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ASSESSING THE PROVISION OF BONE ANCHORED LIMB PROSTHESIS

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RESEARCH ARTICLE

DEVELOPMENT OF A GOVERNMENT CONTINUOUS QUALITY IMPROVEMENT PROCEDURE FOR ASSESSING THE PROVISION OF BONE ANCHORED LIMB PROSTHESIS: A PROCESS RE-DESIGN DESCRIPTIVE STUDY

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ABSTRACT

BACKGROUND: Evidences of sustainable clinical benefits of bone-anchored prosthesis (BAP) using osseointegrated fixation over typical socket-suspended prostheses are becoming more probing. This influx of individuals to be fitted with BAP has pressed government organisations to adjust their policies. However, the appraisal of consumer's experience for the provision of BAP founded by government organisation is yet to be developed. This descriptive study shares the experience gained by a government organisation, namely the Queensland Artificial Limb Service (QALS), while developing a specific BAP-inclusive continuous quality improvement (CQI) procedure.

OBJECTIVE(S): The primary objective was to present the methods and outcomes of key steps required to plan and create this CQI procedure. The secondary objective was to highlight key barriers and facilitators of the transition from a socket-focused to the proposed BAP-inclusive CQI procedure.

METHODOLOGY: The re-design process of the CQI procedure for 65 current QALS's consumers with BAP involved a two-step process for the planning (e.g., case-mix, stakeholder) and creation (e.g., diagnosis, technical options, cost).

FINDINGS: Prosthetists labour toward CQI procedure represented 1.3 hrs out of 22 hrs and AUD$213 out of AUD$3,300 or 6% of the whole procedure for the provision of BAP. The time spent by a prosthetist, consumer and QALS staff represented 24%, 24% and 53% of the time of the CQI procedure, respectively. The cost of prosthetist and QALS staff labour represented 70% and 30% of the CQI procedure, respectively.

CONCLUSIONS: This descriptive study shares the workings and methodology that government organisations, such as QALS, can use to re-design a CQI procedure for comprehensive appraisal of the provision of prosthesis that could be inclusive of BAP and affordable while minimally time-consuming for prosthetists. The transition from a socket-focused to the proposed minimally disruptive BAP-inclusive CQI procedure was facilitated by prior knowledge of BAP treatment, early identification of the stakeholders and adaptation of current CQI procedure.

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KEYWORDS

Amputation; Artificial limb; Bone-anchored prosthesis; Quality improvement; Osseointegrated implants; Osseointegration; Procedure; Prosthesis; Reimbursement.

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LIST OF ABBREVIATIONS

BAP: Bone-anchored prosthesis
SSP: Socket-suspended prostheses
QALS: Queensland Artificial Limb Service
CQI: Continuous quality improvement
PSP: Prosthetic Service Provider
CMS: content management system
PID: Prosthetic Issue Document
VOS: Validation of Services
PSE: Prosthetic Service Evaluation
SF12: Short Form 12V2 Health Survey
PLUS-M™: Prosthetic Limb Users Survey of Mobility
DVA: Rehabilitation Appliance Program of the Department of Veteran Affairs
NDIS: National Disability Insurance Scheme

INTRODUCTION

Strong demand for bone-anchored prostheses

Evidences of sustainable clinical benefits of bone-anchored prosthesis (BAP) using osseointegrated fixation over typical socket-suspended prostheses (SSP) are becoming more probing, particularly for young and active individuals with non-vascular transfemoral amputation.[1-4] Clinical risks with BAP particularly infection and breakage of components are currently deemed acceptable although yet to be resolved satisfactorily.[5-8] Significant improvement in health-related quality of life has driven a steady demand from wide range of individuals with lower limb amputation.[1-4,7-26] Indeed, surgical procedures are growing at an unprecedented pace worldwide.[18, 27, 28]

Health services delivery of bone-anchored prosthesis

This influx of individuals fitted with osseointegrated fixation has pressed government organisations, like the Queensland Artificial Limb Service (QALS), to adjust their policies for fair and equitable provision of BAP.[18, 29]

