

Protocol Implementation for Normothermia in Surgery Settings in Italy: Budget-Impact Analysis

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Roberta Monzani¹
Giovanna Barbera²
Umberto Restelli^{3,4}
Carlotta Galeone⁵
Flavia Petrini⁶

¹Day Hospital Chirurgico, IRCCS Humanitas Research Hospital Rozzano, Rozzano, Italy; ²Independent researcher, Milan, Italy; ³Centre for Health Economics, Social and Health Care Management Carlo Cattaneo University, Castellanza, Italy; ⁴School of Public Health, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa; ⁵Bicocca Applied Statistics Center (B-ASC), Università degli Studi di Milano-Bicocca, Milan, Italy; ⁶Anestesia, Rianimazione e Terapia Intensiva, Università Gabriele d'Annunzio — ASL 2 Abruzzo, Chieti, Italy

Introduction: Hypothermia is a well-known risk of the perioperative period and considered a preventable effect of anesthesia care. Nevertheless, it is not fully controlled, causing a number of adverse outcomes following surgical operations and thus increasing length of stay in hospital and treatment costs. The aim of this study was to assess the budget impact (BI) of the implementation of proactive strategies to prevent inadvertent perioperative hypothermia (IPH) in surgical patients in Italy, as recommended by international guidelines and by a good clinical practice (GCP) guideline of the Italian Society of Anesthesia, Analgesia, Reanimation, and Intensive Care.

Methods: BI was calculated over a 3-year period from the perspective of the Italian National Health Service (NHS). Model inputs were extracted from national literature when available and otherwise from international sources. The reference analytic model was based on the cost-effectiveness analysis of the National Institute for Health and Care Excellence clinical guidance 65. Estimates were based on assessments made about current malpractice in Italy and on a hypothesis of how future practice might change by implementing the GCP. Model output included overall BI results, variations in the number of warmed patients, medical-device average costs and use of mix.

Results: The base-case estimate quantified a decrease of 35% in extra days of hospital stay due to IPH and a net BI of -€60.92 million.

Conclusion: Increasing protocol adoption for preventing IPH would lead to both clinical advantages and significant savings for the NHS. Its large diffusion in Italian hospitals is thus desirable.

Keywords: budget-impact analysis, active-warming systems, inadvertent perioperative hypothermia, Italy, perioperative warming

Introduction

Perioperative hypothermia is defined as central body temperature (CBT) $<36^{\circ}\text{C}$ ¹ during and after surgery. It is a common event, occurring 20%–70%^{2,3} of the time. Mild hypothermia (defined as CBT 34°C – 36°C ⁴) is the most frequent scenario.⁵ Inadvertent perioperative hypothermia (IPH) is mainly a result of anesthesia-induced redistribution of body heat that occurs within the first hour after anesthesia induction. Anesthetic agents impair the body's ability to control and conserve heat by inhibiting vasoconstriction and shivering.⁵

No significant differences have been observed in general and locoregional anesthesia: both end up causing the same result through different actions. Under normal circumstances, the body controls its temperature with very tight tolerance, the core being 2°C – 4°C warmer than the periphery. General anesthesia affects central thermoregulation by impairing peripheral vasoconstriction and the

Correspondence: Carlotta Galeone
Bicocca Applied Statistics Center
(B-ASC), Università degli Studi di Milano-Bicocca, 8 Via Bicocca Degli Arcimboldi, Milan 20126, Italy
Tel +39 02 6448 5823
Email carlotta.galeone@gmail.com

mechanisms of thermogenesis. After induction, a 1°C decrease occurs within 30 minutes, caused by redistribution,⁶ as anesthesia causes vasodilatation, which allows the core's warmer blood to flow freely through the cooler body periphery. As blood circulates, it cools before returning to the heart, thus reducing core temperature. This decline in temperature is known as redistribution temperature drop. Hypothermia is very common during locoregional anesthesia, as this impairs central thermoregulatory control. It has been observed that the combined use of these techniques leads to a piling up of mechanisms that results in more profound hypothermia, especially in elderly people.⁷

IPH is not only uncomfortable for the surgical patient but may also affect patient outcomes and treatment costs. By affecting drug metabolism, PH is associated with prolonged recovery from anesthesia, including the need to prolong the stay in postanesthesia care unit (recovery room).⁸ It is also associated with an increased number of morbid cardiac events (MCEs),⁹ greater intraoperative blood loss,¹⁰ thermal discomfort,¹¹ and increased post-operative wound-infection rates.⁸ Each of these adverse events increases the expenditure of the National Health Service (NHS), and some can affect a patient's long-term quality of life.

