



2018 ACCES23-CMBEC41

Joint Conference
Charlottetown PEI
May 5–8, 2018

IMPLEMENTATION OF A USEFUL LIFE REFERENCE FOR MEDICAL DEVICES IN CANADA

Paul Prowse, Sarah Kelso, Rebecca Austman
Winnipeg Regional Health Authority

INTRODUCTION

Having a reliable guideline of the length of time a medical device will provide value to the health system is useful for long term lifecycle management and replacement planning. There is no comprehensive Canadian reference for useful life of all types of medical devices. The purpose of this project was to develop a useful life reference document that could be used by Clinical Engineers across the Winnipeg health region to improve consistency in the values considered for equipment lifecycle planning, and lay the groundwork for the establishment of a national reference for useful life of medical equipment.

BACKGROUND

We recognize that medical devices will provide value to our health system for an undetermined, finite period of time, and that many factors interact in variable ways to determine when an individual medical device or fleet of devices needs to be removed from service. While this actual determination can be quite complicated, having a baseline estimate of useful life can be a helpful tool in device and fleet lifecycle planning and developing long-term equipment replacement budgets [1]. Useful life is the roughly estimated amount of time (in years) that a medical device can be expected to be used safely, effectively, and economically for its intended purpose.

There is presently no suitable source of useful life data for medical equipment within the Canadian context, with the exception of medical imaging. The Canadian Association of

Radiologists has prepared a lifecycle guidance report for medical imaging equipment in Canada with a key objective of helping organizations determine when to upgrade or replace existing devices [2].

There are other existing sources of useful life data, as listed in Table 1, but these generally do not present a realistic replacement schedule based on our general funding levels within the Canadian healthcare system. For the most part the available sources are U.S.-based and some are significantly outdated. Furthermore, the different sources have developed their useful life guidelines for different purposes; for example the AHA's estimates were developed mainly for accounting purposes, while ASHE's estimates are intended to support equipment replacement planning [3]. As such, varying estimates are sometimes presented for the same equipment type.

AHA's useful life values are determined by the consensus of representatives from appraisal companies and health care systems based on the "most prevalent condition of service" for each asset type [4].

The AHA document uses a unique naming convention, and was adapted by the South Australian Biomedical Engineering Advisory Group to produce a useful life reference that better reflects the South Australian experience, and uses the UMDNS nomenclature system [1].

Table 1 below summarizes the various references that are available to date for estimating useful life of medical equipment.

Table 1. Existing sources addressing the estimated useful life of medical devices

Title	Source	Nomenclature	Comments
Biomedical Benchmark [5]	ECRI, 2010	UMDNS	Considered in our system
Maintenance Expenditure Limits for Medical Materiel (TB MED 7) [6]	U.S. Army, 1992	Unique	Considered in our system
Estimated Useful Lives of Depreciable Hospital Assets [4]	AHA, 2008	Unique	
Life span of Biomedical Devices [1]	BEAG, 2004	UMDNS	Considered in our system Based on AHA document listed above, with some changes to better reflect South Australian experience
Life Expectancy Projection Benchmarks: a How-to guide for Medical Equipment Replacement Programs [7]	McClain for ASHE, 1995	Unique	Based on TBMED7 and manufacturer data; calculates total run time, number of exposures, etc. to determine useful life. Could be more accurate if we had a true measurement of equipment usage. Similar to CAR.
Lifecycle Guidance for Medical Imaging Equipment in Canada [2]	CAR, 2013	Unique	Considered in our system – addresses medical imaging equipment only

METHOD - DEVELOPMENT OF SUITABLE CANADIAN USEFUL LIFE

We consolidated the various useful life sources automatically by aligning the device terms wherever any of the terms in those systems matched the Global Medical Device Nomenclature (GMDN) (used in the Winnipeg Regional Health Authority (WRHA) Medical Equipment Database). For the remaining GMDN terms that did not align with any of the sources, we entered the data manually by matching the GMDN with the closest term from the alternative naming convention when possible.

We calculated the historical lifespan of inactive assets in our database averaged over each GMDN term. By comparing this average lifespan to the average lifespan for that term found in the literature (excluding CAR) we established a baseline ratio of device lifespan in our environment to what is recommended. The comparison included 148 terms and the relative lifespans ranged from 0.2 to 5.0 times the average reported lifespan in the literature. The average factor difference between our historical inventory and recommended lifespan was 1.7. In recognition of the fact that our historical equipment has been replaced beyond the optimal point in its replacement cycle, we chose to reduce this factor by approximately 10% of the equipment's total lifespan. Therefore, we selected 1.5 as the approximate ratio between

the literature's useful life (excluding CAR) and our experience as the standard to be applied across all device types. For device types covered by CAR, we chose to use the reported useful life for medium use assets on the basis that CAR is a Canadian reference and our experience should not be significantly different from the rest of the country.