Indeed, QALS established such procedure allowing financial assistance for consumers choosing BAP that involves seven processes costing AUD$3,300 for 22 hrs of labour per patient during the treatment.[29] Furthermore, cost cross-comparing and cost-effectiveness demonstrated health economic benefits of BAP over SSP from government perspective.[30-32] For instance, provision of BAP costed 21±41% more but increased quality-adjusted life-year by 17±5% compared to SSP leading to an indicative incremental cost effectiveness ratio of approximately AUD $17,000 per quality-adjusted life-year. Despite a partial compensation of the cost by quality-adjusted life-year, the provision of BAP was deemed cost-effective since the incremental cost effectiveness ratio was noticeably below willingness to pay threshold.[33]

Need for government continuous quality improvement procedure

Appraisal of consumer's experience for the provision of BAP by government organisation is yet to be developed. A series of standardised surveys could assess delivery of particular prosthetic care and/or experience with prosthetic components (e.g., SERVQAL, OPUS, QUEST).[34-41] However, their relevance to provision of specific BAP care by government organisations is limited.

QALS has carried out a SSP-focused continuous quality improvement (CQI) procedure detailed below that has emerged through regular revisions over the last decade in response to best practice and legal obligations imposed by government as well as expectations from consumer advisory groups. Whilst some aspects of this CQI procedure are relevant to the provision of BAP, there is a need to further investigate developments of CQI procedure capable of appraising consumer's experience for the provision of BAP by government organisation.

Objectives

The aim of this work was to improve government health service delivery of prosthetic care specific to individuals fitted with BAP. The purpose of this process re-design descriptive study was to share the experience gained by a government organisation while developing a specific BAP-inclusive CQI.

The primary objective was to present the methods of model re-design with particular emphasis on outcomes of key steps required to plan (e.g., case-mix profiling, stakeholder analysis) and create (e.g., diagnosis, pros-cons analysis of technical options, cost) this specific CQI procedure. The secondary objective was to highlight key barriers and facilitators of the transition from a pre-existing SSP-focused to the proposed BAP-inclusive CQI procedure.

METHODS

Setting

The study followed ethical guidelines from the Queensland Health's Health Innovation, Investment and Research Office (HIIRO) responsible for consultation, development and review of State-wide research ethics and research governance policies. This study was undertaken by QALS in the jurisdiction of the Queensland State Government Minister of Health, Australia. With a yearly budget of AUD$5.4 million, QALS provides equitable funding for prosthetic services to 3,600 active consumers annually through a network of up to 10 individual prosthetists referred to as Prosthetic Service Provider (PSP).[29, 30, 33]

Participants

The development of the CQI procedure was led by a QALS steering committee including QALS management team, two researchers in health services, three PSPs and the five first consumers representing 8% of the QALS's population fitted with BAP.[42, 43]

Study design

The descriptive study started in July 2015, shortly after the whole QALS's procedure for provision of BAP was completed.[29] As detailed in **Table 1**, the development of the specific CQI procedure was achieved using the following two-step re-design process:

- Step 1 to plan the procedure, including:
  - Step 1A identifying problems to solve using root cause analysis that involved case-mix profiling achieved by looking at typical demographics, amputation, as well as access to prosthetic care and funders data extracted from QALS client information system.
  - Step 1B identifying deliverables of the CQI procedure that involved stakeholder analysis using typical matrix ranking selected organisations in relation to their power and interest in CQI depending on capacity to influence allocation of resources and to provide prosthetic and medical care, respectively. Stakeholders were classified as controllers (high power, low interest), promoters (high power, high interest), providers (low power, high interest) or advocates (low power, low interests).[44]
- Step 2 to create procedure including:
  - Step 2A diagnosing quantitatively the suitability of the current SSP-focused CQI procedure by counting the number of sections, questions and possible answers in each evaluation form and by categorising the focus of each question as administration (e.g., consumer's identification, processing status, quality control), service (e.g., labour associated with provision of prosthetic services and/or components), prosthesis (e.g., provision of repair, fitting, replacement of prosthetic components and/or cosmetic cover), socket (e.g., light, definitive) or BAP (e.g., provision of all interventions to fit a BAP). Questions focusing on administration, service and BAP were considered relevant while those focusing on prosthesis and socket were deemed partially suitable and irrelevant to appraisal of provision of BAP, respectively.
  - Step 2B exploring options for new specific CQI procedure that relied on pros-cons analysis of pathways and products investigated for administration and analysis of surveys and content management system (CMS).
  - Step 2C adapting the existing CQI procedure to each phasis of BAP treatment, adjusting forms and estimating participants' typical time commitment.[29] Cost for PSPs' contribution and internal labour (e.g., QALS staff time) allocated to CQI procedure (e.g., data collection, entry and reporting) was set at hourly fee of AUD$160 and AUD$30, respectively. All costs are reported in Australian dollars (1 Australian dollar ≈ 0.63 Euro ≈ 0.56 British pound ≈ 0.74 US dollar) according to 2017-18 prices.

