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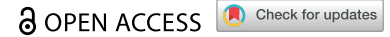


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ORIGINAL RESEARCH



Budget impact analysis on the use of Sysmex PA-100 AST system as a point of care for uncomplicated urinary tract infections detection and treatment in Spanish females

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ABSTRACT

Objective: Efficient diagnostic methods, such as the Sysmex PA-100, provide rapid antimicrobial susceptibility test results directly from urine samples with high sensitivity and specificity, and improve treatment recommendations. Our study analyzes the economic impact of integrating the Sysmex PA-100 to assess its potential benefits and cost implications for uncomplicated urinary tract infection (uUTI) management in Spain.

Methodology: A budget impact model was developed using a decision tree framework to compare current UTI management practices with a new scenario incorporating the Sysmex PA-100. The clinical inputs were extracted from published literature. The model, representing adult females with uUTIs, assessed direct medical and indirect costs over three years, including diagnostic procedures, treatment costs, staff time costs, and productivity loss. The cost data was captured from two Spanish hospitals. Two scenario analyses were conducted in the model: scenario A included costs for antimicrobial resistance (AMR) emergence in patients receiving unnecessary empirical antibiotics, whereas scenario B assumed no AMR costs.

Results: In scenario A, 100% implementation of PA-100 within various Spanish healthcare settings over one year resulted in total cost savings of EUR 323,657,712 (EUR 119.10 per patient per year). The total overall cost savings attributable to the implementation of PA-100 over three years were EUR 970,973,137. In scenario B, the total annual savings were EUR 4,254,795 (EUR 1.57 per patient per year), and the 3-year savings were EUR 12,764,385.

Conclusion: The adoption of this point-of-care system results in overall cost savings, driven by reductions in direct and indirect costs related to UTI management. The model highlights potential savings over three years owing to appropriate rapid management (reduction in time to diagnosis and treatment, which leads to fewer complications and secondary infections) and reduced staff time and productivity loss costs. These findings support the potential benefits of adopting the Sysmex PA-100 to enhance UTI management and allocate healthcare resource utilization in Spain.

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Introduction


Urinary tract infections (UTIs) are a major global health issue, with over 400 million cases reported in 2019¹. Patients often receive empirical broad-spectrum antibiotics due to the 2–3 d delay in obtaining antimicrobial susceptibility test results, which may lead to ineffective treatment and increased drug-resistant uropathogens^{2,3}. The need for more efficient diagnostic methods has led to the development of both laboratory and point-of-care (POC) approaches to enhance immediate and targeted antibiotic treatment^{4,5}.

An uncomplicated urinary tract infection (uUTI) is a bacterial infection that primarily affects the bladder and its surrounding areas. It is often referred to as cystitis or a lower

tract UTI. Common symptoms include frequent urination, a strong urge to urinate, lower abdominal discomfort, and painful urination. Although many uUTIs may resolve without treatment, patients frequently seek medical assistance to relieve their symptoms. The purpose of treatment is to prevent the infection from reaching the kidneys or evolving into a more serious condition, such as pyelonephritis, which can damage the delicate structures in the nephrons and potentially cause hypertension⁶.

UTI diagnosis relies on clinical history and urinalysis, and is confirmed by urine culture. The proper collection of urine samples is essential for accurate evaluation and culture results⁶.

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Epidemiologically, UTIs are at least four times more prevalent in females than males. In the United States, 40% of women experience a UTI during their lifetime. Approximately 10% of women experience UTI annually. Recurrences are common, with nearly 50% of patients experiencing a second infection within a year. In women, UTIs generally occur between the ages of 16 and 35⁶.

In Spain, the most recent study published by EPINE reports that urinary infections account for 19.9% of all community-acquired infections admitted to acute care hospitals. Hospitalization for UTIs has a significant economic impact on healthcare systems, involving high treatment costs and mortality rates. The primary financial burden comes from extended hospital stays. A key factor contributing to these admissions is an increase in antimicrobial resistance (AMR), partly due to the use of outdated empirical treatments. These treatments must be regularly adjusted based on local antibiotic resistance patterns⁷.

The Sysmex PA-100, a groundbreaking device that utilizes nanofluidics and microscopy to conduct rapid antibiotic susceptibility testing (AST) on urine samples, was recently honored with the prestigious £8 million Longitude Prize on AMR. This award recognizes the potential of this system to revolutionize the diagnosis and treatment of UTIs by providing physicians with timely and accurate AST results, thereby facilitating the appropriate use of antibiotics and contributing to the reduction of antibiotic resistance⁸.

A Spanish prospective, non-interventional study conducted at 2 local hospitals evaluated the Sysmex PA-100, a POC analyzer for detecting UTIs and performing antimicrobial susceptibility tests directly from urine. It found that the Sysmex PA-100 provided results for bacteriuria within 15 min and AST within 45 min, with high sensitivity and specificity. The analyzer's performance led to optimal treatment recommendations in 78.4% of cases, suggesting that it could significantly improve the accuracy of UTI management and reduce unnecessary antibiotic use⁹.

Objective

The objective of this study was to conduct an economic analysis to evaluate the impact of adopting the innovative Sysmex PA-100 as a POC across various Spanish settings for the detection of bacteriuria and antimicrobial susceptibility testing in patients with uUTIs.

