to need further manual review/inspection after the analysis by flow cytometry.

3.3 Cost Savings After the Introduction of the UN-Series™

The cost of the reference scenario, for both urine and body fluid samples, is estimated to be €644,133, while the test scenario comes to €304,130. From these results, the saving is €340,003, which corresponds to 0.00051% of the Spanish public health expenditure in 2014 (€66,826 million) [27].

The overall cost per patient using the reference scenario or UN-Series™ techniques is estimated at €6.95 and €3.28, respectively, for urine samples and €2.50 and €0.80, respectively, for body fluid samples. Therefore, savings of €3.67 and €1.70 per patient for urine and

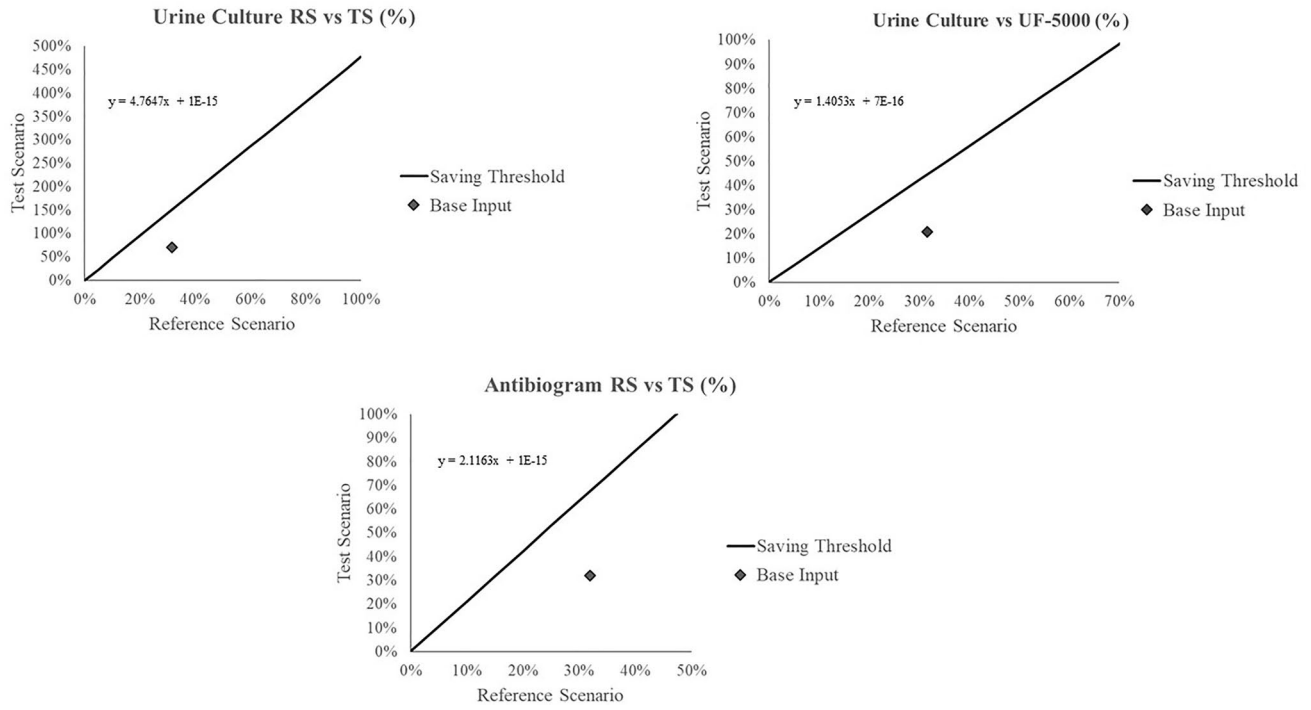

Fig. 3 Two-way sensitivity analysis results

Table 3 Cost analysis and cost savings in euros for operating procedures in clinical laboratories from the test scenario over the reference and test scenario (population)

	Reference scenario	Test scenario	Budget impact
Dipsticks	€32,753 (81,882)	€36,984 (92,549)	€4231
Primary care and emergency	€57,040 (26,830)	€21,325 (26,656)	€ − 35,715
Microbiology	€481,630 (29,199)	€242,900 (19,389)	€ − 238,730
Microalbumin	€71,148 (20,184)	€39,406[a] (92,549)	€ − 31,742
Body fluids	€1563 (625)	€500 (625)	€ − 1063
Total cost	€644,133	€304,130	€ − 340,003

[a]Dipstick cost included

body fluid samples, respectively, are foreseen if the UN-Series™ replaces standard clinical practice within the Spanish NHS.