In all steps, the steering committee considered critical qualitative and quantitative information and applied a typical standards for interactive inquiry process and data-driven collaboration leading to consensus.[45]

RESULTS

Definition of specific procedure

Case mix profile

The characterisation of case-mix presented in **Table 2** involved the 65 QALS consumers fitted with lower limb BAP since 2011, representing 16% and 7% of existing BAP population estimated at 400 in Australia and 950 worldwide, respectively.

Table 1. Timeline and actions of the two-step process taken by the Queensland Artificial Limb Services (QALS) to develop specific Continuous Quality Improvement (CQI) procedure to appraise consumer's experience for provision bone-anchored prostheses (BAP).

Step 1. Plan BAP CQI procedure (06/2016 - 12/2016)		
A **Define project**	**B** **Determine deliverables**	**C** **Review literature**
• Identify problems to solve	• Review regulatory obligations	• Delivery of health care
• Define aim, purpose and objectives	• Conduct stakeholders analysis	• Provision of prosthesis services
• Profile case-mix	• Determine reporting expectations	• Consumer satisfaction survey
Step 2. Redisign BAP CQI procedure (01/2017 - 07/2017)		
A **Assess SSP-focused CQI**	**B** **Explore options**	**C** **Create BAP-inclusive CQI**
• Review current process	• Simulate new workflow	• Adapt CQI procedure to BAP treatment
• Review current forms	• Determine cost-benefits analysis	• Adjust forms
• Review current Content Management System	• Choose most cost-effective procedure	• Determine participants involvements

Table 2. Case-mix profile including demographics, amputation, access to care and funder information for the 65 Queensland Artificial Limb Services (QALS) consumers with lower limb amputation treated with bone-anchored prosthesis (BAP) between 01/2011 and 01/2017 (PSP: Prosthetic Service Provider , DVA: Rehabilitation Appliance Program of the Department of Veteran Affairs, NDIS: National Disability Insurance Scheme).

	Participants		Mean	SD	Range	
	Number	Percentage			Min	Max
Demographics						
Male	50	77	-	-	-	-
Female	15	23	-	-	-	-
Age (years)	65	100	52	13	26	74
Height (m)	58	89	1.75	0.10	1.50	1.94
Mass (kg)	62	95	82.86	17.29	45.00	128.00
Amputation						
Timeline						
Time since first amputation (years)	65	100	20	15	1	66
Time since first surgery for BAP (years	64	98	3	1	0	6
Cause						
Trauma	44	68	-	-	-	-
Vascular insufficiency	9	14	-	-	-	-
Malignant neoplasma	6	9	-	-	-	-
Level of amputation						
Transfemoral	53	82	-	-	-	-
Transtibial	9	14	-	-	-	-
Through Knee	3	5	-	-	-	-
Hip disarticulation	1	2	-	-	-	-
Number of amputations						
Unilateral	58	89	-	-	-	-
Bilateral	5	8	-	-	-	-
Quadrilateral	2	3	-	-	-	-
Access to prosthetic care						
Distance-Residence to PSP (km)	60	92	145	212	5	1,345
Distance-Residence to QALS (km)	62	95	364	499	5	1,771
Funder						
QALS	38	58	-	-	-	-
DVA	8	12	-	-	-	-
NDIS	12	18	-	-	-	-

