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Nuclear Medicine Technologies for Global Health

Proposals for Strengthening Nuclear Medicine Globally Whilst Minimising Proliferation Risks

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Introduction

1. On November 16th 2022, BASIC, the University of Bristol, Imperial College London, The Open University and Rolls-Royce jointly convened a multistakeholder roundtable at the Royal Society in London. After the policy case explored in the first roundtable in 2021, the purpose of the 2022 roundtable was to identify whether there were technologies that might conceivably meet the policy case.

2. This roundtable took place a year after the first, titled, 'Ultra-Proliferation-Resistant Medical Isotope Reactors for the Global South', which explored the policy cases for the PREMIER proposal, presented by Professor Nuttall. He introduced the idea of a theoretical small-scale medical isotope reactor that might be designed and built in the United Kingdom and a partner country for export to states in need of a resilient supply of short-lived medical isotopes to serve the growing health needs of their populations.[1]

3. The objectives of this latest roundtable were to address the concerns raised during the first roundtable, discuss the technological criteria required for such a technology to be exported without

[1] For more information regarding PREMIER, and the discussion of the first roundtable, you can read the report here: https://basicint.org/report-the-case-for-a-proliferation-resistant-medical-isotope-reactor/ (accessed 3. April 2023)

proliferation risks, and the alternative models of supply to address limitations to the current system of supply.

4. The meeting was attended by a combination of policy and technical experts from the British government, civil society, academia, the private sector, nuclear science and technology, non-proliferation and the wider nuclear policy community. The meeting was held under the Chatham House Rule.

The Rationale: Global Public Health Challenges

5. In 2019, the OECD/NEA published a major report entitled 'The Supply of Medical Isotopes', which noted that the period 2012-2019 saw roughly constant global demand for technetium-99m (Tc-99m), as used in roughly 85% of all nuclear medical procedures.[2] That demand, however, is dominated by a 'small number of populous countries and countries with high scan rates'.[3]

6. Looking to the future, millions more patients worldwide can be expected to benefit from diagnostic and therapeutic services made possible by medical isotopes. The roundtable noted that as medical science advances, countries develop, populations grow, and life-expectancy rises, demand for medical isotopes can be expected to increase over the next decades, especially in emerging economies.

7. One issue for the meeting was an assessment of future diagnostic procedures in the countries of the Global South: to what extent can reactor produced Tc-99m be expected to be the dominant requirement in the long term? Such considerations would need to be explored with end-users, perhaps as part of a future 2023/24 workshop.

8. Currently, the global supply of Tc-99m is supplied by an ageing nuclear infrastructure, heavily centralised in a few reactors, mostly in Europe, with the Netherlands being the biggest producer of its precursor isotope, molybdenum-99 (Mo-99).[4] Lighter medical isotopes, such as fluorine-18 used in an advanced diagnostic technique Positron Emission Tomography, are more usually made in particle accelerators, such as cyclotrons.

9. Some medical isotopes have a short half-life to the point that supply chains need to be fast moving and reliable. The most important isotope in current use is Tc-99m, which is derived from Mo-99 which has a half-life of sixty-six hours. This sixty-six-hour window already poses a serious logistical problem for people in countries that cannot produce their own indigenous isotopes, and must rely on an uninterrupted supply from suppliers' countries, a problem heightened when the suppliers are not in their region.

10. The current system is not resistant to shocks and already showing its limits, as seen during the COVID-19 pandemic, or when the United Kingdom left the European Union – and is not viable in the long term with an expected increasing demand. Meeting such needs is therefore important and urgent.

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[2] OECD/NEA (2019), The Supply of Medical Isotopes: An Economic Diagnosis and Possible Solutions, OECD Publishing, Paris, https://doi.org/10.1787/9b326195-en (accessed 10. April 2023)

[3] OECD/NEA (2019), The Supply of Medical Isotopes, p. 43

[4] Radioisotopes in Medicine, World Nuclear Association. Available at: https://world-nuclear.org/information-library/non-power-nuclear-applications/radioisotopes-research/radioisotopes-in-medicine.aspx (accessed 13. April 2023)

11. Thus, any alternative to such a system, should seek to minimise infrastructure requirements, and be resilient to shock – wherever they might come from. Whilst meeting such needs, however, the technology will need to safeguard against proliferation risks that arise whenever nuclear technologies — even those that have an ostensibly peaceful purpose — are exported.

