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ORIGINAL RESEARCH

Cost-Effectiveness of Newborn Screening for Spinal Muscular Atrophy in Australian Hospitals

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ABSTRACT

Introduction: This analysis evaluated the cost-effectiveness of newborn screening (NBS) for spinal muscular atrophy (SMA) from the perspective of Australian state hospital payers.

Methods: A cost–utility analysis consisting of a decision tree and Markov cohort designed to calculate the difference in costs and health outcomes between two scenarios: (1) disease-modifying treatment (DMT) for SMA after diagnosis through NBS, and (2) DMT for SMA after diagnosis as symptoms appear. A population of 295,906 newborns was modeled, based on the total number of live births in Australia in 2023. Inputs included screening parameters, epidemiology inputs, SMA natural history data and DMT parameters (nusinersen and onasemnogene abeparvovec), costs, and health-related quality of life parameters. Assumed participation in NBS was 100%. A one-way sensitivity analysis and probabilistic sensitivity analysis were conducted to examine the impact of parameter uncertainty.

Prior Presentation: This data has been previously presented as a poster at the Australasian Neuromuscular Network's 2023 congress, held 24–26 May 2023, Marcoola, QLD, Australia, and the International Congress on Neuromuscular Diseases 2024 congress, held 25–29 October 2024, Perth, Australia.

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Results: There were 30 patients identified with SMA, of whom 25 patients would be eligible for presymptomatic treatment. NBS for SMA was dominant compared with no NBS for SMA. On a population level, NBS demonstrated a lifetime gain of 267 quality-adjusted life years (QALY) and incremental costs of –AUD$3,983,263 (i.e., cost savings). Every dollar invested in NBS would save hospitals $3.69. Deterministic and probabilistic sensitivity analyses demonstrated the robustness of the base-case results.
Conclusion: NBS for SMA was dominant compared with no NBS for SMA in Australia from a state and territory payer perspective. Universal implementation of NBS for SMA would support access equity, as well as early diagnosis and treatment in infants with SMA, potentially leading to improved outcomes.

Keywords: Cost-utility analysis; Newborn screening; Nusinersen; Onasemnogene abeparvovec; Spinal muscular atrophy

Key Summary Points

Why carry out this study

Spinal muscular atrophy (SMA), a rare, genetic neuromuscular condition with an incidence of 1 in 10,000 live births, results in progressive muscle weakness, atrophy, and premature death without treatment.

Treatment for patients with SMA is most effective when initiated early, ideally before symptoms present. Patients at risk for SMA can be identified early via newborn screening.

Newborn screening (NBS) criteria for SMA varies between states and territories of Australia, making universal implementation a challenge.

What was learned?

NBS for SMA was dominant compared with no NBS for SMA in Australia from a state and territory payer perspective. The model assumed treatment initiation with disease-modifying treatment (DMT) after NBS diagnosis, and, in the case of no NBS, DMT after diagnosis following symptom presentation.

Universal implementation of NBS for SMA would support access equity and potentially lead to improved outcomes in patients with SMA through early detection and treatment initiation.

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INTRODUCTION

Spinal muscular atrophy (SMA) linked to chromosome 5q (SMA-5q) is a rare, genetic neuromuscular condition caused by deficiency of the survival motor neuron (SMN) protein, leading to irreversible brainstem and spinal cord motor neuron loss [1]. The incidence of SMA is 1 in 10,000 live births [2]. The majority of individuals with SMA have biallelic deletions of either exon 7 or 8 of the *survival motor neuron 1* (*SMN1*) gene, which encodes the SMN protein, resulting in progressive skeletal muscle weakness, atrophy, and multisystem morbidity [3, 4]. In the most severe cases, patients are likely to suffer premature death by 2 years of age if left untreated. Patients with SMA-5q can be identified through newborn screening (NBS), which detects the homozygous deletion of *SMN1*, with disease severity and age of onset inversely correlated with the number of *survival motor neuron 2* (*SMN2*) gene copies [1, 5]. Patients vary in the number of copies of the paralogous gene, *SMN2*, which produces 10% of functional SMN protein. Although the SMA phenotype can vary widely, patients may be classified as a clinical type ranging from 0 to 4 based on age of onset and the highest motor milestone achieved, with type 0 (prenatal onset) being the most severe [1, 5].