IPH is both common and preventable. Without perioperative warming, the majority of patients will become at least slightly hypothermic (CBT < 36°C). Measuring CBT, maintaining normothermia, and actively warming patients undergoing surgery is crucial for the prevention of IPH and thus to reduce the number of adverse health outcomes associated with IPH. Notwithstanding its importance, temperature monitoring and active patient warming is not currently a standardized clinical practice in Europe. In this context, a survey conducted on 8,083 surgical procedures found that patient temperature was monitored in 19.4% of interventions and 38.5% of patients had actively been warmed, mainly through forced-air systems.¹²

In consideration of the evidence of positive clinical effects resulting from IPH prevention, many European societies, public authorities, and agencies — following the guidance published by the World Health Organization^{13,14} — recommend maintaining patient normothermia throughout the whole perioperative period. For our purpose, we referred to the National Institute for Health and Care Excellence (NICE) clinical guideline published in 2008 and updated in 2016,¹⁵ a checklist recommended by the Italian NHS,¹⁶ and to a specific

good clinical practice (GCP) guideline published by the Italian Society of Anesthesia, Analgesia, Reanimation, and Intensive Care (Società Italiana di Anestesia, Analgesia, Rianimazione, e Terapia Intensiva [SIAARTI]) in 2017.¹⁷

A reduction in use of health-care resources could be achieved by decreasing the incidence of IPH and thus the incidence of related adverse events. The present study describes a budget impact (BI) model that estimates results of the introduction and diffusion of appropriate protocols aiming to detect this phenomenon and maintain normothermia in the perioperative period in surgical patients. Following the NICE guideline¹⁸ and the SIAARTI GCP,¹⁷ the protocol includes measurement of CBT, maintaining normothermia, and actively warming patients undergoing surgery. BI analyses estimate changes in the budget-holders' resource use for populations that are eligible for the protocol, once this is implemented in current practice in the management of surgical patients. Ultimately, the model allows us to address the issue of affordability of systematic implementation of the protocol for the Italian NHS, and thus represents a useful instrument for health-care budget-holders to investigate and predict how maintaining perioperative normothermia may affect expenditure or budgets for health systems.

Methods

A BI analysis was performed to estimate the financial impact of the introduction of a protocol for monitoring and maintaining perioperative normothermia in Italy compared to the current treatment mix adopted in surgical settings. The aim was to compare the total costs of the current scenario (ie, where IPH-prevention protocols are scarcely adopted) and a future scenario (ie, where IPH-prevention protocols are largely adopted). The perspective of the analysis was of a third-party payer, the NHS, and estimates were conducted over a 3-year time horizon. The model was constructed according to the principles of good practice for BI analysis from the International Society for Pharmacoeconomics and Outcomes Research,¹⁹ and was developed using Microsoft Excel.

Budget-Impact Model

The BI model was based on the cost-effectiveness analysis of the full NICE guideline on this issue — management of IPH in adults¹⁸ — which used a decision-tree model to estimate the impact of various clinical strategies to prevent IPH on the incidence of each adverse health consequence. The economic model was designed to assess the reduction

in resource use that can be achieved by lessening IPH and thus decreasing the incidence of complications associated with IPH.¹⁸ In the BI model, two of these clinical consequences were considered — MCEs and surgical site infections (SSIs) — that according to a recent Cochrane systematic review¹ can be considered most relevant in both clinical and economic terms. In addition, according to the NICE economic model, as mild PH lengthens postoperative recovery and results in unplanned intensive care unit (ICU) patient admission, the expected increase in hospital length of stay (LOS) and postanesthesia care unit length of recovery for hypothermic²⁰ patients has been calculated and compared to the normothermic ones. This information, though not available on Italian databases, was considered applicable to the Italian context according to expert opinion. The BI model provides estimates of the national cost impact arising from implementation of the appropriate perioperative care for normothermia in Italy. These estimates are based on assumptions made on current practice in Italy and hypotheses of how current practice might change following the implementation of the SIAARTI GCP.¹⁷ Univariate sensitivity analysis was performed to assess the robustness of the results from the base case.