Strengthening the Non-Proliferation Regime and Nuclear Security

12. First, participants discussed generic considerations applying to – in principle – any potential technologies, notably with regards to transport, safeguards, and environmental concerns.

13. Any reactor (or alternative production system) should be safe to transport in all scenarios conforming to international law concerning the transport of controlled materials, and the systems materials (e.g., coolant, fissile material) must be environmentally safe and sealed, and shielded from misuse at all times.

14. The propositions should seek to support the research, production, and use of nuclear energy for peaceful purposes (consistent with Article IV of the NPT), as well as strengthen the wider non-proliferation regime. This would provide host countries with renewed impetus to remain within the Treaty on the Non-Proliferation of Nuclear Weapons (NPT) and the International Atomic Energy Agency (IAEA). It is by expanding access to peaceful technologies that the non-proliferation environment is strengthened. People trained in nuclear technologies and a strengthening of regulatory capacity can reinforce that pillar of the NPT's 'Grand Bargain'; i.e., that Non-Nuclear Weapon States will not acquire nuclear weapons, that Nuclear Weapons States will pursue disarmament and that all states can access nuclear technology for peaceful purposes, under safeguards.[5]

15. The 2021 meeting had reaffirmed the necessity and importance of nuclear safeguards. Nothing in the proposals discussed seeks to diminish or alter the safeguards regime. The proposals under consideration are to explore the possibility of technologies that would not lead to nuclear proliferation, even if the host country were to effectively remove itself from the NPT regime for any given reason (treaty withdrawal, state failure, etc). In such a scenario, the workshop asked whether there were technologies that can, by design, significantly reduce proliferation risks compared to more conventional technological options.

Generic Technological Criteria

16. To that end, technical criteria that might be identified for a generic nuclear medicine facility were discussed – such that it might exhibit the medical utility and the strong proliferation resistance credentials identified in 2021. The design considerations at this stage were generic and did not relate to one particular technology type, but rather criteria and constraints required for a nuclear medicine institute in the Global South to meet local, and perhaps regional needs.

[5] NTI, Treaty on the Non-Proliferation of Nuclear Weapons (NPT) https://www.nti.org/education-center/treaties-and-regimes/treaty-on-the-non-proliferation-of-nuclear-weapons/ (accessed 3. April 2023)

17. It was discussed that in order to militate against actions that might be taken subsequent to a national withdrawal from safeguards and IAEA oversight, the technology should be such that there would be no credible prospect for the host country to develop indigenous isotope production modules to fit the medical isotope institute's wider permanent infrastructure.

18. During discussion, it was suggested that a kill-switch might be operated remotely by, for example the UK or the IAEA. This could be operated if the country withdrew from safeguards or tampered with the reactors in any way that would prompt serious international concern.

19. In 2021, it had been noted that the production capability should be fragile and fail-safe. Indeed, modules might be deactivated for transport via gentle destruction consistent with a user agreement. As such the notion of 'killing' the technology safely had been discussed in 2021, but then the idea had been that this capability should be reserved for the local operators – rather than remote.

20. The idea of an international kill-switch was countered, with participants noting that remote-shutdown would be too invasive and difficult to implement robustly. Furthermore, such a remote-shutdown undermines the soft 'selling point' of the idea itself, which stresses sovereignty and security of supply.

Different Isotope Production Models and Concepts of Supply

21. In the following part, two models for production of medical isotopes are presented in depth: a fission-based model PREMIER, and a fusion-based model Micro-NOVA. Finally, the general concept of accelerator-derived isotopes was discussed.