There are currently three approved disease-modifying treatments (DMTs) for patients with SMA [6–8]. Nusinersen and risdiplam are *SMN2* splicing modifiers, and onasemnogene abeparvovec is a one-time, intravenous, adeno-associated virus 9 vector-based gene replacement therapy, which delivers a fully functional copy of human *SMN cDNA* into target cells [6–8]. Although varying in mechanism of action, all three treatments increase SMN production and prevent motor neuron loss and disease progression. Treatment for patients with SMA is most effective when initiated early, ideally before symptoms present [9]. Early identification of patients with SMA through NBS can facilitate diagnosis and treatment initiation in those with clinically silent or presymptomatic SMA.

Several countries have introduced NBS for SMA, including Belgium, Germany, the United States, Italy, and Australia [10]. Most countries utilize consistent NBS criteria across all states or counties. Others, such as Australia, lack national consensus and display variability between states in the conditions that are included in NBS programs, despite over 50 years of NBS experience [11, 12].

A pilot program started in Australia in 2018 screened 202,388 infants and found that SMA fulfilled the criteria for population-wide screening, and the net benefits for lifelong outcomes were acknowledged by stakeholders (e.g., caregivers and healthcare professionals) [13, 14]. The federal government endorsed the use of NBS for SMA and covered treatments costs for all patients with SMA who were eligible in Australia universally; however, individual state and territory governments vary in their cost coverage of NBS for SMA [15].

Since the start of the Australian pilot screening program for SMA, some efforts have supported the use of a consistent framework for inclusion of conditions using criteria closely informed by the Wilson and Junger screening principles [16]. However, NBS programs are independently funded and operated by state and territory governments. Therefore, barriers remain in achieving consistent coverage and universal implementation of NBS for SMA due to differing state- or territory-mandated criteria [11, 12].

Cost-effectiveness analyses can help guide decision-making for payers, weighing the costs versus value of implementing processes like NBS for SMA as evidence-based and effective universal practice. While cost-effectiveness of NBS for SMA has been demonstrated from a federal government perspective, state and territory perspectives have not been examined in depth [17]. This analysis evaluated the cost-effectiveness of NBS for SMA from the perspective of Australian state hospital payers.

METHODS

Model Structure

A cost–utility analysis consisting of a decision tree and Markov cohort was designed to calculate the difference in costs and health outcomes between two scenarios: (1) DMT for SMA after diagnosis through NBS, and (2) DMT for SMA after diagnosis as symptoms appear [18]. A decision tree was used to model the implications of NBS and DMT selection (Fig. 1). The decision tree component of the analysis considered Australian estimates for live births, SMA prevalence, *SMN1* mutation, *SMN2* copy number, and SMA phenotype [4, 13, 19–24]. DMT utilization for eligible presymptomatic patients was sourced from national Pharmaceutical Benefits Scheme (PBS) prescribing data [25]. Those patients not eligible for presymptomatic treatment became eligible for treatment with a DMT once they received a phenotypic diagnosis.

A Markov cohort model was used to model the long-term costs and outcomes, based on the outcomes of the decision tree component of the analysis. Health states were defined by developmental motor milestones: (1) not sitting; (2) sitting without support; (3) walking without support; and (4) broad range of normal development [26–29]. Not sitting was subdivided based on the requirement for non-invasive permanent assisted ventilation (PAV), which is defined as more than 16 h a