Stakeholders analysis

Twenty key stakeholders were identified with half operating at state or national levels as presented in **Figure 1C** and further detailed in **Figure 2** (Supplement). No stakeholder was identified as controllers. As expected, the six (30%) promoters involved the decisional entities around QALS including consumer advisory group, in particular, as well as national government funding agencies. The seven (35%) providers involved all health professionals in the clinical teams responsible for osseointegration treatments in state and interstate, including essentially prosthetists. The seven (35%) advocates included mainly consumer support groups and professional associations as well as other artificial limbs services across Australia.

Creation of specific procedure

Diagnosis of initial CQI procedure

The appraisal of QALS' provision of prosthetic services involved a series of evaluations supported by three paper-based forms including a total of 73 items allowing 240 possible answers. As detailed in **Table 3,** the review this CQI showed that:

- Evaluation A, involving seven steps, relied on Prosthetic Issue Document (PID) to acknowledge PSP's service that triggers QALS' reimbursement. Circulated by mail, the PID included 18 (25%) of all the questions that were completed by PSPs and consumers after each service. A total of 61% of the questions focused on the whole prosthesis.
- Evaluation B, involving four steps, relied on a Validation of Services (VOS) form designed to assess a consumer's satisfaction with quality of the prosthetic service delivered by PSP. The VOS included 25 (34%) of all the questions that were completed by QALS staff while talking to consumers over the phone after each service.
- Evaluation C, involving four steps, relied on Prosthetic Service Evaluation (PSE) form designed to assess overall consumer's experience with service provided by QALS. The PSE included 30 (41%) of all the questions that were completed by consumers yearly.

Overall, 51%, 40% and 9% of the questions were relevant, partially suitable and irrelevant to the development of CQI for BAP, respectively. The content of the paper version of each form was manually tabulated by QALS staff into a purposely-designed CMS, easily adjustable in-house in response to stakeholders' regular changes in reporting expectations, including a series of spreadsheets organising entries, analysis and reporting of consumer experience information.

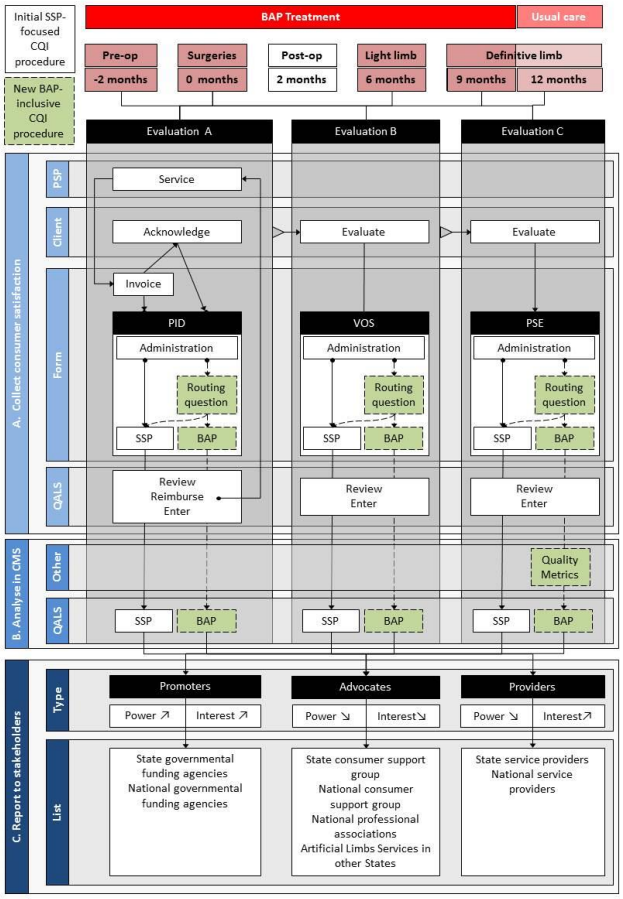

Figure 1. Overview of initial and newly developed specific Continuous Quality Improvement (CQI) procedure to appraise consumer's experience for socket-suspended (SSP) and bone-anchored (BAP) prostheses that involved (A) collection of data with clients and Prosthetic Service Providers (PSP), (B) analysis of the data relying on Content Management System (CMS) and (C) reporting to stakeholders, respectively.