PREMIER

22. Professor William Nuttall from The Open University and Dr Mike Bluck from Imperial College London presented a fission reactor concept known as PREMIER that they suggested might be able to meet most – if not all – of the goals identified in 2021. PREMIER is a theoretical small-scale medical isotope reactor that would be designed and built in the United Kingdom – possibly with a partner country – for export to states in need of a more resilient supply of medical isotopes.

23. Fundamentally, the PREMIER concept is intended to meet anticipated future demand from the Global South for fission-derived and neutron-capture-derived medical isotopes. The main focus would be the production of Mo-99 (for Tc-99m) as used in the vast majority of nuclear medical procedures in the OECD countries today. PREMIER is aligned with a future based on market growth building upon current clinical practice.

24. Isotopes might be produced regionally for rapid distribution to a range of countries (as it occurs today for the Global North countries), or nationally at an institute in the capital city to which patients must travel, or within an existing hospital setting. PREMIER is primarily proposed to meet the needs of the second of these three scenarios. The scale of production is less than required for regional or continental supply, and patients would be expected to arrive for their procedures consistent with an established calendar for PREMIER operations.

25. The PREMIER concept is an industrial system. The modules would be relatively small and designed to fit a standard structure at each host's medical institute building, which would also be supplied by the

UK or its technological-development partner country (see 2021 meeting report).[6] The reactor, in use, should be near impossible to uprate, refuel or tamper with. It would be extremely fragile, including a fail-safe mechanism for safe destruction initiated locally. The reactor module should be impossible to replace with something locally-improvised, and should be of short, limited life (e.g.: five years). Such a short lifespan would help prevent ill-intentioned actors from producing fissile material.

26. PREMIER would be a small isotope production reactor and it would be licensable as an example of a research reactor. It is envisaged that flux in the irradiation zone in a PREMIER reactor would compare with that found in today's larger research and isotope production reactors. PREMIER development, deployment, and support is to be established as an international endeavour and there would be international support to policy development, regulatory provisions, and regulatory action. It is expected that the IAEA and other trusted partners would be involved.

27. The fuel type would be Low-Enriched Uranium (LEU). It was argued that the presence of significant amounts of Highly-Enriched Uranium, albeit even if in a difficult chemical form, could provide a possible incentive for an unconstrained state motivated by a goal of nuclear weapons development to take the reactor apart following an exit from the NPT regime.

28. Professor Nuttall and Dr Bluck suggested that there are three main areas of proliferation concern associated with a fission-based solution. These are: i) repurposing of the reactor core material, or fuel elements for direct use in a weapon; ii) misuse of 'targets' and associated capabilities intended for use in fission product isotope production, and iii) misuse of the irradiation zone in the reactor. While all three concerns are real, and require care to ensure that the goals identified in 2021 are met, it is the third requirement that has received the most care and attention in the last year.

29. As regards the decisions around fuels and targets, the PREMIER concept builds upon established norms and best practice. In particular it aligns with the goals of the US-led Reduced Enrichment for Research and Test Reactors programme (RERTR).[7] As the name suggests, RERTR has rightly been focussed on uranium enrichment levels. The PREMIER concept also seeks to develop barriers to diversion grounded in materials science and reactor core design.

30. The reactor would be shipped – enclosed and with the fuel – to willing countries, which does raise the question of the transport and the risk associated with it. The weight of the reactors was also raised, as it could be extremely heavy and thus hard to ship. Furthermore, the cost of shipping would likely be extremely high as only a few shipping lines are willing to ship radioactive materials.[8] This could create a resiliency issue, as PREMIER would be dependent on a few shipping lines and therefore point of failure, which could decide to stop such an activity or could be halted by an external global crisis (such as a pandemic).