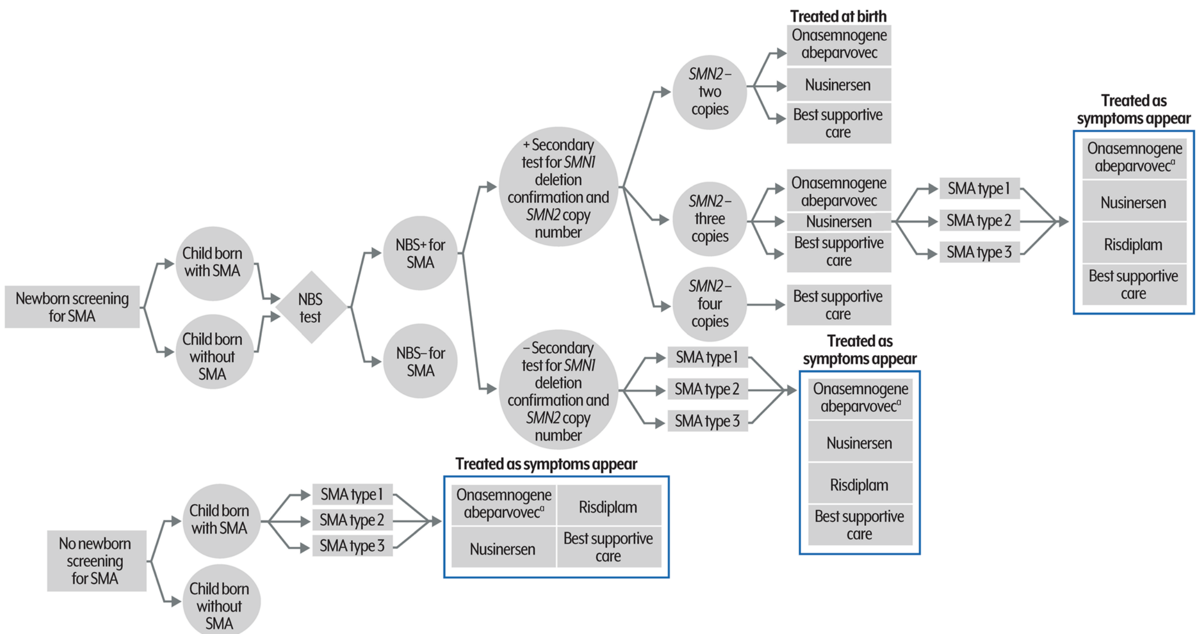

Fig. 1 Model structure. *NBS* newborn screening, *SMA* spinal muscular atrophy, *SMN1 survival motor neuron 1* gene, *SMN2 survival motor neuron 2* gene. [a]Onasemnogene abeparvovec SMA type 1 only. First-tier NBS is conducted from a dried sample via polymerase chain reaction assay and analyzed for homozygous deletion of exon 7 of the *SMN1* gene. One allelic deletion of exon 7 on the *SMN1* gene is not captured by NBS (considered to be false negatives). For those who are *SMN1* deletion-positive, second-tier screening is performed via digital droplet polymerase chain reaction to determine *SMN2* gene copy number [43]

day for more than 2 weeks in the absence of an obvious reversible cause. Costs and health outcomes were discounted at 5% per annum, in line with Australian health technology assessment guidelines [30]. A lifetime time horizon was modeled in alignment with similar evaluations [18, 31]. The model perspective was that of the state or territory payer; thus, each state and territory was modeled individually. An aggregate of all payers was used to estimate the cost-effectiveness of NBS for SMA in Australia.

Population

A population of 295,906 newborns (New South Wales, 94,680; Australian Capital Territory, 5267; Victoria, 76,332; South Australia, 18,920; Western Australia, 31,209; Northern Territory, 3496; Queensland, 60,505; Tasmania, 5497) was modeled, based on the total number of live births in 2023 [32]. Six-monthly cycles were applied for the first 3 years, to capture the rapid rate of motor development change during the first 3 years of life [33]. Twelve-monthly cycles were applied thereafter to reflect the reduced likelihood of developmental milestone change after the first 3 years of life [34].

Model Inputs

Inputs included screening parameters, epidemiology inputs, SMA natural history data, and DMT parameters, costs, and quality of life parameters. Assumed participation in NBS was

