Unbundling payments for radioisotopes from radiopharmaceuticals and from diagnostic procedures: A tool to support the implementation of full-cost recovery

NEA discussion document

This discussion paper was prepared by the NEA Secretariat of the High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR) in consultation with HLG-MR members and molybdenum-99/technetium-99m ($^{99}Mo/^{99m}Tc$) supply chain participants. It does not necessarily represent a consensus view of the HLG-MR but is presented to enable discussions and further analysis among the members of the HLG-MR, other stakeholders and decision-makers. The individuals and organisation that contributed to the document are not responsible for the opinions or judgements it contains.

Introduction

The objective of the NEA's HLG-MR policy approach is to ensure a long-term secure supply. The HLG-MR has determined that to attain that objective, a necessary (but not sufficient) requirement is that irradiation services in the $^{99}Mo/^{99m}Tc$ supply chain must be provided on a full-cost recovery (FCR) basis (OECD-NEA, 2011). The HLG-MR policy approach also recommended that supply chain participants should implement payment reforms that promote full-cost recovery within their reimbursement systems. Reforms might include separate radioisotope pricing or auditing, separate radioisotope payment, differential radioisotope payment for FCR, or other approaches to promote a complete transition to full-cost recovery.

Why FCR is necessary

The HLG-MR determined that FCR was a key action to ensure the long-term security of supply, in order to:

- Ensure sufficient funds for current irradiators whose governments have indicated that they will not continue subsidisation of ^{99}Mo production.
- Encourage new infrastructure investment (reactor and non-reactor) by making the provision of irradiation services economically sustainable.
  - Recognising not only that most of the current irradiators are old and potentially less reliable, but also that most will be stopping production within the next decade and thus replacement infrastructure is necessary.
- Fund the provision of outage reserve capacity, which is necessary to back-up irradiation services and ensure consistent provision of medical isotopes.
- Facilitate the development of non-HEU-based $^{99}Mo/^{99m}Tc$ production sources (e.g. by converting to using low enriched uranium (LEU) targets).

A more fulsome discussion of the need for and benefits of FCR can be found in previous NEA reports (OECD-NEA, 2011 and 2010).

Barriers to implementation

While the HLG-MR clearly sees the need for FCR, it also recognises that there are two important barriers to its implementation:

- Some irradiators are not implementing full-cost recovery given long-term contracts with processors and/or ongoing government support.
- Downstream participants (mid-chain and end users) are not accepting the price increases necessary for full-cost recovery, or they are selecting lower priced $^{99}Mo/^{99m}Tc$, which tends come from subsidised sources, rather than supporting higher cost $^{99}Mo/^{99m}Tc$ from full-cost recovery sources.

Reasons for the second barrier

The underlying reasons for the first barrier do not require further explanation within this document. More discussion is presented in previous NEA reports (OECD-NEA, 2011 and 2010). However, the issues regarding the second barrier are more nuanced and therefore merit further discussion in this document.

The NEA economic study (OECD-NEA, 2010) demonstrated that moving to full-cost recovery for irradiation services would have a very small impact on the costs of the patient procedure because the ^{99m}Tc is a very small component of the total procedure costs. However, the study also pointed out that upstream supply chain costs would increase substantially:

- From the radiopharmacy, radiopharmaceutical cost of ^{99m}Tc will increase by 10% to 28.5%.
- From the generator manufacturer, cost increases of generators of 52% to 144%.

This means that, while an increase of EUR 1 may seem insignificant when compared to an imaging procedure that is reimbursed at a rate of EUR 245, it is an important amount when compared to the cost of the ^{99m}Tc used in that procedure, at a value of EUR 11. Therefore, the payment by the end-payer of the small increase is necessary to allow FCR to occur.

However, in many cases final users are not willing to accept price increases. This may be because they do not fully understand the value of the underlying isotope and the benefits it brings to patient care. The HLG-MR policy report noted that increasing understanding of the value of the isotope may help support the acceptance of the price increases that are necessary for ensuring long-term supply security.

A further complication is that reimbursement rates for procedures include many other costs other than just the isotope (e.g. costs of doctors, operations, nurses, consumables, SPECT camera, the cold kit, etc.). As a result, even where hospitals or practitioners understand the value of the isotope, they may not agree to absorb price increases (even minor ones) given other price pressures they are facing, such as cuts to broader reimbursement rates.

In addition, the practitioner may not even be aware of the cost increases for the isotope if those costs are buried in the overall costs of the broader radiopharmaceutical or diagnostic procedure. In such a case, the practitioner may value the isotope and be willing to pay an additional amount to support long-term supply security, but end up fighting against higher prices for the bundled radiopharmaceutical as they are not aware that the increases are related to the isotope.

It also must be pointed out that the NEA economic study was done using a weighted global average cost for nuclear diagnostic scans. It is clear (and noted in the study) that some scans cost more than others and therefore the impact could be a much larger share of the procedure costs for some scans, greatly increasing the difficulty for hospitals to absorb the expected cost changes.

A further point is that the percentages and values expressed in the NEA economic study only account for the move to full-cost recovery isolated from the need to pay for outage reserve capacity and from the cost impacts of LEU conversion. While the NEA recognises that the move to full-cost recovery should outweigh the other two impacts, they will still be important and further strain the supply chain's ability to pay. The additional cost increases to account for these other factors may further build resistance to accepting price increases as the end payer will only see the increase of the bundled radiopharmaceutical but not the underlying reasons for the price increases.

Role of unbundling for addressing the second barrier

One suggested tool for reforming the reimbursement system to facilitate the move to FCR is to unbundle payments for the imaging diagnostic procedure. This reform would separate the payments for the radioisotope from the radiopharmaceutical and from the diagnostic procedure. Unbundling would not directly address the first barrier to implementation, as this requires governments to stop subsidising the provision of irradiation services for ^{99}Mo production. Other actions are being taken to address that issue.