31. The international shipment of entire nuclear reactor cores for civil purposes is unusual but not entirely without precedent. There are related histories concerning nuclear powered conventional ships (e.g., cargo ships and ice-breakers) and developments led by Russia for movable barges carrying reactors

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[7] Reduced Enrichment for Research and Test Reactors (RERTR) Program. https://www.rertr.anl.gov/ (accessed 20. April 2023)

[8] Stefan Hoeft, Maritime Shipments of Radioactive Material. Available at: https://gnssn.iaea.org/main/Med-Net/ARTEMIS%20Core%20Documents%20%20Public/Information%20on%20Maritime%20Shipments/361_Paper_MARITIME%20SHIPMENTS%20OF%20RADIOACTIVE%20MATERIAL.pdf (accessed 13. May 2023)

for electricity generation and district heating (e.g., the *Akademik Lomonosov*). Similarly, in 1955, the US developed the Geneva Reactor at Oak Ridge National Laboratory and transported it to Switzerland for operation and display at the First International Conference on the Peaceful Uses of Atomic Energy.[9]

32. A PREMIER fission module (reactor core) would be owned by the recipient country. There would be an opportunity for that country to return the module for disposal in the UK, or in a partner country, at the end of its life if the host country so wished. Typically, the host country would return a spent module to the UK – which would either recycle it or dispose of it – and would then issue a new one on safe receipt of the previous module if the user so requested. It was argued that this model, however, might create a medical dependency over time from host countries. It was also described as a 'subscription' model, although no formal contractual obligation to continue would exist.

33. Well-established diagnostic isotopes, such as Tc-99m, might be made available on a regular schedule once a week, which according to Professor Nuttall could amply meet the medical needs of the medical institute. This is a demand issue that would need to be explored in a user-oriented discussion meeting in future workshops.

34. It was suggested where there is high demand, the lack of on-demand and storable medical isotopes would probably be problematic. Professor Nuttall countered that neither diagnosis nor therapy were such, that the patient could not reasonably wait a few days: he stressed that the issue of importance is clinical access, rather than daily access. Furthermore, once a production facility is available, it is relatively easy to increase throughput as the quantities of material destined for an individual patient are tiny. Hence, patients might reasonably come to the medical institute for their treatment on clinical days that occur once per week. As such the issue of high demand would become the need to handle a large number of patients all at once. This is another matter to consider in a future meeting with end-user experts in attendance.

35. Professor Nuttall and Dr Bluck reported that, over the past year, one design challenge had become the main focus of their concern, and that they believe that they have found a possible solution. Arguably any fission reactor capable of producing medical isotopes is also capable of converting fertile actinides into weapons-usable fissile material. The neutron fluxes necessary for medical isotope manufacture are sufficient to be a cause for concern in non-proliferation terms. Furthermore, fissile material is long-lived (Pu-239 has a half-life of 24,000 years) whereas today's diagnostic medical isotopes have a half-life measured in days and hours. As such fissile material is accumulating in a reactor whereas medical isotopes are short-lived. While that last aspect might appear problematic, it holds within it the path to progress for the PREMIER concept.

36. Nuttall and Bluck posited that the production of significant quantities of fissile material (kilograms) might be expected to take a long time especially with a reactor with a very small flux zone. Such a reactor would be optimised to produce very small amounts (grams) of medical isotopes very quickly. They suggested that the medical and non-proliferation goals of PREMIER could be met if, for reactor physics reasons, the reactor could only run on a low duty cycle — say for one day a week at full power. That would allow for timely medical isotope production, but would effectively block the ability to accumulate worrying quantities of fissile material, noting that the reactor core itself would have a limited (5-year) life.

[9] ORNL Review, 75 years of science and technology, A Swimming Pool Reactor in Geneva. Available at: https://www.ornl.gov/blog/ornl-review/swimming-pool-reactor-geneva (accessed 20. April 2023)

37. Dr Bluck presented an outline concept of such a reactor developed using relatively-standard light water reactor nuclear engineering. A key concern of the team is to note that a high flux zone is required both for benign medical isotope production and also for nefarious fissile material production. Furthermore, as noted earlier, fissile material has a long half-life and hence accumulates in a reactor neutron flux. Medical isotopes however are short-lived and need to be prepared relatively quickly. The PREMIER concept relies upon a physically small irradiation zone coupled with very-time limited operations. Key to the concept is that the reactor cannot operate continuously, by design. Dr Bluck added that a boiling water high flux reactor with a small irradiation zone could be designed to only operate at full power for one day per week.