Table 1 Model inputs

Description	Variable	Source
Epidemiology inputs		
Incidence of SMA	1/10,000	SMA Australia [35]
SMN1 deletion[a]	88.3%	Li et al. 2024 [36]
SMN2—two copies	55%	D'Silva et al. 2022 [13]; Kariyawasam et al. 2023 [21]
SMN2—three copies	39%	D'Silva et al. 2022 [13]; Kariyawasam et al. 2023 [21]
SMN2—four copies	6%	D'Silva et al. 2022 [13]; Kariyawasam et al. 2023 [21]
SMA type 1	60%	Lally et al. 2017 [22]; Verhaart et al. 2017 [4]; Glascock et al. 2018 [24]
SMA type 2	30%	Lally et al. 2017 [22]; Verhaart et al. 2017 [4]; Glascock et al. 2018 [24]
SMA type 3	10%	Lally et al. 2017 [22]; Verhaart et al. 2017 [4]; Glascock et al. 2018 [24]
Cost inputs		
Non-sitting (PAV) annual hospital cost	$115,973	IHACPA 2023 [37]; Expert opinion
Non-sitting annual hospital cost	$42,780	IHACPA 2023 [37]; Expert opinion
Sitting annual hospital cost	$22,028	IHACPA 2023 [37]; Expert opinion
Walking annual hospital cost	$8588	IHACPA 2023 [37]; Expert opinion
Normal development annual hospital cost	$0	IHACPA 2023 [37]; Expert opinion
Utility inputs		
Non-sitting with ventilation support utility	0	Shih et al. 2021 [12]; Belter et al. 2020 [38]
Non-sitting utility	0.02	Shih et al. 2021 [12]; Belter et al. 2020 [38]; Ellis et al. 2019 [39]; Chambers et al. 2020 [40]
Sitting utility	0.11	Shih et al. 2021 [12]; Belter et al. 2020 [38]; Chambers et al. 2020 [40]
Walking utility	0.38	Shih et al. 2021 [12]; Belter et al. 2020 [38]
Normal development utility	Age-specific general population	Ellis et al. 2019 [39]; Ara and Brazier 2010 [41]

PAV permanent assisted ventilation, *SMA* spinal muscular atrophy, *SMN1* *survival motor neuron 1* gene, *SMN2* *survival motor neuron 2* gene

[a]11.7% of patients were estimated to have heterozygous deletion or point mutation on the *SMN1* gene and returned a negative NBS result [36]

100%. Further SMA-related epidemiology inputs and sources are presented in Table 1.

Screening Parameters

All newborns are eligible for NBS, which is provided by state government-funded hospitals. NBS uptake is approximately 99% in all newborns in Australia [42]. First-tier NBS is conducted from a dried blood sample via polymerase chain reaction assay and analyzed for homozygous deletion of exon 7 of the *SMN1* gene [43]. If a patient has one allelic deletion of exon 7 on the *SMN1* gene, they are considered to have carrier status and not reported by NBS. For those who have a homozygous *SMN1* deletion, a second-tier screening (for *SMN1* deletion positive) is performed via digital droplet polymerase chain reaction to determine *SMN2* copy number, though the availability of this testing may vary according to region.

Epidemiological Inputs

SMA incidence in Australia was estimated as 1 in every 10,000 live births, of which up to 11.7% are estimated to be compound heterozygous for a deletion and disease-associated sequence variant in *SMN1* or have homozygous or compound heterozygous disease-associated sequence variants in the *SMN1* gene and return a negative NBS result [35, 36]. False-positive results were not possible considering the confirmation received from second-tier testing [44]. Patients with false-negative results were assumed to develop symptomatic SMA types 1, 2, or 3. The percentages of symptomatic patients diagnosed with SMA types 1, 2, and 3 were 60%, 30%, and 10%, respectively [2, 22, 23, 35]. Australian data on *SMN2* copy number were used to inform the percentage of patients with two (55%), three (39%), or four (6%) *SMN2* copies [21].

Clinical Inputs

DMT selection for presymptomatic patients with SMA on the PBS included nusinersen and onasemnogene abeparvovec; both for patients with up to three *SMN2* copies [30]. Risdiplam has since been approved for presymptomatic patients with up to three *SMN2* copies, but was not included in this analysis [7]. Onasemnogene abeparvovec is available for symptomatic patients up to the age of 9 months, and nusinersen and risdiplam are available for symptomatic patients with SMA types 1, 2, or 3. Utilization of each DMT was estimated from PBS prescribing data and validated with local clinicians with experience in treating SMA [25]. Presymptomatic patients were assumed to receive DMT within the first 6 months of life, and symptomatic patients were assumed to receive DMT within the first 6 months of symptom development. For those who did not receive presymptomatic treatment, the age of symptom development varied based on the severity of SMA developed [45]. Transitions between health states in the short-term period of the Markov model were driven by developmental milestone outcomes from clinical trial evidence. Individual data sources were used for each DMT for both presymptomatic and symptomatic scenarios.