Assumptions

Baseline risk of hypothermia estimated by the NICE was based on a cohort with average anesthesia duration >60 minutes. At the same time, the baseline risk of hypothermia applied to the analysis was estimated for patients with American Society of Anesthesiologists (ASA) risk grade I under general anesthesia. The probability of a patient experiencing a specific consequence was assumed to be independent of their probability of experiencing a different one, and the hospital LOS impact each of them had was assumed to be the same, regardless of whether the event occurred in a hypothermic or normothermic patient. Finally, the analysis assumed that the LOS attributable to each adverse consequence was additive. The BI model adopted the same assumptions as the economic model constructed by the NICE. These assumptions were considered generalizable to health-care settings of other high-income countries, and were also deemed valid for the Italian context on the basis of SIAARTI experts.

Eligible Population

The SIAARTI GCP¹⁷ guideline recommended monitoring and actively warming adult patients undergoing surgery in general or regional anesthesia, or a combination of the two, for longer

than 30 minutes. As adult surgical patients are at risk of developing IPH at any stage of the perioperative pathway, monitoring and warming should affect the whole perioperative period (preoperative, intraoperative, and postoperative). Surgical operations lasting >30 minutes performed on adult patients (age>18 years), both under general and locoregional anesthesia, were the target of the BI model. The number of surgical interventions performed on the adult population in a year was not available from institutional sources in Italy. This was thus estimated on the basis of 2016 hospital-discharge data published by the Italian Ministry of Health,²¹ with reference to the national number of discharges in both ordinary and daytime regimes and grouped according to clinical code aggregates of interventions. This initial estimate was gauged to consider possible interventions not performed as the primary intervention (+10%, based on expert opinion), interventions performed on the pediatric population (−4%),²² and interventions lasting <30 minutes (−15%).²³ Total operations carried out in 1 year in Italy was estimated to number about 3.7 million, while the number of target interventions for the present BI model was approximately 3 million (Figure 1).

Epidemiological Inputs

The BI model considered SSIs and MCEs adverse IPH consequences, both having an impact on hospital LOS for a surgical patient. For each adverse event, the model required inputs of baseline risk in normothermic patients, relative risk (RR) in the hypothermic patient group, and extra LOS associated with postoperative complications. If available, data inputs for Italy were taken from national literature or institutional reports. Otherwise, they were taken from the NICE Guideline.¹⁸ All model parameters adopted (Table 1) were validated by expert opinions. Baseline risk for SSIs in Italy were extrapolated from a report of the SSI Surveillance Service published in 2014.²² A total of 355 surgical wards collected data between 2009 and 2011. In sum, 60,460 operations across eleven surgical categories were observed and 1,628 SSIs reported. This corresponds to an incidence of 2.6%, which was applied as the baseline risk of SSIs in normothermic patients.

As a result of a detailed literature review, the NICE clinical guideline¹⁸ found an RR for SSI in the hypothermic patient group of 4 (95% CI 1.6–10.2). The guideline assumed that the average extra LOS in hypothermic patients receiving intermediate and major surgery was equal to the average increased LOS reported by Coello et al²⁴ of 11.37 days. For minor-surgery patients, the NICE group considered the extra LOS for a superficial SSI reported by Coello et al of 2.8 days