Table 3. Overview of structure with number of sections, questions and possible answers and percentage of questions focusing on administration, service, prosthesis, socket or bone-anchored prosthesis (BAP) for each initial form of the continuous quality improvement (CQI) procedure used by Queensland Artificial Limb Services (QALS). PID: Prosthetic Issue Document, VOS: Validation of Services, PSE: Prosthetic Service Evaluation.

	Evaluation A PID	Evaluation B VOS	Evaluation C PSE	CQI
Structure (Number)				
Sections	4	6	7	17
Questions	18	25	30	73
Answers	51	79	110	240
Focus (Percentage of questions)				
Administration	24	57	7	28
Service	0	0	53	22
Prosthesis	61	37	30	40
Socket	13	5	10	9
BAP	2	1	0	1

Explore options for specific CQI

Opportunity for redesigning a specific CQI procedure relying on new pathways, forms and cloud-based technological platform was initially investigated.[37, 46, 47] Quote from external professional provider with relevant programming skills indicated that such project will require approximately 200 hrs of labour at the cost of AUD$33,000.

Alternatively, keeping the current delivery pathway and adjusting forms and CMS was considered. We made the assumption that these adjustments could be achieved in approximately 120 hrs for in-house knowledgeable staff labour at an internal cost of AUD$3,600. The latter option was deemed the most sensible and cost-effective.

Creation of BAP-inclusive CQI procedure

A dynamic overview of the proposed BAP-inclusive CQI procedure in **Figure 1** detailed the intersections between phases of the treatment and each of the three sequential evaluations with emphasis on contribution of participants, documents and forms used, the tasks achieved, CMS used to collect, analysis and report consumer experiences outcomes.

Evaluations A and B were required to be completed after each service that occurred typically at least four times during the first year of the BAP treatment between pre-operative consultation and fitting of definitive prosthesis. Evaluation C occurs usually at least once a year after delivery of definitive prosthesis.

The adaptation and reorganisation of all forms was achieved by implementing basic principles of so-called computerized adaptive testing.[48] The first part of all forms involving administration items, mainly focusing on identification of consumer and processing information, remained unchanged. However, a two-answer routing question was added at the end of administration section asking consumers what type of attachment they use. The SSP users were directed to the second part including essential questions in current forms related to socket and prosthesis cleaned of any BAP related items. Those using BAP were directed to the third part including newly developed questions. Practically, this third part in PID and VOS forms required consumers to indicate at which of

the five stages of the treatment they were at. Developments of the third section in the PSE form was more involved and lead to design of custom-made survey including 32 questions as outlined in **Table 4** to assess clinical outcomes in six domains.[49] Benefits were assessed into two domains including the health-related quality of life and mobility outcome using the standardized self-report Short Form 12V2 Health Survey (SF12) and Prosthetic Limb Users Survey of Mobility (PLUS-M™) 12-item short forms, respectively.[39, 48] Safety was assessed by self-reporting selected adverse events into four domains including fixation stability, fixation integrity, injuries as infections.[5]

As presented in **Table 5**, resources provided to PSP's efforts toward CQI procedure represented 1.3 hrs out of 22 hrs and AUD$213 out of AUD$3,300 or 6% of the whole procedure for the provision of the BAP detailed previously.[29] The time spend by PSP, consumer and QALS staff represented approximately, 24%, 24% and 53% of the time of the whole procedure, respectively. The cost for reimbursement of PSP's and QALS staff labour represented 70% and 30% of the total costs of the CQI administration per consumer, respectively. Altogether, the typical total cost per consumer for the first year of treatment with BAP was approximately AUD$416.