The clinical trials informing transition probabilities were SHINE/ENDEAR, NURTURE, CS2/CS12, START/ STR1VE/STR1VE-EU, SPR1NT, and FIREFISH [46–56]. Patients with SMA type 1 and those identified by NBS started in health state D (not sitting) and symptomatic patients with SMA types 2 and 3 began in health state C (sitting) and B (walking), respectively. Motor milestones achieved were assumed to occur within 36 months [57]. Patients receiving an active DMT did not lose motor milestones, based on long-term evidence [49, 58]. Long-term survival was modeled individually for each health state based on published natural history data and Australian general population mortality data [5, 59–61]. Ages at the start of model cycle 1 were 6, 18, and 48 months for patients with SMA types 1, 2, and 3, respectively [61]. The model used perfect DMT compliance and assumed no milestone regression while receiving active treatment.

Cost Inputs

Costs included the cost of the NBS heel-prick test, the cost of the second-tier test, and hospital-based healthcare costs. DMT costs were not considered, as these are not funded by Australian states. A sensitivity analysis was conducted that included the published prices of DMTs [30]. The cost of the heel-prick test and the cost of second-tier *SMN2* quantitation to the hospital was estimated to be $5 and $350 Australian dollars, respectively [62]. As this analysis evaluated the cost-effectiveness of NBS from a public hospital perspective, only hospital resource use and costs were considered. This included acute inpatient hospitalizations and outpatient visits. Inpatient rehabilitation is infrequent in Australia and thus was not included. Palliative care costs were considered for 63% of those who died in the 'C (sitter)' or 'D (non-sitter)' health states, based on the percentage of patients who die in hospital [63].

There were no published Australian studies that considered hospital specific resource use for SMA stratified by SMA type. Evidence from other countries was identified and validated by Australian clinicians to reflect Australian SMA care models [64–69]. Hospital costs were sourced from Australian public hospital cost data (2023–2024) [37]. The annual cost applied in each health state was: $42,780 for not sitting; $115,973 for not sitting with PAV; $22,028 for sitting; and $8588 for standing. Broad range of normal development incurred no additional hospital costs. It is important to note that DMT costs were not considered as these are not funded by Australian states, but DMT administration was considered for lumbar puncture (<18 years of age: $1921; ≥18 years of age: $960) and intravenous infusion ($493) [37]. Oral therapy incurred no administration cost.

Health-Related Quality of Life Inputs

Quality-adjusted life years (QALY) were calculated using health-state specific utilities. Values were sourced from an Australian cost-effectiveness analysis [12]. The following utilities were applied: 0.0 for required assisted ventilation; 0.02 for non-sitting; 0.11 for sitting; and 0.38 for walking. General population utility estimates for broad range of normal development were derived per cycle and validated with Australian utility values [41, 70].

Sensitivity Analyses

A one-way sensitivity analysis and a probabilistic sensitivity analysis were conducted to examine the impact of parameter uncertainty.

Ethics Approval

No new studies with human participants were included in this analysis, and, therefore, Institutional Review Board approval was not required, patient consent to participate was not necessary, and the Declaration of Helsinki 1964 does not apply.

RESULTS

NBS for SMA was modeled for 295,906 neonates, based on the total number of live births in 2023. A total of 30 patients with SMA were identified, of whom 25 would be eligible for presymptomatic treatment (Table 2). NBS for SMA was dominant compared with no NBS for SMA. On a population level, NBS demonstrated a lifetime gain of 267 QALY and incremental costs of –$3,983,263 (i.e., cost savings) (Table 3) (equal to 9.0 QALY gained and $134,612 cost savings over a lifetime time horizon per SMA case).

Every dollar invested in NBS would save hospitals $3.69 because of earlier access to DMTs and prevention of irreversible motor neuron loss. The greatest benefit (cost saved and QALY gained) was observed in the states with greater birth rates (New South Wales and Victoria) (Table 4).

Sensitivity Analyses

Deterministic (Fig. 2) and probabilistic (Fig. 3) sensitivity analyses demonstrated the robustness of the base-case results. The deterministic sensitivity analysis identified general population utility, sitting health state utility, and sitting health state cost as having the greatest

Table 2 NBS outcomes

Outcome	NBS	Non-NBS	Increment (NBS − non-NBS)
Number of tests performed	295,936	29.6	295,906
NBS heel prick	295,906	0	295,906
DNA blood test	29.6	29.6	0
Number of cases treated	29.6	29.6	0.0
Patients identified and treated presymptomatically	24.5	0.0	25
Patients identified presymptomatically but treated symptomatically	1.6	0.0	1.6
Patients identified and treated symptomatically	3.5	29.6	−26.1