This analysis aims to provide decision-makers with detailed insights into the potential cost consequences and benefits of integrating this technology into the Spanish healthcare system. By assessing both the direct and indirect economic effects, this study seeks to support informed policies and operational decisions regarding the implementation of advanced diagnostic tools.

Additionally, the findings will contribute to a better understanding of how technological advancements can influence healthcare resource utilization and patient outcomes in the context of uUTI management in Spain.

Methodology

Study design

We performed a comprehensive literature review to gather recent and pertinent data on costs and clinical outcomes associated with uUTIs.

To validate the assumptions and inputs used in the model, we conducted a Delphi panel composed of 4 experts; two health economists and two Spanish urology experts from Hospital Universitario 12 de Octubre, Madrid and the Microbiology Laboratory, Fundacio Puigvert, Barcelona, Spain. We collected insights from experts through three rounds virtual meetings by using the quasi-Delphi panel approach. The experts' insights included the current local clinical practice and treatment patterns within the Spanish healthcare settings. The collected experts responses were subsequently analyzed and reviewed by the authors to confirm their accuracy and relevance.

The cost inputs for the model were captured to reflect the Spanish societal healthcare perspective and to ensure that they accurately represented the context of the Spanish healthcare settings.

Model design

The budget impact model (BIM), employing a decision tree framework, was developed using Microsoft Excel to quantify the economic implications of the 100% adoption of the Sysmex PA-100 within various POC settings in the Spanish healthcare system. This model focuses on the detection of uUTIs and antimicrobial susceptibility testing (AST) directly from urine samples.

The model encompasses two scenarios: Current scenario: In this scenario, patients with uUTIs in different healthcare settings are managed in one of three ways: (a) prescribed empirical antibiotic (AB) without diagnostic testing, (b) prescribed empirical AB following the dipstick detection of bacteriuria, or (c) prescribed AB following the dipstick detection of bacteriuria and subsequent laboratory-based culture microbiological diagnostics and AST. New scenario: This scenario simulates the 100% adoption of the Sysmex PA-100 in Spanish practice.

Patients start the model with uUTI and progress to resolution after initial AB treatment or persistence of the infection. Unresolved infections may lead to one of the following outcomes: prolonged AB treatment, local AB resistance necessitating an alternative AB, incorrect pathogen diagnosis requiring a shift to another first-line AB, recurrent UTI (rUTI), or progression to complicated UTI (cUTI). The target population is presented in [Table 1](#)^{10–12} and all treatment schedules and durations are listed in [Table S1](#)^{13–19}. The clinical probabilities associated with each health state^{12,18,20} were derived from the published literature ([Tables 1 and 2](#)).

The model results were evaluated over three years, and the 2024 price list was utilized from Spanish public hospital data in Euros. The model decision tree structure is shown in [Figure 1](#).

Table 1. The budget impact model inputs.

Input	Base-Case	Low value	High value	Study type and sample size	Reference
Model's Population					
Female Population	24,790,000	19,832,000	29,748,000	Statistical portal for 170 industries from 150+ countries	10
Female Population of age 15–64 Years	66%	53%	79%	United Nations Population Fund data	11
Female Population 65 Years and older	21%	17%	25%	portal	11
Incidence of uUTI per year	12.6%	10%	15%	Retrospective observational study using the Spanish Hospitalisation Minimum Data Set (CMBD) with codification by ICD9 on 259,804 hospitalisations for UTIs.	7
Population at point of care					
Inpatients	4.60%	3.7%	5.5%	Review article relied on National Hospital Ambulatory Medical Care Survey on 117 million visits	12
Emergency Department Visits	21.30%	17.0%	25.6%		12
Health state probabilities in case of first-line antibiotic failure					
Probability of Prolonged AB Use – Intermediate Bacteria Susceptibility	27.2%	22%	33%	Nationwide study in 20 different Spanish sites conducted on 2,292 valid <i>Escherichia coli</i> strains	18
AB Resistance Probability	6.2%	5%	7%	Assumption	18
Probability of Switched AB – Wrong Pathogen Detection	21.6%	17%	26%		
Probability of Prognosis to cUTI	1.0%	0.8%	1.2%	Review article	12
Probability of rUTI in case of first-line antibiotic failure	44.0%	35%	53%	Review article	20
Requested diagnostic (POC) at healthcare settings – Current scenario					
Request of Bacterial Culture	26.30%	21%	32%	Cross-sectional, internet-based questionnaire	30
Dipstick	38.20%	31%	46%	study answered by 1,239 GPs affiliated with the largest Spanish scientific society in primary care	30
Empiric Antibiotic without testing	35.50%	28%	43%		
Sysmex PA-100 Adoption in new Scenario					
Sysmex PA-100 – Year 1	100%	80%	100%	Assumption	

Abbreviations. POC, Point of Care; AB, Antibiotic; cUTI, complicated urinary tract infection; rUTI, recurrent urinary tract infection; uUTI, uncomplicated urinary tract infection; ICD9, International Classification of Diseases 9; GPs, general practitioners.