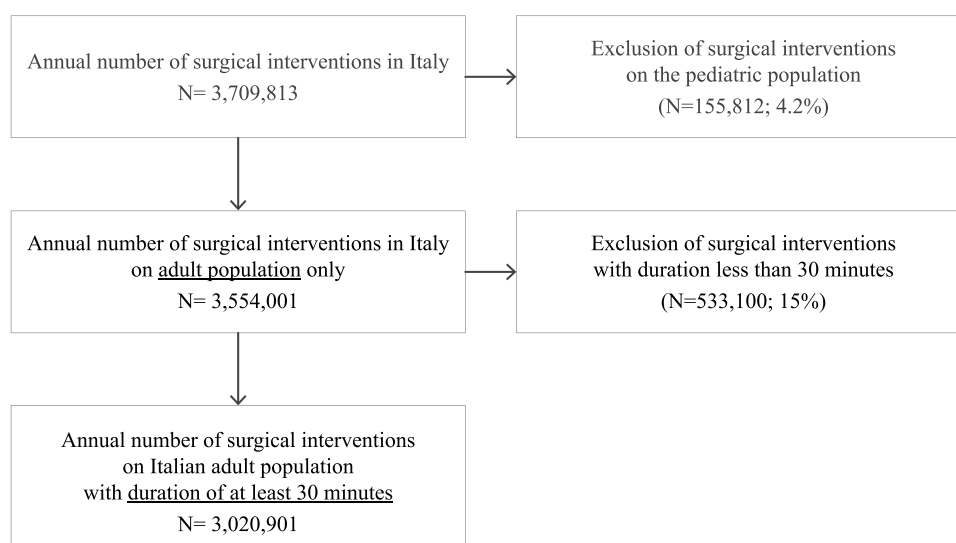


Figure 1 Target population.

(95% CI 2.2–3.5).¹⁸ Based on the results of a cohort study published in 2001 by Polanczyk et al,²⁵ the NICE guideline identified the baseline risk of MCEs for the normothermic patient group. All risk rates are summarized in Table 1. Hospital-episode statistics referring to the UK were considered to identify the extra LOS in hospitals associated with each type of event: the average extra LOS for an MCE was 7.8 hospital days. The estimated RR of an MCE in the IPH-patient group was 2.2 (95% CI 1.1–4.7).

Mild-hypothermia effects cover a broad range of complications, including bloodloss, increased transfusion rates, and reduced metabolism of most drugs. Consequently, IPH lengthens postoperative recovery and results in unplanned patient ICU admission. As baseline for the duration of hospital stay, the NICE guideline considered 0.25 days for minor surgery, 1 day for intermediate surgery, and 4 days for major surgery, an estimated increase of 19% (95% CI 7%–31%) in total LOS.¹⁸ This LOS lengthening was applied to all hypothermic patients in the model. Since there were no Italian data available, the distribution of patients by age and type of surgery from Germany was adopted in the model,²⁶ since the German setting was considered adequately comparable to Italy on the basis of SIAARTI experts involved (Table 1).

Current Scenario

The number of medical devices used in current practice was estimated by analyzing data published on national expenditure on medical devices in 2016 by the Italian Ministry of Health.²⁷ Expenditure attributable to all medical devices generally used

in clinical settings to maintain normothermia was considered: both active-warming systems that transfer heat to the patient (usually forced-air systems and conductive blankets or mattresses) and passive insulation systems that decrease heat loss, but will not add any benefit in maintenance of perioperative normothermia (usually insulation blankets).²⁸ In addition, expenditure for warming-fluid devices and probes for CBT monitoring was included. The estimated share of patients yearly warmed in Italy reached 32%. The proportion of medical devices for patient warming in the current Italian scenario, estimated from Italian Ministry of Health 2016 data,²⁷ is reported in Figure 2. The incidence estimate of PH in the current scenario was calculated by weighting the incidence of IPH associated with the use of each warming system (or alternatively, no use of device), as reported in the NICE guideline (Chapter 13¹⁸ — “Cost-effective analysis”) by the usage share of the same medical devices.

Future Scenario

The GCP guideline published by SIAARTI¹⁷ recommends warming patients intraoperatively from induction of anesthesia using a forced-air device when anesthesia lasts >30 minutes or they are at higher risk of IPH, and suggests the use of a resistive heating mattress or blanket if a forced-air warming device is not suitable. Reflecting this recommendation, current practice is expected to change gradually following the implementation of the guideline, and 3 years from now, the share of warmed patients should reach 85%. At the same time, with protocol implementation, CBT is systematically measured and patients mainly warmed through forced-air systems.