38. Professor Nuttall referred to the existence of more radical conceptual idea developed by the PREMIER team, but the common philosophical thread is that the reactor must be incapable of running continuously at full power, or near full power while also going beyond non-proliferation best practice in terms of core design, fuel, and isotope production targets. The wider policy challenges that PREMIER must meet are as described at the 2021 roundtable.

Micro-NOVA

39. Professor Tom Scott and Dr Tom Wallace-Smith from Bristol University introduced an alternative to the current model for production of medical isotopes in the Micro-NOVA concept, which would produce medical isotopes through a fusion reaction. Micro-NOVA would be a compact neutron source that would enable cheap, safe, and reliable production of high-energy neutrons at a high flux. Micro-NOVA should not be confused with magnetic confinement fusion (e.g., tokamak fusion), or with inertial confinement fusion (e.g., laser fusion); rather it has closer links to electro-static confinement fusion and ‘fusors’.

40. Micro-NOVA would be fairly easy to ship, as it does not weigh as much as a fission core would. Furthermore, it could be configured in different ways to produce different isotopes. Micro-NOVA could run fusion with three different fuel types: i) Deuterium/Tritium (DT) which would produce 14.1 MeV neutrons; ii) DD fusion cycle, which would produce 2.45 MeV neutrons; iii) and Helium-3/Deuterium cycle which would produce protons.

41. The two former fuel types would produce fast neutrons compared to fission, and hence would have a potential for proliferation issues. However, the Bristol researchers suggested that these systems could be throttled on particle production to reduce any proliferation concerns. Others wondered how robust such measures might be to deliberate circumvention by a malevolent user, freed from IAEA oversight following NPT withdrawal, etc.

42. It was suggested that the third fuel type, producing protons, would be an effective way to produce light isotopes like fluorine-18 or carbon-11. Through a material upgrade produced in the Micro-NOVA system, the fluxes and directionality of the protons can be controlled. The clear alternative route to such isotopes would be accelerator-based (e.g., cyclotron) technology. Such technologies, while mature, are likely to be far more complex and costly. Cyclotrons were considered explicitly later in the Roundtable.

43. Whilst PREMIER seeks to reduce proliferation risk by providing space and time restricted neutron flux (restricted to one day per week and five years operation), the full non-proliferation implications of a Micro-NOVA based neutron source remain to be assessed. Micro-NOVA might allow countries to possess more fully indigenous capabilities than the PREMIER alternative, but the relevant technical assessments have not yet been done.

44. Micro-NOVA would not require a heavily-centralised production of medical isotopes. For example, it would not require a special medical institute in the capital city of the host country, but rather it could be deployed in every hospital, as it would be cheap enough to manufacture and to ship. Thus, the Micro-NOVA model might avoid a dependency on shipping lines for new module delivery, or on direct isotope supply from any specific Western country. However, it will be important that Micro-NOVA is designed such that it cannot be repurposed in terms of fuels or capabilities into a form that would represent a proliferation or security threat. For example, a variant of the concept designed to operate without tritium should be such that it could not be converted to utilise, or produce, tritium. If there are possible proliferation risks associated with the Micro-Nova concept then the generic policy concerns explored at the 2021 Roundtable and in the early phase of the 2022 Roundtable must be remembered.

45. Finally, as it could be used continuously, it was raised that such a model could relatively easily win the hearts and minds of host countries, but great care would need to be taken that the technology would not in any way risk a worsening of the global non-proliferation regime including in scenarios of wilful state-initiated NPT or IAEA withdrawal, as thus far no consideration has been given as to how continuous operations could be blocked, or whether such measures might be necessary.

Accelerators

46. The 2022 Roundtable was convened to explore any technologies that might meet the 2021 Roundtable goals. As the fission concept was developed in response to such goals, the alignment was straightforward. Micro-NOVA was presented as a technology that might be able to play a useful role, but for which further non-proliferation risk assessment is required and, of course, the established commercial techniques of accelerator-based medical isotope production also needed to be considered. At this stage in the meeting the prospects for accelerator-based technology and the possibility of a UK non-proliferation gift related to medical peaceful uses was discussed.

