Rev Esp Cardiol. 2018;xx(x):xxx–xxx

Special article

Criteria for the Management of Technological Assets in Cardiovascular Imaging

Ignacio Fernández Lozano,[a,*] Eduardo Pozo Osinalde,[b] Ignacio García Bolao,[c] Soledad Ojeda Pineda,[d] Luis Rodríguez Padial,[e] and Andrés Íñiguez Romo[f]

[a] Servicio de Cardiología, Hospital Puerta de Hierro, Majadahonda, Madrid, Spain
[b] Unidad de Imagen Cardiovascular, Servicio de Cardiología, Hospital Clínico San Carlos, Centro Nacional de Investigaciones Cardiovasculares Carlos III (CNIC), Madrid, Spain
[c] Servicio de Cardiología, Clínica Universitaria de Navarra, Pamplona, Navarra, Spain
[d] Servicio de Cardiología, Hospital Universitario Reina Sofía, Córdoba, Spain
[e] Servicio de Cardiología, Hospital Virgen de la Salud, Toledo, Spain
[f] Servicio de Cardiología, Complejo Hospitalario de Vigo, Vigo, Pontevedra, Spain

Keywords:
Technology
Equipment
Renovation
Cardiac imaging

ABSTRACT

Adequate, updated and functional technology is essential in cardiology. In Spain, the economic scenario has strongly impacted technology renewal programs and obsolescence is a growing problem. The current report attempts to describe the current situation and the conditions that must concur to update, replace or adopt new technologies in the field of cardiology.

Criterios de gestión de activos tecnológicos de imagen cardiovascular

Palabras clave:
Tecnología
Equipamiento
Renovación
Imagen cardiaca

RESUMEN

En cardiología, es esencial disponer de tecnología adecuada, actualizada y en buenas condiciones de funcionamiento. En España, el marco económico ha impactado fuertemente en los programas de renovación de tecnología y la obsolescencia es un problema creciente. El actual informe trata de dar respuesta al momento y las condiciones que deben concurrir para plantear la actualización, el reemplazo o la adopción de nuevas tecnologías en el ámbito de la cardiología.

Abbreviations

CMR: cardiac magnetic resonance
COCIR: European Coordination Committee of the Radiological Electromedical and Healthcare IT Industry
CT: computed tomography
DICOM: Digital Imaging and Communications in Medicine
Fenin: Spanish Federation of Healthcare Technology Companies
IVUS: intravascular ultrasound

INTRODUCTION

Few specialties depend on technology for patient diagnosis and treatment as much as cardiology. Modern cardiology practice relies on the availability of the appropriate technology and its correct operation and functioning. The current economic situation has had a strong impact on technology renewal programs and obsolescence is a growing problem in the European health sector, as indicated by the latest reports available on this topic.[1,2]

The current report of the Executive Committee of the Spanish Society of Cardiology attempts to describe the current situation and the conditions that must align for technologies in the cardiology field to be updated, replaced, or adopted. The ultimate aim is to uphold quality of care, improve efficiency, maintain the safety of medical activity, and facilitate innovation in a setting of health system sustainability, based on evidence-based criteria that provide objective elements for decision-making.

FUNDAMENTALS

Prepared by the Spanish Agency of Medicines and Medical Devices (AEMPS), Circular No. 3/2012 makes recommendations on

* Corresponding author: Unidad de Arritmias, Hospital Puerta de Hierro, Manuel de Falla 1, 28222 Majadahonda, Madrid, Spain.
E-mail address: iflozano@secardiologia.es (I. Fernández Lozano).

https://doi.org/10.1016/j.rec.2018.02.023
1885-5857/

Please cite this article in press as: Fernández Lozano I, et al. Criteria for the Management of Technological Assets in Cardiovascular Imaging. *Rev Esp Cardiol.* 2018. https://doi.org/10.1016/j.rec.2018.02.023

technical assistance for medical devices in health centers[3] based on European legislation (Directives 90/385/CEE,[4] 93/42/CEE,[5] and 98/79/CE[6]). The memorandum establishes that "medical devices must not compromise the health or safety of patients, users, or third parties when properly installed and maintained and must be used according to their intended purpose" and that "the health authorities of the Member States must adopt the necessary measures and carry out the appropriate monitoring to ensure that these guidelines are effectively met for the products marketed, placed in service, installed, maintained, and used in their territories". As for equipment maintenance, the circular states that "the products must be correctly installed and properly maintained in such a way as to guarantee that, during their period of use, they maintain the safety and performance intended by their manufacturer".