For some device types, this method provided estimate useful lives as high as 20-30 years. Experientially, this may be accurate, but to ensure clinical relevance and a reasonable estimate for future planning purposes the maximum lifespan was restricted to 15 years [2].

Where the useful life reported in the literature differed between sources, the following priority of sources was established:

1. "Lifecycle Guidance for Medical Imaging Equipment in Canada" [2]
2. "Biomedical Benchmark" * 1.5 [5]
3. "Maintenance Expenditure Limits for Medical Materiel" (TB MED 7) * 1.5 [6]
4. "Life span of Biomedical Devices" * 1.5 [1]
5. Historical lifespan of inactive assets in that GMDN

All were limited to a maximum of 15 years.

We captured all the useful life data in a single spreadsheet which automatically

calculated the appropriate useful life based on the priority described above. This provided a standard useful life that could be consistently referenced by anyone across our health authority.

In instances where there was no literature reference for the GMDN of interest, there may be a UMDNS term or term from TB MED 7 that fits the GMDN from which the useful life would be appropriate. In these cases, we updated the useful life for that GMDN term manually on the master useful life reference document with a note referencing the source and surrogate term. This process facilitates the development of an increasingly complete estimate of useful lives for our health authority per GMDN.

DISCUSSION

Estimated useful life is a helpful planning tool, but certainly not a clear gauge of the number of years a medical device will actually provide value to the enterprise, or of pending replacement necessity. The amount of time for which a device is useful to the enterprise is largely based on wide variety of extrinsic factors such as: presence of and structure of maintenance program, availability of parts and technical support, use case, and changes in clinical requirements. In some cases the actual useful life span of a device may vary from the estimated useful life by a factor of two, three, or more [3].

“The fact that a piece of equipment is approaching or beyond its projected useful life expectancy is not a sufficient reason on its own to replace the item” [7]. The expiration of the useful life does not by any means imply that a device must or even should be replaced. This reference would be intended for a planning horizon of not shorter than 2-3 years, and particularly useful when developing long term plans for medical equipment replacement and overall lifecycle management.

In general, planning and funding allocation for equipment replacements should be approached 1-2 years in advance of the actual replacement, and at this time all other relevant factors should also be assessed, beyond just the reference useful life. The practical end of life of medical devices will be influenced by a

large number of complex and interrelated factors including repair cost, manufacturer support status, clinical functionality, unresolved alerts/recalls, and reliability.

There is limited information on how the different sources referenced above established their own useful life data (whether through expert review, from manufacturer recommendations, though financial analysis or some combination thereof). Furthermore, our own historical data does not necessarily reflect optimized replacement timing. While the records from our health authority span approximately 15 years, the number of devices taken out of service within certain device types may be relatively few. Therefore the accuracy of the factor difference between the literature and our experience may not reflect expected or appropriate factor difference. Averaging these factors over all device types helps to mediate these extreme cases.

NEXT STEPS

This useful life reference created is based entirely on the experience of our health authority. In order to better assess the true useful life for equipment in Canada, a larger sample of historical lifespans is necessary. The successful implementation of a repository for such information requires standardized device nomenclature and failure codes from any reporting facilities in order to be able to compile and analyze the data. It is proposed that a guidance document be created to outline these requirements and assist the participating sites with compliance.

CONCLUSION

In efforts to demonstrate serious underfunding of medical equipment, the application of useful life data across a complete equipment inventory will be useful to estimate the capital equipment funds required to maintain our existing inventory and determine the average investment required per funding cycle.

REFERENCES

- [1] Biomedical Engineering Advisory Group of the South Australian Government (BEAG), "Life span of biomedical devices guidance paper", 2004.
- [2] Canadian Association of Radiologists (CAR), "Lifecycle guidance for medical imaging equipment in Canada", 2013.
- [3] ECRI Institute, "Estimated life expectancy of medical devices", *Health Devices*, 29(9), p. 343, 2000;.
- [4] American Hospital Association, "Estimated useful lives of depreciable hospital assets", Health Forum, Inc. Chicago, IL, 2008.
- [5] ECRI, "Biomedical Benchmark" [Expected Life], 2010.
- [6] U. S. Army Medical Materiel Agency, "Maintenance Expenditure Limits for Medical Materiel (TB MED 7)", 1992.
- [7] J.P. McClain. "Life expectancy projection benchmarks: a how-to guide for medical equipment replacement programs", *ASHE Healthcare Facility Management Series*, 1995.