Table I Epidemiological and cost model input parameters

	Input parameter	Source
Epidemiological inputs		
SSI incidence in Italy	2.6%	Marchi et al ²²
SSI RR in hypothermic patients	4	Full NICE guideline ¹⁸
SSI length of stay	2.8 days for minor surgery 11.37 days for intermediate and major surgery	Full NICE guideline ¹⁸
MCE incidence by age (years)	0 for 18–34 0.8% for 35–49 2.4% for 50–69 4.5% for >70	Full NICE guideline ¹⁸
MCE RR	2.2	Full NICE guideline ¹⁸
MCE LOS	7.8 days	Full NICE guideline ¹⁸
LOS due to unplanned ICU admission	0.25 days for minor surgery 1 day for intermediate surgery; 4 days for major surgery	Full NICE guideline ¹⁸
Incidence of unplanned ICU admission	19%	Full NICE guideline ¹⁸
Distribution of surgical procedures by age (years)	18–34: 12% 35–49: 18% 50–69: 36% >70: 34%	German DRG, Federal Health Reporting ²⁶
Distribution of surgical procedures by type of surgery	Minor surgery: 48% Intermediate surgery: 30% Major surgery: 22%	German DRG, Federal Health Reporting ²⁶
Cost inputs		
Hospital stay	€279	Lagostena ²⁹
Average device costs for warmed patients	€9.8 in current scenario €27.4 in future scenario	Based on national expenditure in medical devices 2016 ²⁷

Abbreviations: ICU, intensive care unit; LOS, length of stay; MCE, morbid cardiac event; RR, relative risk; SSI, surgical site infection.

Medical device–usage proportions are 86% forced-air and 14% resistive heating devices. Warmed fluids are suppose to be used for all major surgery interventions and half the intermediate surgery ones. In the first and second year following protocol implementation, the proportion of warmed patients gradually increases to 50% and then to 70%.

Costs

Direct costs of medical devices for monitoring CBT and maintaining normothermia and of hospital stay in surgical ward were considered, as the model focuses on prolongation of hospital LOS for a hypothermic patient. Hospital-

stay costs were estimated based on data published in standard hospital cost studies conducted by the Italian Health Network for the sharing of standard costs, indicators, and results of health activities. The available data refer to Galliera Hospital in Genoa²⁹ and show the total average production cost incurred by the hospital for all patients discharged from the General Surgery Department during 2015. The cost was indexed at 2019 money values in accordance with the rate of change in hospital-service prices, as estimated by the corresponding subindex of the Italian price index for the whole society by the National Institute for Statistics,³⁰ and was €279 per patient per day.

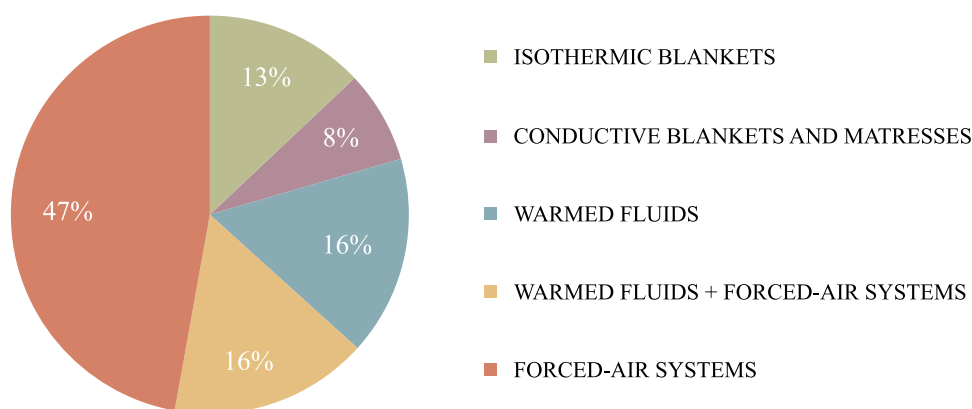


Figure 2 Medical devices for patient warming in the current Italian scenario.

This included physician, nurse, and other staff costs, drugs, medical devices, and a share of general hospital costs. Costs of lab tests, X-rays, surgical procedures, and operating room were not considered in this cost of hospital-stay assessment. Average medical device costs were estimated as the weighted average of prices of tenders assigned in Italy in 2016, inflated to 2019 prices, and weighted by the corresponding volumes purchased. The assessed average cost for medical devices considered in the current scenario was €9.8, referring to the 32% share of interventions with patient warming. In the future scenario, the average cost for medical devices in implementation of the protocol on 85% of interventions increased to €27.4. This cost included probes for monitoring CBT and active-warming systems, as previously indicated.