In this regard, the Canadian Association of Radiologists has issued recommendations on the useful life of imaging equipment based on a comprehensive review of the available literature.[7] A clinical use exceeding 15 years is not generally recommended for any technology. The association also estimated equipment durability according to its degree of use, categorized as high (24 hours 5 d/wk or 750 8-hour shifts/y), medium (16 hours 5 d/wk or 500 8-hour shifts/y), and low (8 hours 5 d/wk or 250 8-hour shifts/y). Finally, the authors note that ultrasound equipment can experience an accelerated obsolescence because optimal technological upgrades are essential to maintain high diagnostic performance. The expert committee of the Spanish Society of Cardiology (SEC) has similarly established longevity recommendations for equipment used in cardiological diagnostic procedures based on their degree of use (Table 1).

On the other hand, the European Coordination Committee of the Radiological, Electromedical, and Healthcare IT Industry (COCIR), representing the medical technology industry in Europe, recommends adherence to its "Golden Rules"for the optimal functioning of medical equipment.[1] These rules advise the following:

- At least 60% of the installed equipment should be less than 5 years old: these systems adequately reflect the current state of the technology.
- No more than 30% of the installed equipment should be between 6 and 10 years old: although these systems are still suitable for their purpose, their replacement should be considered.
- No more than 10% of the installed equipment should be more than 10 years old: this medical technology is outdated and difficult to maintain and repair.

In addition, the committee makes some general recommendations:

- Replace obsolescent equipment that cannot be upgraded.
- Use new funding models with the support of the European Fund for Strategic Investments to convert investment in technological innovation in health into a strategy to increase the efficiency and accessibility of health systems and improve clinical outcomes.
- Adopt a patient-centered approach to reduce and optimize radiation doses.

The Spanish Society of Cardiology supports these recommendations and believes that their adoption would guarantee the correct functioning of the systems installed, their appropriate use, quality of care, treatment suitability, and patient safety.

CARDIAC IMAGING

Echocardiography

Importance and Current Technological Situation in Spain

Because echocardiography is an easily accessible, safe, and examiner-dependent imaging technique, innovations in both hardware and software are pivotal and the renewal recommendations are thus reduced to 5 to 7 years. This recommendation is vitally important in the case of echocardiography, whose widespread availability in recent years has made it an essential test for the management of cardiac patients, with a corresponding exponential increase in its indication.

Spain is far from meeting the Golden Rules standards regarding equipment renewal, and 1 out of every 3 ultrasound scanners is obsolete, with an age exceeding 10 years (Figure 1).[2]

The scant maintenance of ultrasound equipment is also troubling. More than two-thirds do not undergo preventive maintenance procedures guaranteeing their functioning and calibration and, therefore, image quality and accuracy.[2,8]

Technological Resource Recommendations

In 2011, the American Society of Echocardiography issued quality recommendations for echocardiography laboratories.[9] First, laboratories must be accredited by the Intersocietal Commission for the Accreditation of Echocardiography Laboratories. Echocardiography

Table 1
Expected Lifespan of Radiology Equipment According to Use

Equipment type	Life expectancy based on use* (y)			Use (exams/y)		
	High	Moderate	Low	High	Moderate	Low
Portable X-ray	11	13	15	> 6000	3000-6000	< 3000
X-ray fluoroscopy	9	11	13	> 4000	2000-4000	< 2000
Interventional integrated C-arm fluoroscopy	9	11	13	> 4000	2000-4000	< 2000
Mobile C-arm fluoroscopy	9	11	13	> 2000	1000-2000	< 1000
Interventional angiography	7	10	12	> 4000	2000-4000	< 2000
Catheterization laboratory	7	10	12	> 3000	1500-3000	< 1500
Electrophysiology laboratory	7	10	12	> 3000	1500-3000	< 1500
Cardiac CT	9	11	13	> 15 000	7500-15 000	< 7500
CMR	9	11	14	> 8000	4000-8000	< 4000
Echocardiography	9	10	12	> 4000	2000-4000	< 2000

CMR, cardiac magnetic resonance; CT, computed tomography.
* High use: 24 hours 5 d/wk or 750 8-hour shifts. Moderate use: 16 hours 5 d/wk or 500 8-hours shifts. Low use: 8 hours 5 d/wk or 250 8-hour shifts.

Please cite this article in press as: Fernández Lozano I, et al. Criteria for the Management of Technological Assets in Cardiovascular Imaging. *Rev Esp Cardiol.* 2018. https://doi.org/10.1016/j.rec.2018.02.023