Table 4. Overview of 32 questions asked in third part of the Prosthetic Service Evaluation (PSE) form extracted from two standards surveys and eight specifically-designed questions to assess six evaluation domains related to benefits and safety experienced by consumers fitted with bone-anchored prosthesis provided by QALS.

Domains and Questions	Number of questions	Validation	
		Standard	Customized
1. Benefits			
1.1. Health-related quality of life			
• Short Form 12V2 Health Survey (SF12)	12	x	
1.2. Mobility outcome			
• Prosthetic Limb Users Survey of Mobility (PLUS-M™) 12-item short form	12	x	
2. Safety			
2.1. Fixation stability			
• Has the osseointegrated fixation been formally diagnosed as loose by treating clinicians (e.g., surgeon) during the last 12 months?	1		x
2.2. Fixation integrity			
• Have you experienced one or more bone fractures around the fixation including fracture of proximal joint (e.g., Greater Trochanter) during the last 12 months?	1		x
• How many times the internal part of the fixation in contact with the bone has been broken or replaced during the last 12 months?	1		x
• How many times the external part of the fixation connecting to the prosthesis (e.g., taper sleeve, abutment) has been repaired or replaced during the last 12 months?	1		x
2.3. Injuries			
• How many falls have you experienced in the last 12 months?	1		x
2.4. Infection			
• How many episodes of infections requiring a course of oral antibiotics for a week of less have you experienced in the last 12 months?	1		x
• How many episodes of infections requiring a course of oral or intra-venous antibiotics for more than a week have you experienced in the last 12 months?	1		x
• Have you been taking antibiotics continuously for more than four weeks during the last 12 months?	1		x

DISCUSSION

Outcomes

This study revealed that a government organisation, such as QALS, can redesign a CQI procedure for comprehensive appraisal of the provision of prosthesis that could be inclusive of BAP while been minimally time-consuming for PSPs and affordable.

The transition from a SSP-focused to the proposed minimally disruptive BAP-inclusive CQI procedure was facilitated by the following redesign inputs:

- **Capitalising on prior knowledge.** Initial understanding of specific rehabilitation program following BAP treatment was gained during development of the QALS overall procedure to support provision of BAP. This elucidated involvements of PSP in the delivery of services and components during treatment that was essential to determine workload and cost.[29]

- **Identification of the stakeholders.** Early selection, organisation of key stakeholders helped to ascertain common and separate expectations and subsequently prioritise reporting requirements.
- **Adapting current CQI procedure.** Redesigning a BAP-specific CQI might lead to increased delivery efficiency and, more importantly, suitability of tailored forms providing distinctive results for this group of consumers. However, such parallel CQI procedure has several shortcomings including, but not limited to, confusion of consumers used to initial CQI, significant cost required to build dedicated CMS, lack of consistency in reporting limiting benchmarking with other consumers.[49] Alternatively, keeping the initial procedure relying on three evaluations but adapting the forms and CMS was deemed the most sensible and cost-effective option.

The main obstacles to the development of BAP-inclusive CQI procedure were associated with adjustments of PSE form, particularly the selection of relevant outcomes to consider. Only confounders of customer's experience responsible for potential cross-correlation with provision of particular components and clinical outcomes were selected from classification of benefits and safety of BAP

treatment presented by Frossard (2015) further detailed in **Figure 3** (Supplement).[49] Also challenging was to balance the selection of outcomes (inclusion vs exclusion), the choice of instrument to measure selected outcomes (e.g., preference on validated over in-house design self-reported surveys) and the overall length of the survey (e.g., preference on short over long forms of surveys). Generic health-related quality of life measures were achieved using validated and widely used SF12 because the outcome could be readily benchmarked and converted in quality-adjusted life-year required for subsequent cost-utility analyses.[31, 33] Mobility outcomes associated with actual usage of the prosthesis using T-score from PLUS-M™ could be supplemented by physical tasks such as Time Up and Go and 6-Minute Walk accessible from consumer's passport completed by PSP after fitting of definitive components as described in Frossard et al (2017), if needed.[29]

Table 5. Breakdown of typical time commitment and costs associated with administration of the QALS's Continuous Quality Improvement (CQI) procedure for Evaluations A and B that repeated four times during the course of BAP treatment and Evaluation C that is conducted once and repeated yearly (Prosthetic Service Provider (PSP) labour = AUD$160 per hour accordingly to the schedule of allowable fixed expenses in QALS' procedure, QALS' staff time = AUD$30 per hour).