Results

Starting from the target population (Figure 1), the model assessed resource and BI associated with diffusion of the protocol for preventing IPH, calculated as the difference in population-resource use and costs, respectively, between current and future scenarios. In the future scenario the number of patients undergoing surgery with application of the protocol increased from 966,000 in the current scenario to 2.5 million (Table 2). Implementing the protocol resulted in additional costs due to increased use of forced-air warming systems and inductive-heating mattresses and blankets. From the combination of raised number of warmed patients and exclusive use of active-warming systems, medical device

Table 2 Budget Impact Model Results

	Current scenario	Future scenario			Incremental costs
	32% protocol adoption	1 year: 50% protocol adoption	2 years: 70% protocol adoption	3 years: 85% protocol adoption	
Hospital-stay cost (€)	279	279	279	279	
Annual procedures >30 (n)	3,020,901	3,020,901	3,020,901	3,020,901	
Share of patients warmed	32%	50%	70%	85%	
Patients warmed (n)	966,418	1,510,450	2,114,630	2,567,766	
Extra days due to IPH (n)	1,251,613	1,102,334	939,429	815,099	
Average device cost (€)	9.8	20.3	24.9	27.4	
Annual cost of warming (€)	9,481,217	30,764,345	52,637,561	70,371,290	60,890,073
IPH incidence, minor surgery	20.1%	17.8%	15.3%	13.4%	
IPH incidence, intermediate surgery	48.2%	42.5%	36.2%	31.5%	
IPH incidence, major surgery	42.4%	37.2%	31.6%	27.3%	
Annual cost due to adverse IPH events (€)	349,284,227	307,630,635	262,168,458	227,471,403	-121,812,824
Total annual cost (€)	358,765,444	388,394,980	314,806,019	297,842,693	
Net benefit (€)		-20,370,464	-23,588,961	-16,963,326	-60,922,751

Abbreviation: IPH, inadvertent perioperative hypothermia.

expenditure increased €60.89 million (from €9.5 million in the current scenario to €70.3 in the future one). The model estimated consistent benefits and savings from this protocol's implementation: fewer patients becoming hypothermic during surgery, and consequently a substantial reduction in costs arising from the management of adverse events caused by IPH. Combining the results of increased LOS for a hypothermic patient with the amount of hypothermic patients for the number of national procedures per year, the model estimated a total of 436,000 full days of hospital stay due to IPH could be prevented. This result impacted in reduction of costs by almost €121.8 million and simultaneously increasing the quality of life of patients who avoided the consequences of IPH. As shown in Figure 3, the overall BI on the NHS arising from increased expenditure for combined medical devices and lower costs due to a decrease in IPH incidence was estimated at net savings of almost €60.92 million in the third year of protocol implementation.

Sensitivity Analysis

One-way sensitivity analyses were performed by changing base-case parameters of the model, and shown in a tornado diagram (Figure 4). A range of variability equal to 20% of the central value was considered, assuming this as

a reasonably wide range, for the reference population. Cost of medical devices in current and future scenarios and cost of hospital stay in surgical wards varied within $\pm 20\%$. Incidence of accidental hypothermia range was $\pm 20\%$. The results of the sensitivity analysis showed that all input variables reacted to changes in net benefit directly (Figure 4), with the exception of device costs in the future scenario and incidence of IPH, for which a cost increment was associated with a decrease in potential savings. Other conditions being equal, the analysis showed a greater sensitivity of net benefit to cost of hospitalization and incidence of IPH (the variation was more than proportional).

Discussion

This study provides estimates of the impact on national cost of the implementation of the SIAARTI GCP guidance on preventing IPH in Italy. The present BI model found relevant savings for the Italian NHS. To our knowledge, this is the first evidence in an Italian context, and to date, few similar studies on the estimation of cost reductions due to effectiveness of thermal care-bundle implementation in preventing IPH have been published.^{31,32} A recent Australian pharmacoeconomic study estimated important savings in IPH prevention to the health system consistent to our results.³²

Several original items were computed in the present analysis, eg, estimated number of surgical interventions