The model provided outputs detailing the total costs of medications and diagnostics as well as the breakdown of other direct and indirect costs. These annual costs were presented as target population total costs and on a per patient per year basis. Two scenario analyses were conducted using the proposed model. The first scenario included the costs associated with the emergence of AMR in patients who received unnecessary empirical antibiotics. In the second scenario, it was assumed that AMR did not occur in any patient.

Population

The model was designed to represent the adult female population in Spain, with a focus on individuals presenting with uUTIs in two healthcare settings within the Spanish healthcare system. Healthcare settings were considered in the model to be present at three points: Inpatients: patients who have acquired hospital-associated uUTIs and are hospitalized; Outpatients: patients who have acquired community-associated uUTIs and visit outpatient clinics; Emergency department patients: individuals with community-acquired uUTIs who seek care in emergency departments.

These categories of healthcare settings are detailed in Table 1, which illustrates the distribution and characteristics of the target population in the model. Female population of age 15–64 years and from 65 years and older were extracted from statistics data portals^{10,11}. While the incidence of uUTI per year was captured from a retrospective observational

study using the Spanish Hospitalisation Minimum Data Set (CMBD) with codification by the International Classification of Diseases 9 (ICD9) on 259,804 hospitalisations for UTIs⁷.

Treatments

For simplification, the model assumed that all females with uUTI and rUTI suffered from uncomplicated cystitis caused by *Escherichia coli* (*E. coli*), whereas cUTI patients were assumed to have pyelonephritis. This simplification may not accurately reflect the diverse etiology and clinical presentations of uUTIs and cUTIs; however, this assumption simplifies the model by standardizing the etiology and clinical presentation of these infections and it was validated.

The initial first-line AB prescribed to all uUTI patients in the model was nitrofurantoin microcrystals. The model also considered possible reasons for unresolved uUTI infections despite initial AB treatment, including: (1) the presence of an “intermediate” sensitive microorganism requiring an extended AB regimen, (2) a local resistant microorganism necessitating a different AB (3) incorrect pathogen diagnosis requiring a switch to another first-line AB, (4) rUTI requiring a prolonged AB regimen, (5) cUTI necessitating an alternative AB regimen.

In the study, patients who underwent urine culture tests and antimicrobial susceptibility testing (AST) were initially treated with empirical nitrofurantoin microcrystals for a duration of two days, pending the results from the laboratory. Upon receipt of the laboratory results, patients were either maintained on the nitrofurantoin microcrystal regimen or

Table 2. Success and failure probabilities for each diagnostic tool.

Input	Base-case	Low value	High value	Study type and sample size	Reference
Probability of Diagnostic Test Outcome					
Probability of uUTI resolved with Empirical AB – No Testing	66%	53%	79%	A retrospective database analysis of 4,792 patients	21
Probability of uUTI not resolved with Empirical AB – No Testing	34%	27%	41%		21
Probability of uUTI resolved with Empirical AB – Dipstick	66%	53%	79%		21
Probability of uUTI not resolved with Empirical AB – Dipstick	34%	27%	41%		21
Probability of uUTI resolved with Empirical AB – Dipstick Prior to Bacterial Culture + AST Results	66%	53%	79%		21
Probability of uUTI resolved with AB Shift based on – Bacterial Culture + AST Results	27%	21.95%	32.93%	Expert opinion	Delphi Panel
Probability of uUTI not resolved with AB – Bacterial Culture + AST	7%	5.49%	8.23%		Delphi Panel
Probability of uUTI resolved with AB – Sysmex PA-100/Optimal Treatment	78.4%	63%	94%	Prospective, non-interventional study conducted on 278 patients	9
Probability of uUTI not resolved with AB – Sysmex PA-100	21.6%	17%	26%		9

Abbreviations. AB, Antibiotic; uUTI, uncomplicated urinary tract infection; AST, antimicrobial susceptibility test.

shifted to an alternative antibiotic regimen based on the lab results findings.

Diagnosics

The distribution and market share of POCs utilized across different Spanish healthcare settings in both the current and new scenarios are outlined in Table 1.

The success and failure probabilities of each diagnostic tool incorporated into the model were captured from two different studies (Table 2). The performance of Sysmex PA-100 antimicrobial susceptibility test results were based on the optimal treatment recommendation result of a Spanish study that evaluated the Sysmex PA-100 POC analyzer for detecting UTIs and performing antimicrobial susceptibility tests directly from urine and comparing its results to standard microbiology methods in 278 female patients⁹. While the failure probability associated with the empirical antibiotic, administered in the three-management methodologies within the current scenario—without diagnostic tests, after dipstick testing, and as a pre-treatment prior to receiving laboratory results—were extracted from a retrospective database analysis of 4,792 patients at 15 institutions in the United States²¹. Moreover, the assumption of the failure of the laboratory-based bacterial culture and AST was based on the probability of the presence of contaminated samples that most commonly related to delayed processing and inappropriate storage of urine samples till processing, which was indicated by our Delphi panel as 20%. Finally, the probability of failure of the dipstick was assumed to be equal to the failure rate of the empirical AB without diagnostics²¹.