47. Dr Hywel Owen of UKRI STFC Daresbury Laboratory discussed accelerator-derived medical isotopes (such as F-18). The main accelerator type proposed for commercial isotope production is the cyclotron. Whilst there are some developments to make these more compact, there is no particular UK industry connection to the major cyclotron manufacturers such as IBA (Belgium) or ACSI (Canada). There are a number of technology developments in cyclotrons that could either cut costs (smaller cyclotrons), increase production capacity (higher current or more target stations), or increase capability (accessing higher output energy above 30 MeV). There are a number of ways UK researchers and UK industry could partner in these areas and targeted development funds could perhaps build relevant capacity for a credible and substantial UK offer. It was suggested that a public-private collaboration with a non-UK based company, however, could be a good way to move away from the risk of a perceived colonial framing of a British solution to problems affecting the Global South. It was further noted that both PREMIER and Micro-NOVA would rely on a global partnership model.

48. Great strides have been made in adopting superconducting technology in medical cyclotrons for radiotherapy. Indeed, most new radiotherapy cyclotrons now use superconducting coils, and the reliability demands of radiotherapy are higher than for isotope production. Hence, superconducting cyclotrons are most certainly reliable enough for use in isotope production. For Mo-99 production, a number of cyclotron methods have been pursued, and the TRIUMF laboratory in Canada has spun out a company, ARTMS, whose product may be licensed. Whether such an innovation favours, or disfavours, the opportunity for a UK non-proliferation gift related to such innovation remains to be seen.

49. Regular power supply is required for accelerators, estimated at 10s of kWs. It was, however, raised that many countries do not have access to constant and uninterrupted supply of electricity. Nevertheless, it was suggested that modern batteries and other storage technologies like hydrogen could offset problems around continuous power supply.

50. Furthermore, it is essential that there is direct engagement in the host country between the technology developers and technology implementers, to ensure that the accelerators could be effectively used.

51. If the UK were to partner in the development of a new cyclotron-based offering, as with Micro-NOVA the proposition would need care to ensure that it is not in any way increasing non-proliferation risk even in states that might wilfully exit the NPT regime. Initial considerations would imply that such a test is not onerous as cyclotrons are generally regarded as a low-risk technology, but such matters nevertheless deserve some care and thought, if for example neutron-producing cyclotron systems become available.

Conclusion

52. The three models described above might actually be more complementary to each other than first expected. It was noted that, if technologies are compliant with the goals outlined at the 2021 Roundtable, then host countries might first start with a relatively small, accessible, and inexpensive technology (Micro-NOVA), before moving to more complex systems such as accelerators, and finally PREMIER. Such a sequence however might be challenged. For example, the host country might develop credible arguments concerning the need for certain heavier medical isotopes and hence express a need for neutron-based isotope production.

53. It was noted that, arguably, the NPT provides a right for a host country to insist on a fission reactor solution, even if offerings based on cyclotrons or a fusion-based source seem better to international eyes who take a highly-cautious approach to any nuclear technology proliferation. To respect the NPT treaty, and to respect potential host countries' decision making, there needs to be a fission-based offer on the table for as long as such a technological approach has any credible merit.

54. The issue of concern is that the prospective host country might procure a more traditional, and hence more problematic, design than the PREMIER concept – if the PREMIER concept were not available or affordable. Of course, if offered as a UK gift then notions of host country cost become irrelevant. Short of a gift, then subsidy will be essential – the UK should seek to offer its new technology at prices far below the global price of a traditional isotope reactor.

55. Considerations of locality need to be led on a country-basis, as the Global South is not a grouping of homogenous countries with similar needs throughout. The full range of diverse perspectives and concerns needs to be heard before decisions are made. Policy should progress on the basis of volunteerism, optimism, and enthusiasm.

56. Whilst technologies are important, they should follow policy needs and not the other way around. Hence next meeting should seek to engage with medical professionals and end-users to better assess their needs, as well as officials from possible end-user states to understand their assessments of the opportunities and limitations of the technologies.

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