DNA deoxyribonucleic acid, *NBS* newborn screening

Table 3 Cost-effectiveness results

Strategy	Costs	Incremental costs	QALYs	Incremental QALYs	ICER
NBS for SMA	$5,728,793	– $3,983,263	384	267	Dominant (less costly, more effective)
No NBS	$9,712,057		118		

ICER incremental cost-effectiveness ratio, *NBS* newborn screening, *SMA* spinal muscular atrophy, *QALY* quality-adjusted life-years

Table 4 Model results for each state or territory

Setting	Presymptomatic cases treated	Incremental cost	Incremental QALY
Australia	24.54	– $3,983,263	266.62
New South Wales	7.85	– $1,274,526	85.33
Australian Capital Territory	0.44	– $70,918	4.75
Victoria	6.33	– $1,027,734	68.90
South Australia	1.57	– $254,704	17.04
Western Australia	2.59	– $420,188	28.11
Northern Territory	0.29	– $46,978	3.11
Queensland	5.02	– $814,279	54.45
Tasmania	0.46	– $73,991	4.94

QALY quality-adjusted life-years

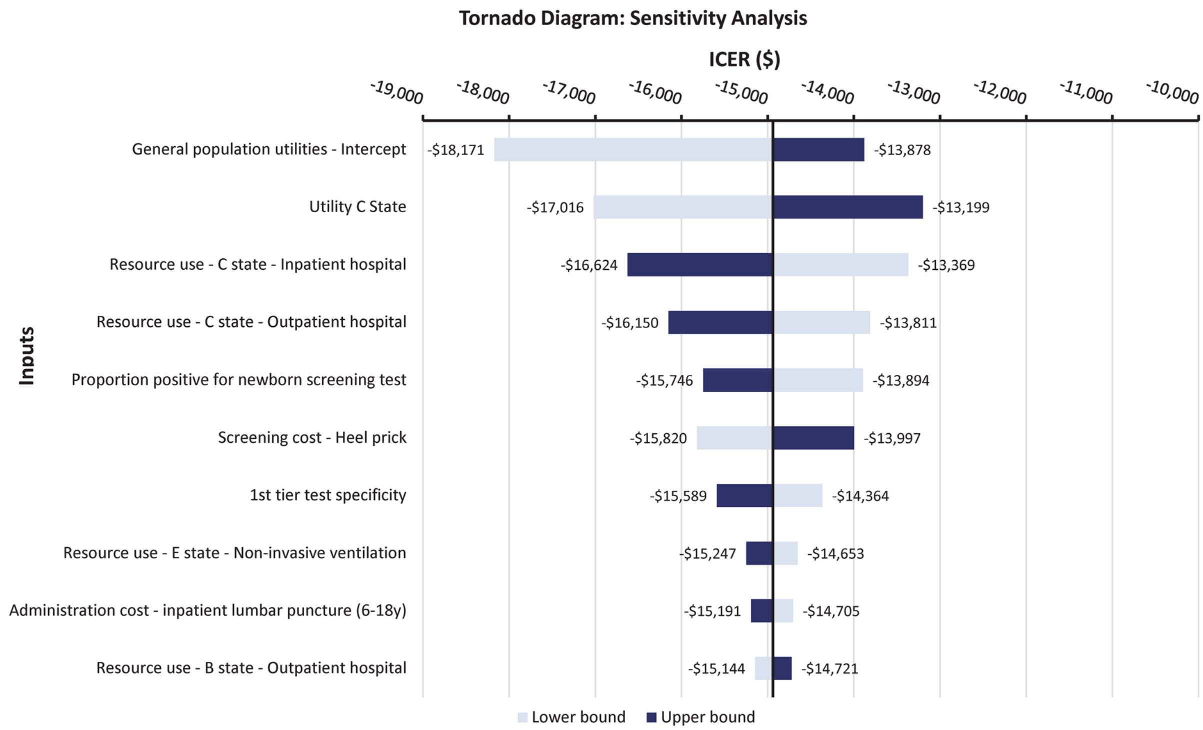

Fig. 2 Tornado diagram for the deterministic sensitivity analysis. *ICER* incremental cost-effectiveness ratio