Costs and resources utilized

The model incorporated both direct medical and indirect costs associated with uUTI management across various healthcare settings in Spain. The direct medical costs included urologist consultation fees in different healthcare settings, costs of antibiotics and diagnostic procedures, costs associated with unresolved infections post first-line AB (follow-up visits, bacterial cultures, AST, imaging, and laboratory tests; in

cases of cUTI only, and hospitalizations for rUTI and cUTI cases), and healthcare staff time costs (for laboratory-based bacterial culture + AST; 23 min spent by the pathologist to process urine samples from receipt to inoculation and 28 min for total processing time after inoculation)²². Patients in the unresolved infection health state incurred the costs associated with the resolved infection health state, as well as additional expenses related to the treatment and management of their unresolved infection. Additionally, all of these patients required laboratory-based bacterial culture and AST to confirm the presence of bacteriuria and determine the appropriate antibiotic treatment.

Hospitalization costs were estimated to be 0.7% for rUTI patients requiring 3 days of hospitalization and 61.9% for cUTI patients requiring 4 days based on data from a Spanish study analyzing UTI hospitalization trends from 2000 to 2015⁷.

Additionally, the model incorporated the probability of AMR resulting from unnecessary empirical antibiotic (AB) use in the absence of confirmatory diagnostic tests for bacteriuria. It was assumed that 60% of patients who received empirical antibiotics without prior bacteriuria confirmation were prescribed unnecessary treatment, a figure derived from a British observational study on the use of empirical antibiotics in adult women with UTIs in general practice¹⁷. Furthermore, 22.7% of these patients receiving unnecessary antibiotics were considered at risk of AMR based on data from a comparative analysis of national action plans in Italy, the Netherlands, and Spain²³. The average hospital stay for patients with AMR was estimated to be 8.7 d, reflecting data from a cohort of 58,286 patients with incident bacterial infection-related hospitalizations recorded in the French national health data system from January 1, 2015, to December 31, 2015²⁴. In the model, patients with AMR were considered to have one inpatient stay; the cost per stay included all hospitalization days, procedures, and physician visits required to manage the AMR case. Two scenario analyses were conducted within our model. The first scenario included costs associated with the emergence of AMR for 22.7% of the 60% of patients who received unnecessary empirical Abs as mentioned above²³. By contrast, the second scenario assumed no