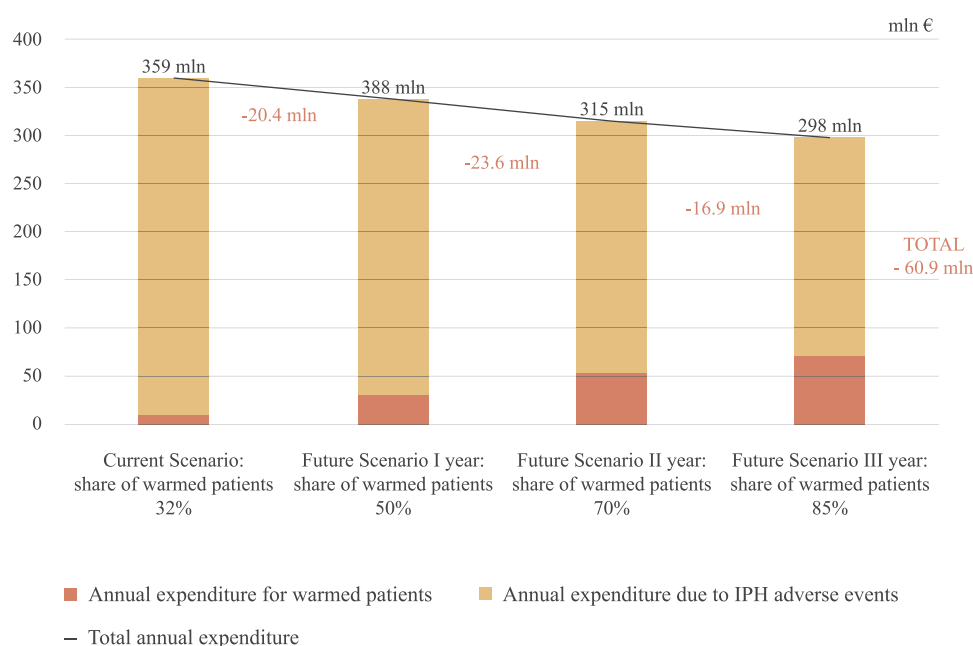


Figure 3 Estimated annual total and incremental budget impact for each year of the time frame for warming patients intraoperatively in Italy.

Abbreviations: MLN, million; IPH, inadvertent perioperative hypothermia.

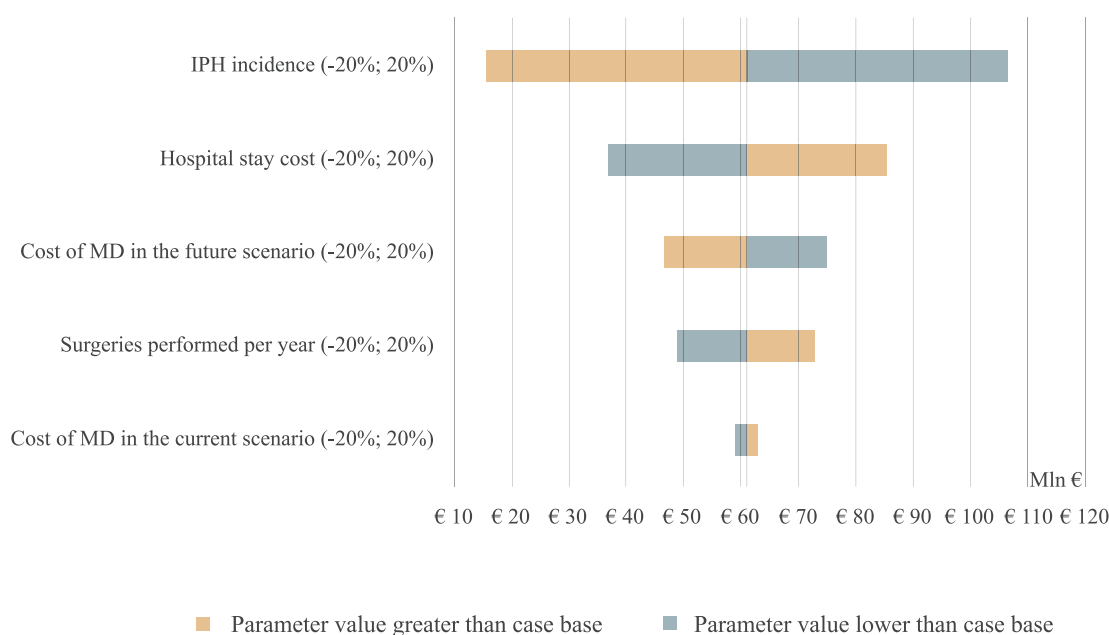


Figure 4 Tornado diagram for sensitivity analyses. Central value: base-case budget-impact savings of €60.9 million.