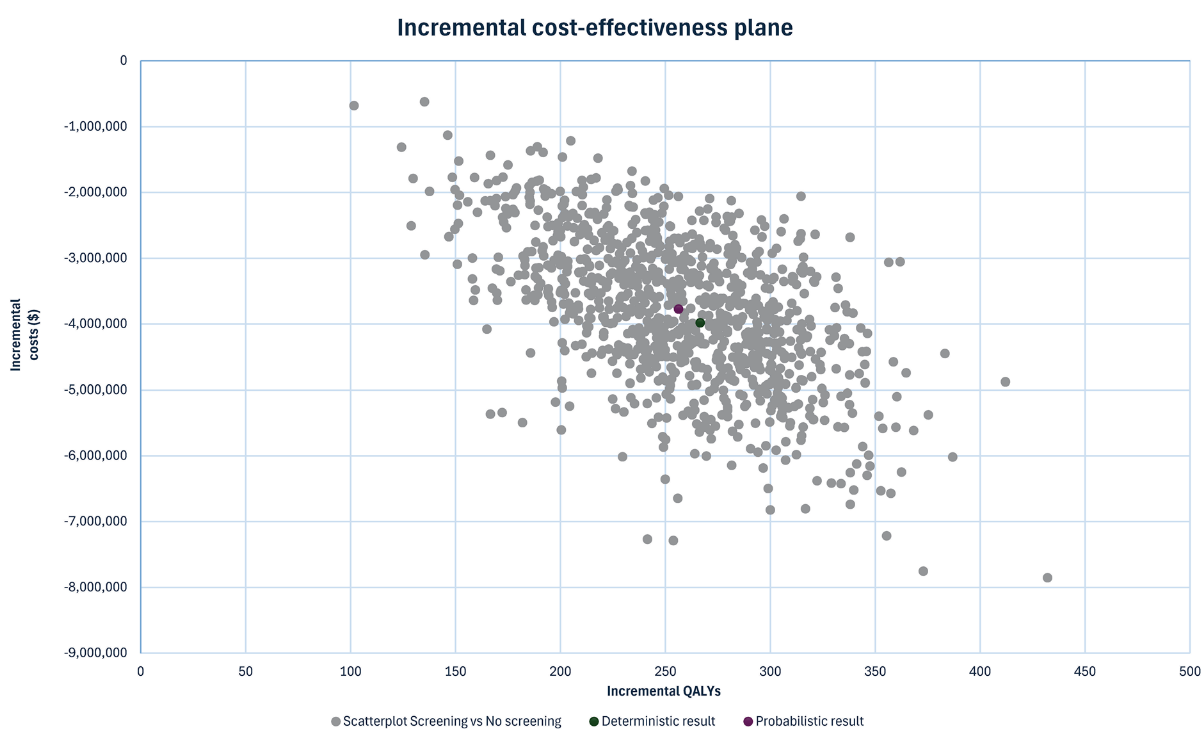

Fig. 3 Probabilistic sensitivity analysis results: incremental cost-effectiveness plane. *QALY* quality-adjusted life-year

impact on the incremental cost-effectiveness ratio; however, NBS for SMA remained less costly and more effective for each scenario tested. The probabilistic sensitivity analysis demonstrated moderate variability; however, NBS for SMA remained less costly and more effective in 99% of 1000 modeled scenarios. NBS for SMA was less costly and more effective when DMT costs were included in the analysis.

DISCUSSION

To our knowledge, this is the first study which examines the cost-effectiveness of NBS for SMA from an Australian public hospital perspective. In Australia, NBS is delivered at a state level whereas SMA therapies are funded by the federal government via the PBS. Given that public hospitals are funded by state and territory governments, the findings of our study emphasize the importance of considering cost-effectiveness from the state government payer perspective.

The scenario of routine NBS availability for SMA in Australia was dominant (i.e., less costly and more effective) compared with a scenario without NBS, with the greatest benefit in states with the greatest birth rates. Despite this finding, we promote equity of NBS and treatment access for all patients, regardless of geographic location, in line with the Newborn Screening National Policy Framework [71]. Implementing NBS for SMA is a cost-effective use of resources from the perspective of Australian state hospitals. Through early identification of patients with SMA via NBS, patients are likely to avoid treatment delays and experience improved health outcomes.