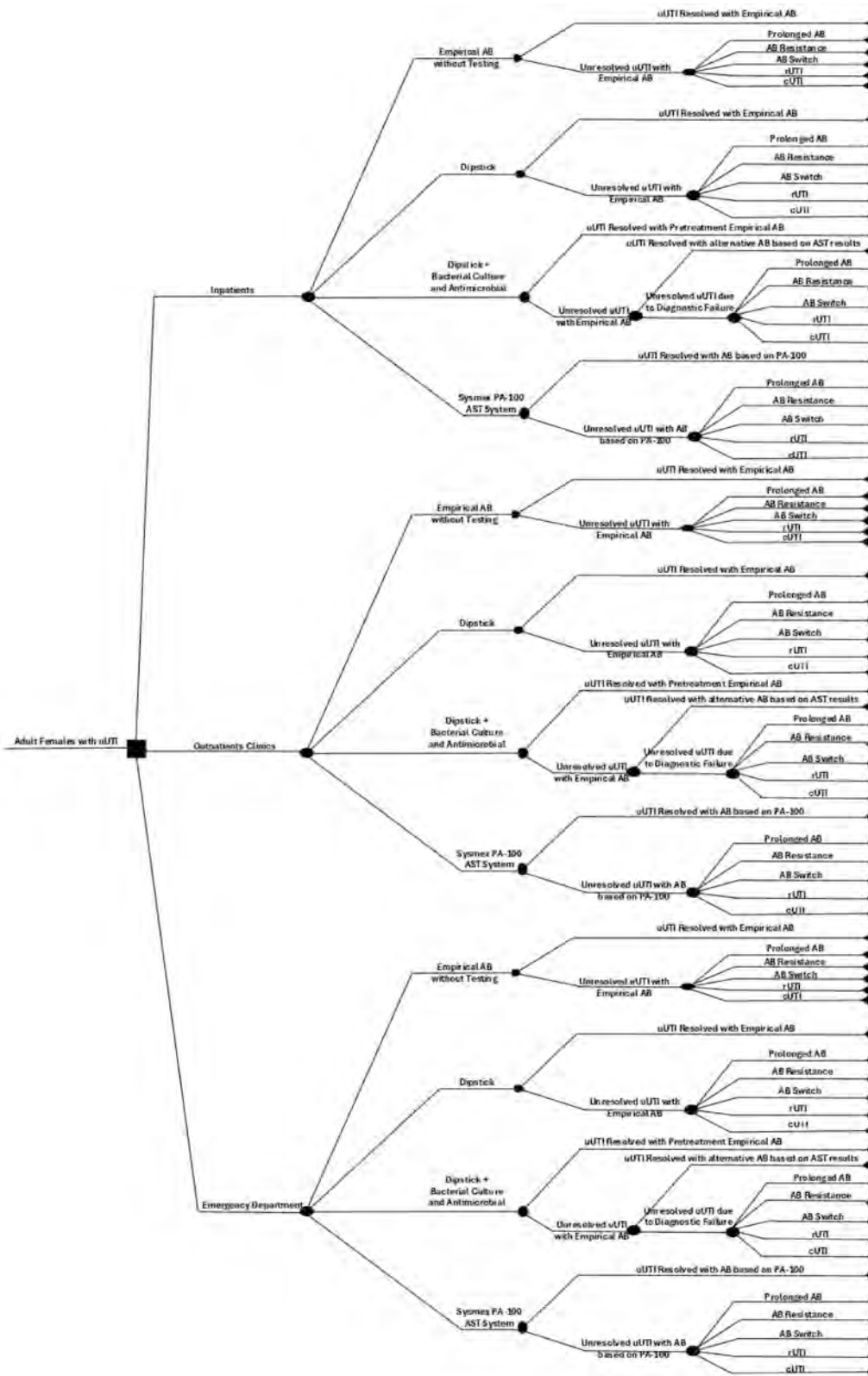


Figure 1. The model decision tree. Abbreviations. AB, Antibiotic; cUTI, complicated urinary tract infection; rUTI, recurrent urinary tract infection; uUTI, uncomplicated urinary tract infection.

AMR emergence; therefore, no additional costs were considered. The unit costs utilized in the model are listed in Table 3.

For indirect costs, it was assumed that patients in the model who underwent urine culture tests and AST to receive

appropriate antibiotics for their uUTI experienced two days of lost productivity. These two lost productivity days account for the costs associated with pain, anxiety, and suffering resulting from the 2–3-day delay in receiving appropriate antibiotic treatment following laboratory diagnostics.

Productivity losses associated with unresolved uUTI were considered, whereas resolved infections were considered to cause no productivity loss. Productivity losses were estimated as per our Delphi panel as 1 day for patients requiring prolonged AB, AB shifts, or having AB-resistant uUTI. For rUTI and cUTI, productivity losses were 2 and 10 d, respectively. The average daily wage of Spanish patients was estimated based on the 2023 Spanish gross domestic product published by the World Bank²⁵. In addition, the model calculated productivity loss specifically for Spanish employed females aged 65 years and younger, taking into account the gender salary discrepancy that exists in Spanish society^{26,27}.

Sensitivity analysis

Sensitivity and scenario analyses were conducted to assess the robustness of the model's input parameters and structural assumptions. A one-way sensitivity analysis was performed with base case values adjusted by $\pm 20\%$ or confidence intervals for clinical data if available, and results were visualized using a Tornado diagram to illustrate the variability in probabilities and costs and its impact on the final results.

Results

Base-case results

The base case results of the model are presented in Table 4 and Figures 2 and 3. For the scenario analysis including AMR costs, our BIM indicated that the 100% implementation of PA-100 within various healthcare settings in Spain over a one-year period resulted in total cost savings of EUR 323,657,712 (EUR 119 per patient per year), owing to fewer physician visits, hospitalization, and productivity loss costs. The total overall cost savings attributable to the implementation of PA-100 over the three years were EUR 970,973,137. Additionally, the model also showed cost savings for the scenario analysis that did not include AMR costs, as follows:

the total annual one-year savings were EUR 4,254,795 (EUR 1.57 per patient per year), and the total three-year savings were EUR 12,764,385.

Sensitivity analyses results

One-way sensitivity analyses were performed to test the robustness of the results. The most important parameters that affected the results were the probability of uUTI resolved with AB – Sysmex PA-100, the number of female patients, and the incidence of uUTIs. Figure 4 shows the results of one-way sensitivity analyses as a tornado diagram.

Discussion

UTIs are a significant global health burden that affect millions of people annually. *E. coli* is a common uropathogen; however, its increasing antibiotic resistance poses a major threat. Overuse, prolonged treatment, and inappropriate prescription of broad-spectrum antibiotics have contributed to this problem. To combat antibiotic resistance in UTIs, it is crucial to optimize treatment strategies, including appropriate antibiotic selection and duration²⁸.

A study conducted in South Wales assessed the accuracy of empirical antibiotic prescriptions in women with suspected UTIs. The research examined the correlation between empirical treatment decisions and subsequent urine culture results in 113 women. The findings revealed a significant mismatch between empirical AB prescriptions and actual UTI diagnoses. While 61% of the women received empirical antibiotics, a substantial proportion of these prescriptions were unnecessary, and 60% of the women prescribed antibiotics had negative urine cultures. Conversely, 25% of women with positive cultures did not receive antibiotics¹⁷.

These results highlight the need for revised strategies for antibiotic prescription in UTIs. Current practices do not effectively target those who require treatment, leading to the overprescription and undertreatment of infections¹⁷. To

Table 3. The unit costs utilized in the model.