3.4 Sensitivity Analysis

The robustness of the analysis was shown by the results from the OWSA and the TWSA, confirming the results obtained (Figs. 2 and 3, respectively). The parameters with the highest impact on the results are those concerning the proportion of samples involved in the urine culture, antibiogram and microalbuminuria assessment. Figure 2 shows that, in both analyses, the base case is located within the area under the curve, where savings for the NHS would be expected.

4 Discussion

This study demonstrates significant annual cost savings resulting from the implementation of the UN-Series™ system of automated analysers for urinalysis. On average, more than half of the total savings would be achieved in microbiology laboratories (€238,730 vs €340,003). It is noteworthy that a substantial annual cost savings would be achieved for microalbuminuria assessment (€31,742 vs €340,003). As only 15–20% of urine samples were finally positive for microalbuminuria in the reference scenario, the need for and the high cost of immunochemical analysis of urine samples would be reduced by primary screening with the UN system.

Implementing the UN-Series™ system could contribute to synergies between microbiology and clinical analysis laboratories, with a major impact on management and coordination between reference hospitals and peripheral centres without laboratory services. Nonetheless, further studies are needed for evidence of savings through this synergy. In our healthcare community area, the evaluation of body fluids and

urine needs to be optimised. The examination of a sample is often delayed for an extended period between sample collection at peripheral centres and delivery to the reference laboratory. This period is crucial, as sample instability and analytical failures are associated with time elapsed since sample collection [23]. From our point of view, investments in sample shipment from peripheral centres could be made using the savings provided by implementation of the UN-Series™. These improvements could not only contribute to reducing turnaround times but also reduce erroneous results or unnecessary treatments. Certainly, further investigation would be needed to demonstrate such a benefit.

We have found 57 publications that evaluate the performance of the different devices that constitute the Sysmex urine analysers. These studies show evidence of good agreement between the parameters analysed by each device and the corresponding gold standard (Table S2) [1, 2, 11, 13–16, 23–25]. Interestingly, the outcomes returned by the analysers are always given in the same units (µL), which provides standardisation of results.

Additionally, implementing the UN-Series™ would contribute to optimising working time for laboratory personnel [26]. The substantial time savings we have estimated would free up time to work on other laboratory requests that are frequently deferred due to the high workload of urinalysis (Table 2) [2, 5, 10, 11, 23]. Therefore, this kind of automated analysis system would allow physicians to focus on diagnostic tasks and achieve better diagnostic quality.

There are some limitations that came up in this pharmacoeconomic study, as reality was simplified in order to develop the model. The sample size and clinical data used in this analysis came only from a single site, La Mancha Centro Hospital. This information was used to calculate the proportions for the flowchart in both scenarios, which might differ at other hospitals and/or clinical practices in Spain based on patient characteristics (e.g. different cut-off points used by each hospital).

5 Conclusion

In conclusion, we have demonstrated significant total annual cost savings for a reference laboratory with clinical analysis and microbiology units due to the implementation of an integrated and automated system of urine analysers such as the Sysmex UN-Series™. Working time savings are also achieved for laboratory personnel. Although the costs of routine urine screening are noticeably increased by automated analysers, the study shows significant total annual savings, and with the added benefit of time savings, the UN-Series™ system could help to improve other laboratory services.

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Availability of Data and Materials The datasets generated and/or analysed during this study are available from the corresponding author on reasonable request.

Compliance with Ethical Standards

Funding Óscar Herráez Carrera and María Del Monte Jarabo Bueno state that they have not received any grants to support this work.

Conflict of interest Óscar Herráez Carrera and María Del Monte Jarabo Bueno declare that they have no conflicts of interest.

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