Several studies have evaluated the cost-effectiveness of NBS for SMA [12, 18, 31, 72–76]. One Australian study evaluated the cost-effectiveness of NBS and treatment with onasemnogene abeparvovec and nusinersen from a societal perspective over a 60-year time horizon [12], and the results demonstrated a 9.93 QALY gain per presymptomatic infant with SMA treated with DMT, which was similar to the findings of our analysis when viewed at a per-patient level. Differences in cost were likely attributable to the difference in payer, as we assessed cost-effectiveness from the hospital perspective. A publication from the Netherlands evaluated the cost-effectiveness of NBS versus no NBS for SMA, and included all types of SMA (1, 2, and 3) and a variable number of *SMN2* gene copies [18]. This study demonstrated that early identification and treatment of SMA versus later symptomatic treatment after clinical diagnosis improved health outcomes and was less costly, which aligns with our results. This study used a similar structure and approaches aligned with the Australian Government guidelines and other published models to confirm the lifelong benefits of NBS for SMA.

Limitations

Study limitations include the lack of long-term effects or clinical equivalence of treatments, the lack of randomized controlled trial data, and the fact that effective prices were unknown. Varied healthcare resource utilization between individuals was not accounted for, and instead utilization estimates were compared with standard practice in major pediatric hospitals for validation. Similar to other studies, economic and health-related quality of life measures were not taken into consideration, although these may be factors to consider in the future [77]. The costs of treatments were not included in the model; however, other models have evaluated cost-effectiveness with onasemnogene abeparvovec compared with nusinersen [26, 78].

Considering a state hospital perspective necessitated a micro-costing analysis to ensure costs were specific to the state payer. Australian-specific hospital resource use for SMA was not identified. We applied local costs to resource use from other markets and validated them against Australian care standards with input from local treating clinicians [64–68]. One study has quantified the total cost of SMA in Australia by SMA type [40]. The costs in more severe disease states in our model were similar to direct costs reported; however, our less severe health states had lower costs. This is to be expected, given that more severe health states are more likely to require hospital-based services, whereas less severe health states are more likely to incur out of hospital care and disability support costs, which are funded federally.

CONCLUSIONS

NBS for SMA was dominant compared with no NBS for SMA in Australia from a state and territory payer perspective. Universal implementation of NBS for SMA would support access equity. Likewise, early diagnosis and treatment of patients with SMA identified through NBS leads to improved health outcomes due to prevention of irreversible motor neuron loss. NBS for SMA is cost-saving and should be implemented in all Australian hospitals.

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Data Availability. The data sets used and analyzed during the present study are available from the corresponding author on reasonable request. All authors had full access to all of the data (including statistical reports and tables) related to the study.

Declarations

Conflict of Interest. Ian R. Woodcock has received honoraria for work performed with Novartis, Biogen, Roche, Avidity and Pfizer. Damian Clark and Didu S. Kariyawasam, have nothing to disclose. Nicholas J.C. Smith has been an invited member of the Novartis Australian SMA advisory Group; he has received consulting fees from Forge Biologics and Actelion Pharmaceuticals and Research support from Abeona Therapeutics, Ultragenyx, Bluebird bio and Cyclo Therapeutics. Maina P. Kava has received an honorarium for participation in a scientific advisory board for Roche. Eppie M. Yiu has received honoraria from Biogen and Roche for participation in scientific advisory boards, honoraria from Biogen paid to their institution for participation in educational activities, and research support from Biogen, Roche, and Novartis. Matthias Bischof and Jane Adams are employees of Novartis and own Novartis stock or other equities. Adrian Peacock is an employee of HTANALYSTS, which undertakes paid health economics consultancy work for industry and

Government. Colman Taylor received grants/contracts through the George Institute for Global Health from the Baxter Healthcare Corporation and worked as a consultant providing project oversight for a government review of chemotherapy funding; received grants through the George Institute for Global Health from CSL Bioplasma to conduct the FLUID-TRIPS study; received a grant through the George Institute for Global Health from the National Health and Medical Research Council to fund the PLUS study. He is also co-owner of Health Technology Analysts Pty Ltd (HTANALYSTS), which undertakes consultancy work for pharmaceutical companies, medical device companies, not-for-profit entities, and the Australian Government.

Ethical Approval. This article is based on a cost-utility analysis using a combination of decision tree and Markov model structures. No new studies with human participants were included in this analysis, and, therefore, Institutional Review Board approval was not required, patient consent to participate was not necessary, and the Declaration of Helsinki 1964 does not apply.

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