Input	Base-case	Low value	High value
Nitrofurantoin macrocrystal 50 mg	EUR 0.17	EUR 0.14	EUR 0.21
Co-trimoxazole 160 mg/800 mg	EUR 0.70	EUR 0.56	EUR 0.84
Fosfomycin trometamol 3 g	EUR 4.73	EUR 3.78	EUR 5.68
Amoxicillin/Clavulanic 875/12.5 mg	EUR 0.34	EUR 0.27	EUR 0.41
Cost of urine culture test per patient	EUR 9.00	EUR 7.20	EUR 10.80
Cost of antibiotic susceptibility testing	EUR 12.00	EUR 9.60	EUR 14.40
Pathologist Salary per month	EUR 3,350.00	EUR 2,680.00	EUR 4,020.00
Cost of dipstick test per patient	EUR 3.75	EUR 3.00	EUR 4.50
Urologist Outpatient Visit Cost	EUR 197.00	EUR 157.60	EUR 236.40
Urologist Inpatient Visit Cost	EUR 255.00	EUR 204.00	EUR 306.00
Urologist Costs of follow-up appointments	EUR 99.00	EUR 79.20	EUR 118.80
Hospitalization Day Cost	EUR 691.00	EUR 552.80	EUR 829.20
Emergency Department Visit Cost	EUR 255.00	EUR 204.00	EUR 306.00
UT Ultrasound	EUR 114.00	EUR 91.20	EUR 136.80
UT CT Scan	EUR 202.00	EUR 161.60	EUR 242.40
Complete Blood Count	EUR 5.20	EUR 4.16	EUR 6.24
Bacteria Blood Cultures	EUR 14.00	EUR 11.20	EUR 16.80
Kidney Function Tests	EUR 6.00	EUR 4.80	EUR 7.20
PA-100 Test	EUR 29.50	EUR 23.60	EUR 35.40
Inpatient Hospitalization Cost	EUR 3,700.00	EUR 2,960.00	EUR 4,440.00
Average Income Per Day	EUR 115.84	EUR 92.67	EUR 139.01

Abbreviations. CT, Computed Tomography; cUTI, complicated urinary tract infection; UT, urinary tract.

Table 4. Base-case results of the model over 1 year.

Scenario A: Results for scenario analysis with antimicrobial resistance costs						
Medication and Diagnostics Costs*	Current scenario	New scenario	Other Direct and Indirect Costs**	Current scenario	New scenario	Total costs
Total Costs Per Year	EUR 72,343,019	EUR 121,336,077.73	Other Direct and Indirect Costs per year	EUR 1,042,007,752	EUR 669,356,981.15	Total costs per year
Budget Impact per year	EUR 48,993,058.81			-EUR 372,650,771.29		-EUR 323,657,712
Costs PPPY	EUR 26.62	EUR 44.65	Other Direct and Indirect Costs PPPY	EUR 383.45	EUR 246.32	Total costs PPPY
Budget Impact PPPY		EUR 18.03		-EUR 137.13		-EUR 119.10
Scenario B: Results for Scenario Analysis without Antimicrobial Resistance Costs						
Medication & Diagnostics Costs	Current scenario	New scenario	Other Direct and Indirect Costs	Current scenario	New scenario	Total costs
Total Costs Per Year	EUR 72,343,019	EUR 121,336,077.73	Other Direct and Indirect Costs per year	EUR 722,604,835	EUR 669,356,981.15	Total costs per year
Budget Impact per year	EUR 48,993,058.81			-EUR 53,247,853.79		-EUR 4,254,795
Costs PPPY	EUR 26.62	EUR 44.65	Other Direct and Indirect Costs PPPY	EUR 265.91	EUR 246.32	Total costs PPPY
Budget Impact PPPY		EUR 18.03		EUR 19.59		-EUR 1.57

Abbreviation. PPPY, per patient per year.

**includes medical diagnostics and treatments costs only, *includes physician visits, hospitalization, pathologist costs, indirect costs and antimicrobial resistance costs if applicable.

improve patient care and address concerns about antibiotic resistance, it is essential to develop more accurate diagnostic tools and refine prescription guidelines.

Within our BIM, the introduction of PA-100 demonstrated a reduction in first-line antibiotic (AB) failure rates, which was attributable to its high overall categorical agreement with the reference microbiological methods. This improvement is expected to reduce the need for additional medications and diagnostic procedures, thereby reducing the overall burden on the healthcare system. Moreover, PA-100 significantly shortened the time required for bacteriuria detection and antimicrobial susceptibility testing by up to 45 min, compared with the 2–3 d typically required for laboratory-based tests. This reduction in diagnostic turn-around time is anticipated to enhance patient throughput and satisfaction by minimizing the duration of patient suffering and discomfort in cases with no treatment or inadequate antimicrobial selection. By expediting diagnosis and treatment, PA-100 can contribute to more efficient healthcare delivery and improved patient outcomes. Additionally, the reduction in the time to diagnosis and treatment may lead to fewer complications and secondary infections, further alleviating the strain on healthcare resources and potentially decreasing overall healthcare costs.

Therefore, the results of our model showed that PA-100 could lead to more precise and timely interventions, reducing the risk of complications and improving the overall treatment efficacy. By streamlining the decision-making process, physicians can tailor treatments to individual patient needs, optimize resource use, and potentially lower healthcare costs associated with prolonged or ineffective treatments. This approach may also support more effective antibiotic stewardship, reducing the likelihood of resistance development and improving long-term patient outcomes.

However, the uptake of POC tests (POCT) in many countries remains low, but many studies have shown that these tests result in favorable cost-effectiveness compared to usual care, and the implementation of POCT is recommended owing to the generation of efficiency gains, optimization of processes, and appropriate utilization of resources²⁹.