Step	Participant	Task	PSP		Consumer		QALS		Overall	
			(Hrs)	($)	(Hrs)	($)	(Hrs)	($)	(Hrs)	($)
Repeated at each phase of BAP treatment (~2 to 9 months)										
Evaluation A										
1	PSP	Send invoice for a service to QALS	0.17	$27					0.17	$27
2	PSP	Send PID to client	0.17	$27					0.17	$27
3	Consumer	Acknowledge PSP service using PID			0.25	$0			0.25	$0
4	Consumer	Sent PID to QALS			0.08	$0			0.08	$0
5	QALS	Review invoice sent by PSP					0.25	$8	0.25	$8
6	QALS	Review PID sent by client					0.25	$8	0.25	$8
7	QALS	Reimbourse PSP for service					0.25	$8	0.25	$8
Evaluation B										
1	Consumer	Evaluate PSP and QALS service using VOS			0.25	$0			0.25	$0
2	Consumer	Sent VOS to QALS			0.08	$0			0.08	$0
3	QALS	Review VOS sent by client					0.50	$15	0.50	$15
4	QALS	Tabulate information into registry					0.25	$8	0.25	$8
		Total for each phase of treatment	0.33	$53	0.67	$0	1.50	$45	2.50	$98
		Total for all phases of treatment	1.33	$213	2.67	$0	6.00	$180	10.00	$393
One-off yearly upon completion of BAP treatment (12 months)										
Evaluation C										
1	Client	Evaluate PSP and QALS service using PSE							0.25	$0
2	Client	Sent PSE to QALS							0.08	$0
3	QALS	Review PSE sent by client					0.50	$15	0.50	$15
4	QALS	Tabulate information into registry					0.25	$8	0.25	$8
		Total for yearly assessment	0.00	$0	0.00	$0	0.75	$23	1.08	$23
		Total for year of treatment	1.33	$213	2.67	$0	6.75	$203	11.08	$416

For the safety outcomes, a decision was made to discard issues of soft tissues management, skin at stoma interface and phantom pain as they have no established links with prosthetic components. Adverse events associated with fixation stability and integrity as well as injuries and infections were applicable since they might be inherent with the load generated by prosthetic components and, therefore, might have potential legal bearings. Another hurdle to overcome was the lack of validated instruments to report advert events and complications. Alternatively, a custom-made survey involving a short series of eight questions was collectively elaborated, pilot tested with selected consumers and implemented.

Limitations

The PSE form might be deemed onerous by some consumers because of redundancy of SF12 and PLUS-M with regular follow ups conducted by treating clinical teams. Purposely designed survey lacked typical statistical validation. Other limitations derived from typical intrinsic shortcomings of prospective study presenting the initial steps of action research cycle. Beyond the scope of this study, the lack of actual long-term consumer's experience data limited the validation of this proposed CQI procedure.

The generalization of the outcomes must be considered carefully. The proposed CQI was purposely designed to fulfil specific needs for an Australian State organisation providing funding for prosthetic care only. However, stakeholders and treatment pathways for provision of BAP could differ between jurisdictions, particularly in European and North American countries.[33] Indeed, the scalability of this CQI procedure within and between jurisdictions is yet to be established, particularly its capacity to integrate requests from broader stakeholders, the geographical spread of consumers extending to rural areas with limited access to a PSP, the increasing number of treatment sites in Australia and abroad as surgeries are more routinely performed. Nonetheless, a series of valuable insights provided could be readily integrated by other organisations while customizing their own BAP-inclusive CQI procedure, including the importance of understanding rehabilitation programs, identification and organisation of the stakeholders (e.g., local, regional, national), benefits and ways to adapt existing procedures (e.g., pathways, forms and CMS), methods to determine involvement of participants (e.g., consumers, PSPs, funder) as well as consideration for confounders of customer's experience with provision of BAP (e.g., clinical benefits and safety).