Unbundling reimbursements for the isotope, from the radiopharmaceutical and from the diagnostic procedure could increase transparency in individual jurisdictions on the cost of the isotope and cost increases as they arise. For example, when costs rise because of the move to full-cost recovery for irradiation services, paying for outage reserve capacity and transitioning to using LEU targets, health care system could request that the price increases are defended. This would create greater understanding on the essential nature of the cost increases.

In addition, such unbundling would make transparent when cost issues are not related to the isotope, but to cost increases for cold kits or procedures.

Unbundling is also a tool to facilitate the provision of the data necessary to allow health care systems to assess whether the reimbursements or payments are sufficient to ensure full-cost recovery for the isotope production. This assessment is an important action to encourage the long-term supply security of the medical isotope.

The provision of this data would also clearly demonstrate the costs of the ^{99m}Tc – an essential component of the imaging diagnostic procedure – and provide greater clarity to hospitals and radiopharmacies on where savings can be found (e.g. not from aggressive negotiations on price of the isotope but from more efficient use). A clearer understanding of the actual cost of the required isotope would encourage greater efficiencies in the use of ^{99m}Tc (such as through better elution patterns, reducing doses, using only stress tests when rest tests are unnecessary), supporting the ALARA[1] principle on radiation exposure and possibly lowering medical insurance costs because of less waste.

Possibly most important, the greater clarity and transparency on the ^{99m}Tc as a separate product with its own cost would create the opportunity for a mentality shift of radiopharmacies, hospitals and medical practitioners by increasing their awareness of the value of the isotope.

Separate reimbursement rates may also help focus attention on issues not directly related to the implementation of full-cost recovery but equally important for overall long-term security of supply. These issues relate to the necessity of nuclear safety and security, facilitating innovation in diagnostics, creating a smooth transition to FCR and supporting non-proliferation goals.

1. As low as reasonable achievable.

Unbundling, by providing transparency on the cost of the isotope, would allow for the identification of the costs related to nuclear security and safety in the development of the isotope. Full-cost recovery prices of ^{99m}Tc must include the $^{99}Mo/^{99m}Tc$-related cost at the reactors, processors, generator manufacturers and radiopharmacies for:

- nuclear safety;
- nuclear security (protection, including supporting non-proliferation);
- nuclear waste disposal;
- decommissioning and dismantling of nuclear facilities; and
- ensuring good manufacturing practices (GMP).

These are core costs that cannot be compromised. While there are regulations to ensure that these requirements are met, too much downward price pressure from downstream payers could, potentially, cause some suppliers to try to save costs on one or more of these aspects, potentially compromising nuclear safety and security.

Bundled reimbursements may hide the costs of the underlying components that make up the diagnostic procedure. Unbundling would separate the costs of those components and allow a more transparent comparison of ^{99m}Tc from traditional sources, from non-traditional sources and alternative isotopes, facilitating innovation in diagnostic exams by isolating the cost of the isotope from the other components. For example, separate reimbursement would allow for the clear comparison of ^{99m}Tc produced from cyclotrons compared to traditional production in a research reactor.

Unbundling could also facilitate a smoother transition to FCR and provide some price stability for end payers by allowing for the development of a transparent schedule of price changes from irradiators down the supply chain. This could help with the acceptance of the price increases associated with moving to full-cost recovery, and increase understanding within the supply chain on why costs need to rise.

In relation to the non-proliferation goal of minimising highly enriched uranium use for civilian purposes, if unbundling can be used to facilitate the move to full-cost recovery, it will make the transition to using LEU targets or alternative non-HEU-based technologies for ^{99}Mo production more economically viable. The situation is not LEU-based vs HEU-based, but LEU-based vs subsidised HEU-based. The transition to non-HEU sources is essential for security of supply as the supply of HEU for medical isotope production will be limited in the future (OECD-NEA, 2012).

Finally, an unbundled rate is one way of implementing price differentials for LEU-based and HEU-based ^{99m}Tc, recognising the differences in costs (OECD-NEA, 2012). Transparent prices and separate reimbursement may give clarity on the differences between fully-cost recovery LEU- and HEU-based ^{99m}Tc, and subsidised HEU-based ^{99m}Tc. This transparency would facilitate the implementation of differential pricing for HEU and LEU-based ^{99m}Tc.

Conclusions

This paper is written to provide a basis for further discussion on the use of separate reimbursement to encourage the move to full-cost recovery. Separate reimbursement is one tool that could be used by public and private health insurance to support the move to ensuring sufficient reimbursement rates (or payments) for $^{99}Mo/^{99m}Tc$ while the industry moves to full-cost recovery for irradiation services, paying for outage reserve capacity and transitioning to using LEU targets. Other tools are available (such as differential payments, separate radioisotope payments, auditing) that could lead to similar outcomes that support the changes necessary in the $^{99}Mo/^{99m}Tc$ supply chain to ensure a long-term reliable supply of these important medical isotopes.

References

OECD-NEA (2012), *The Supply of Medical Radioisotopes: Market Impacts of Converting to Low-Enriched Uranium Targets for Medical Isotope Production,* OECD, Paris, France (forthcoming).

OECD-NEA (2011), *The Supply of Medical Radioisotopes: the Path to Reliability,* OECD, Paris, France, ISBN 978-92-64-99164-4.

OECD-NEA (2010), *The Supply of Medical Radioisotopes: An Economic Study of the Molybdenun-99 Supply Chain,* OECD, Paris, France, ISBN 978-92-64-99149-1.