This study has several strengths that enhance its credibility and relevance. It is based on a thorough literature review and incorporates validation through structured interviews with a Spanish Delphi panel to ensure the accuracy and applicability of the model's assumptions. The BIM, designed using a decision tree framework, offers a detailed comparison between current practices and the integration of the Sysmex PA-100, effectively capturing both direct medical and indirect costs, such as productivity losses. The inclusion of sensitivity analysis adds robustness to the findings, affirming the reliability of the results. Furthermore, by evaluating the impact of the Sysmex PA-100 based on its high overall categorical agreement, this study provides valuable insights into its potential to enhance UTI management and reduce drug resistance, while the captured cost inputs reflect the specific economic context of the Spanish healthcare system.

Our study has some limitations. First, as previously mentioned, the model assumes that all uUTIs are caused by *E.*

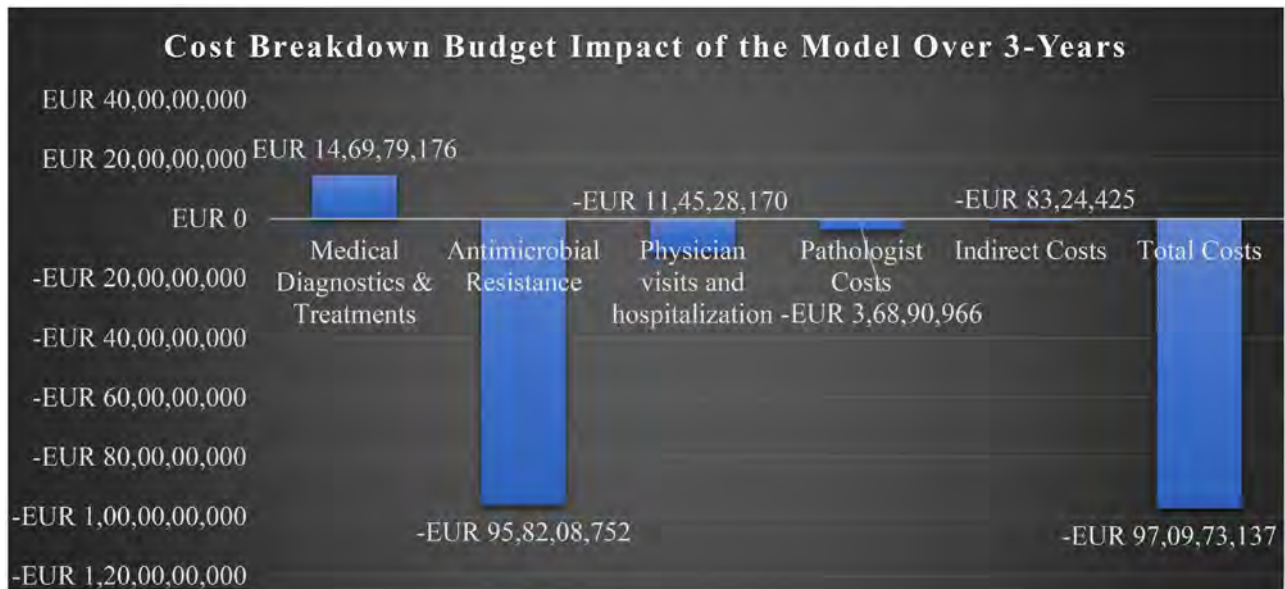


Figure 2. Costs components associated with implementation of PA-100 in Spain over 3-years.