Abbreviations: MD, medical devices; MLN, million; IPH, inadvertent perioperative hypothermia.

performed in Italy each year — an information not immediately available from public data — and an estimate of usage share of medical devices for normothermia maintenance in surgical settings in Italy. These data on the real-life utilization of medical devices, based on the institutional database,²⁷ allowed us to perform a realistic assessment of current practice in the present scenario and could be useful to health-care budget-holders to understand the impact of protocol implementation on their budget, on the population's health and on health-care resources during the same period.

Our BI analyses found that protocol implementation for preventing IPH in surgery settings in Italy caused important additional costs, due to the increased number of patients needing warming devices (from 32% of patients undergoing surgery in the current scenario to 85% in the future scenario) and to a change in the mix of medical devices for patient warming to be adopted in future scenarios. In fact, in the future scenario the adoption of a consistent increment in proportion of the most efficacious medical devices in preventing IPH (ie, the active-warming systems) was expected, as recommended by the SIAARTI GCP guidance.¹⁷ These, however, are generally more expensive than passive devices. The BI model estimated an important increase in cost for medical devices (an increment of more than sevenfold the total cost in the current scenario), but at the same time, this model estimated crucial savings for the Italian NHS. In fact, by implementing the IPH-prevention protocol in the future scenario, the model estimated

a considerable reduction in costs from adverse events caused by hypothermia, given the smaller number of patients expected to become hypothermic during surgery. LOS was estimated to decrease by 35% (from 1.25 million in the current scenario to 815,000 in the future one), with saved resources amounting to almost €122 million. Finally, the BI model estimated a net benefit of IPH prevention to the Italian NHS of €60.62 million. This result highlights that protocol implementation not only guarantees an improvement in clinical patient care and consequently in quality of life of patients after surgery, but it is also a sustainable strategy for NHS savings. Sensitivity analyses showed that model conclusions were robust with respect to the variability of input parameters, and cost reductions emerged in all cases considered. Preventing IPH-protocol implementation is crucial to reduce SSIs, ie, the most common health care-associated infections,^{33–35} and their incidence reduction should be a main goal for health-care budget-holders (also to fight increasing antibiotic resistance). This would also lead to an improvement in hospital-productivity indices, such as bed-rotation index or number of hospital discharges.

This study has some limitations. Hypothermia-risk assumptions were based on a cohort with a mean duration of anesthesia >60 minutes, and this may have led to overestimation of risk of hypothermia received with shorter procedures. Also, the baseline risk of hypothermia estimated for patients with ASA risk grade I treated under general

anesthesia may have underestimated the risk in patients with higher ASA risk grades or those having combined regional and general anesthesia. Model implementation considered epidemiological inputs not strictly referring to the Italian population, due to a lack of national data. However, data from other high-income European Union countries were considered adequate for the Italian clinical context by expert opinion. In the model, only two adverse events associated with IPH were considered (ie, MCEs and SSIs), since according to recent evidence these complications can be considered the most relevant in both clinical and economic terms.¹ Moreover, we assumed that patients were warmed intraoperatively only, despite the NICE guideline¹⁸ recommending warming patients throughout the entire perioperative pathway. Including other consequences due to IPH and considering prewarming in the BI model would probably increase the estimation of net savings for the NHS in the future scenario.

The present BI model considered direct health costs only. Moreover, the LOS costs considered in the present model are an underestimate of the real ones, in consideration of possible extra costs due to return to operating rooms, additional lab tests, or diagnostic tests due to complications. On the other hand, the adoption of new active-warming systems may impact on total cost of health-care personnel, due to training time and additional energy consumption associated with increasing use of warming systems. None of these costs was considered, due to the absence of specific data.

Conclusion

Based on BI analysis, the introduction and implementation of perioperative normothermia best care, as recommended by international guidelines and the SIAARTI GCP guideline, would result in both clinical and economic advantages for the Italian NHS. The model estimated relevant savings for hospitals. It is thus advantageous from the economic and clinical point of view for the SIAARTI GCP guideline on perioperative normothermia to be widely adopted in Italian hospitals. In consideration of our favorable findings, further studies from other European countries are awaited.

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Disclosure

The authors report no conflicts of interest in this work.

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