Future studies

Future developments of the proposed CQI procedure will be facilitated by additional

longitudinal studies providing experience outcomes for a large cohort of BAP users over an extended period of time that could be benchmarked against other BAP or SSP users.

Possibilities for additional cross-sectional studies are endless, particularly for the ones correlating experience with provision of BAP accordingly to technological platform supporting CQI procedure (e.g., online forms, cloud-based CMS), provision standards of components (e.g., microprocessor prosthetic knees) and clinical outcomes (e.g., Health-related quality of life, mobility, fixation stability and integrity, injuries, infections) with different type of fixations (e.g., screw-type, press-fit).[2, 50-54]

CONCLUSIONS

The early development of a CQI procedure, including the management of barriers and transferable facilitators, to appraise the provision of BAP by a governmental organization was shared for the first time. This work was an initial effort toward the assessment of fair and equitable governmental financial assistance programs for individuals choosing BAP. Altogether, this study should be considered as a stepping-stone providing a working approach for BAP-inclusive CQI to other organizations worldwide.

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DECLARATION OF CONFLICTING INTERESTS

The authors have no conflict of interest.

AUTHOR CONTRIBUTION

- **Laurent Frossard** has developed the study design including collection, analysis, presentation the data as well as writing this manuscript.
- **Luciann Ferrada** has contributed to the collection and analysis of the data as well as the writing of the manuscript.
- **Tanya Quincey** has contributed to the collection and analysis of the data as well as the writing of the manuscript.
- **Brendan Burkett** has contributed to the writing and reviewing of the manuscript.
- **Debra Berg** has lead the whole project including the study design, collection, analysis, presentation the data as well as writing this manuscript.

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SUPPLEMENTS

Development of a Government Continuous Quality Improvement Procedure for the Provision of Bone-Anchored Prosthesis Using Osseointegration Fixation

Figure 2. Stakeholder matrix included the groups of controllers, promoters, providers and advocates of the Continuous Quality Improvement (CQI) procedure depending on power (capacity to influence allocation of resources) and interest (capacity to provide prosthetic and medical care).

Power: Capacity to influence resources	Low / High	Controllers	Promoters

			• **State governmental funding agencies**:
			  ○ Consumer advisory group (CAG)
			  ○ QALS's Executive Committee
			  ○ Medical Aids Subsidy Scheme (MASS)
			  ○ Queensland Health
			• **National governmental funding agencies:**
			  ○ Department of Veteran Affairs (DVA)
			  ○ National Disability Insurance Scheme (NDIS)

		• **State consumer support group**:
		  ○ Amputees and Families Support Group QLD Inc
		• **National consumer support group**:
		  ○ Limb4life
		• **National professional associations**:
		  ○ Australian National Membership Society of the International Society of Prosthetic and Orthotics (ANMS-ISPO)
		  ○ Australian Orthotic and Prosthetic Association (AOPA)
		• **Artificial Limbs Services in other States:**
		  ○ Orthotics and Prosthetics South Australia (OPSA)
		  ○ EnableNSW
		  ○ Victorian Artificial Limb Program (VALP)
			• **State service providers:**
			  ○ Prosthetic Service Providers (PSP)
			  ○ Physiotherapists
			  ○ Occupation therapists
			  ○ General practitioners
			  ○ Clinical teams
			• **National service providers:**
			  ○ Prosthetic Service Providers (PSP)
			  ○ Surgeons

		Advocates	**Providers**
		Low	**High**
		Capacity of provide medical and prosthetic care Interest	

Figure 3. Overview of evaluation framework to extract clinical benefits (top) and harms (bottom) as presented in "Frossard L. Evaluation framework to assess benefits and harms of bone-anchored prosthesis. 6th International Conference Advances in Orthopaedic Osseointegration. 2015. Las Vegas, Nevada, USA. p 20" available from: https://eprints.qut.edu.au/82763/