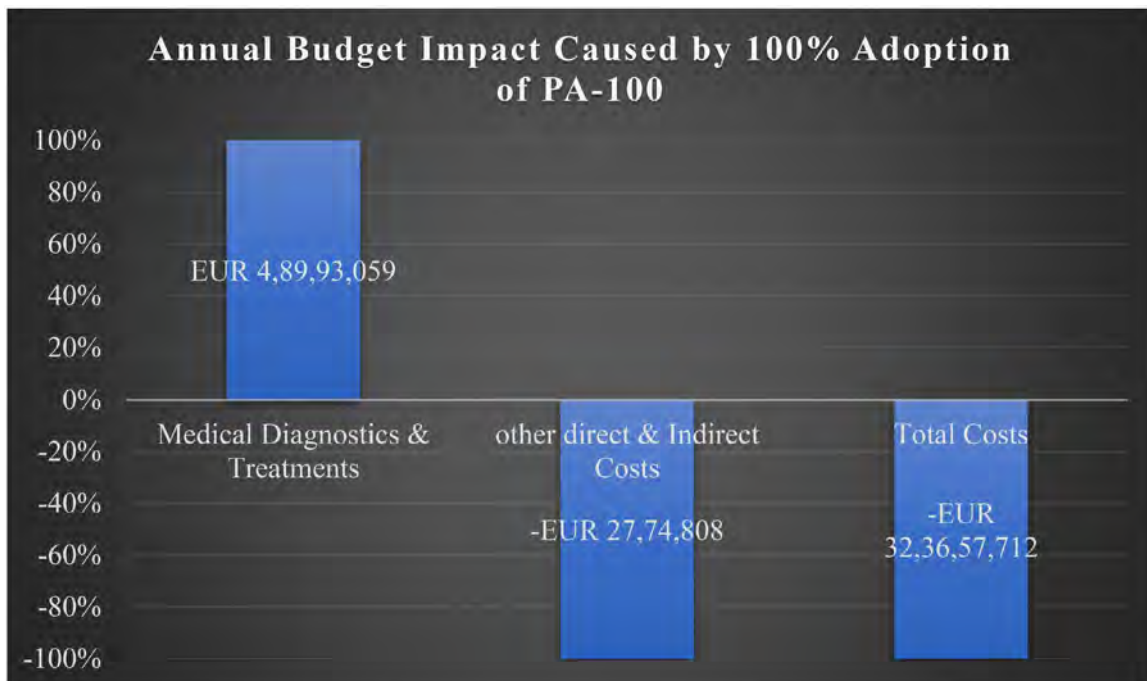


Figure 3. The annual costs associated with implementation of PA-100 within the Spanish healthcare system.

coli cystitis and all cUTIs are caused by pyelonephritis, this assumption was taken to simplify the model by standardizing the etiology and clinical presentation of uUTIs and cUTIs in both arms. Second, there was a necessity to use an expert panel for some model input parameters for matter of inputs validation and reliability. Third, the model did not consider different hospitalization rates among different age groups due to the lack of data. Fourth, we captured the success and failure probabilities of each diagnostic tool from two different studies as it would be difficult to find all the efficacy data from the same study. Additionally, the model did not account for the probability of diagnostic failure and the subsequent associated costs for patients in an unresolved health

state, as our focus was specifically on the costs associated with initial diagnostic testing.

Conclusion

The integration of the Sysmex PA-100 into Spanish healthcare settings demonstrates promising economic value despite an initial increase in medication and diagnostic costs. The 100% adoption of this point-of-care system results in overall cost savings, driven by reductions in direct and indirect costs related to UTI management. The model highlights potential savings over three years owing to appropriate rapid management (reduction in time to diagnosis and treatment,

Tornado Diagram

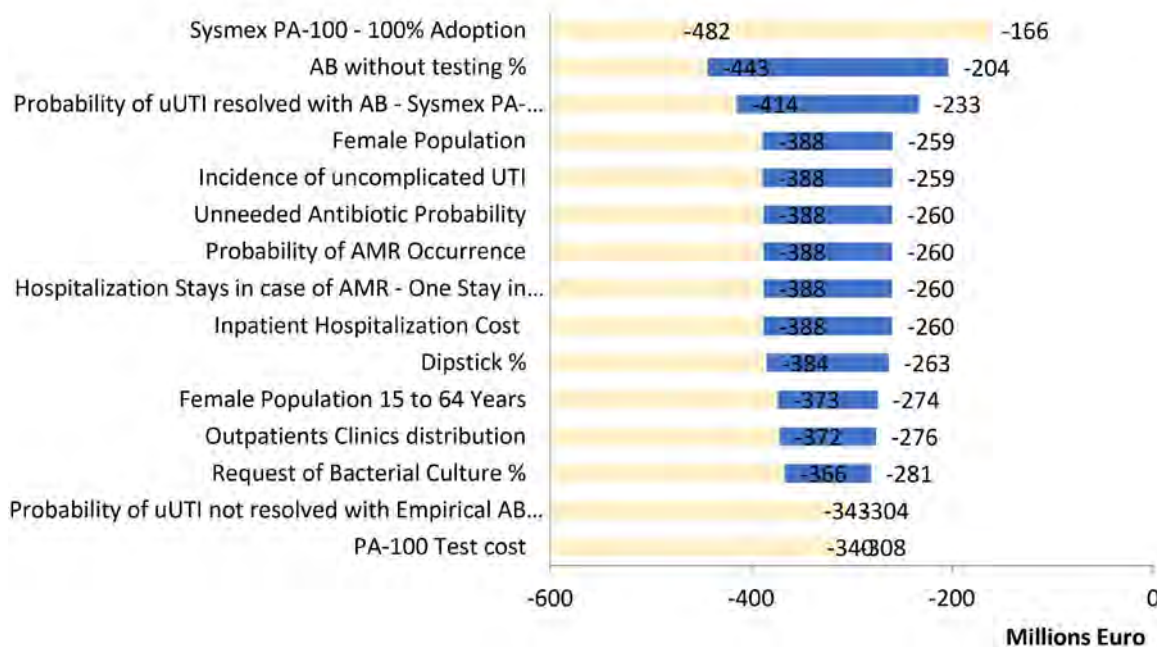


Figure 4. The one-way sensitivity analyses of annual savings with AMR. Abbreviations. AB, Antibiotic; uUTI, uncomplicated urinary tract infection; AMR, Anti-Microbial Resistance. The blue color indicates the output low value, the light color indicates the output high value.

which leads to fewer complications and secondary infections) and reduced staff time and productivity loss costs. These findings support the potential benefits of adopting the Sysmex PA-100 to enhance UTI management and allocate healthcare resource utilization in Spain.

Transparency

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Authors contributions

GE and HZ: conducting the analysis and writing the manuscript. JP: interpretation of data, revision of the manuscript, and local clinical practice validation. All authors revised the article and approved the submitted version.

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