



INTERNATIONAL WORKSHOP ON MEDICAL RADIOISOTOPES SUPPLY

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I-131 Supply : Myth, Reality... and Dreams in 5 Questions

1- Is I-131 a « important » isotope ?

YES...

- ⚗ 1st patient treated March 1941 (mixture of I-130 and I-131 produced by cyclotron)
- ⚗ No other radionuclide achieved (yet...) same success and acceptance that « RAI » had for treatment of thyroid diseases
- ⚗ Best example of Theranostics !
- ⚗ Not substituable in its current indication in most of the case

...BUT

- ⚗ Long consider a « by-product » or a « waste »
- ⚗ Never priced at its real value: the cheapest and among the most efficient anti-cancer drug :
 - Cost range of a RAI therapy in the US : 3600\$ (review 2022, NIH), likely half of that in Europe
 - 97% of people diagnosed with thyroid cancer and treated will live at least 5 years.
- ⚗ A comparative point of most recent cancer drug: KEYTRUDA (pembrolizumab)
 - 21G\$ sales in 2022:
 - for its main indications, the average survival is 1.6 years... MSD report average cost of 150,000\$/year
- ⚗ The current economical model is hardly sustainable



2- Is Global demand of I-131 growing ?

YES ... but

- ⚗ Although incidence of thyroid cancer (all types) is indeed growing...
- ⚗ ...there is an « overdiagnosis » effect

HOWEVER

- ⚗ Growing/ageing global population leads to effective new cases of thyroid cancer
- ⚗ Demand of I-131 is growing particularly in eastern asia (China)
- ⚗ New use of I-131 in RLT could further increase the demand
 - Neurological diseases (I-131 MIBG..)
 - Lymphoma/Leukemia
 - Antibody Drug Conjugates

3- Is there a risk of global shortage ?

(Short, Mid or Long Term)

NO... in theory

- ✿ Global supply is based on 4 main providers and 2 technologies:
 - IRE, NTP : U5 Fission base producers : main contributors
 - POLATOM, ANSTO: Activation of Te130
- ✿ Russia is supplying some markets but current supply is less reliable
- ✿ The current outage of Maria Research Reactor does create tension on the global market but with limited effect in the US and EU

BUT...

- ⚗ Fission base supply is directly linked to Mo99 demand...
 - ... but the global demand on Mo99 is slightly but steadily declining
- ⚗ Transition to LEU did not reduce the global offer of Mo99...
 - ... but reduced the production efficiency of I-131
- ⚗ Production by activation means access to neutron beams...
 - ... but in competition with new isotopes in growing demand → Lu-177
- ⚗ Activation in new validated research reactors is possible
 - ... but requires a steady and long term irradiation scheduling
- ⚗ Target irradiation dedicated for production of I-131 is possible
 - ... but would come at cost not compatible with current healthcare coverage

4- What would happen if the global supply does not meet any longer the demand?

A major deterioration in the medical benefit rendered

- ⚗ With no substitution possible, selection of patients will apply
- ⚗ Mortality in thyroid cancer (when I-131 sensitive) will grow
- ⚗ Morbi-mortality in certain hyperthyroidism will grow

5- Solutions to secure the supply ?

First do not reduce capacity...

- ❁ Eliminating our dependence on LEU to produce Mo-99 is certainly a respectable goal
- ❁ Any shift from LEU base production process to any other technology will create a loss of potential capacity of production of I-131
- ❁ In any case and as of today, production of I-131 is totally dependent upon research reactor whatever the technology used

Make the I-131 business sustainable

- ⚗ Make it sustainable for every actor of the value chain
 - From irradiation to patients
 - With profitability fairly distributed between the different players
- ⚗ I-131 has been “beating” cancer for 80 years: it deserves a fair reward on its price
 - If I-131 would be made available only today, with the full medical benefit and proven efficacy of the product how much “Healthcare System” would be ready to pay?

Find « extra » or « spare » capacity

Increase capacity from the I-131 Production process by activation of Te-130 isotope

- ⚗ Secure « neutron beam access » compatible with continuous production flow
- ⚗ Secure « neutron beam access » on the short AND long term
- ⚗ Qualified reactors network
- ⚗ Appropriate scheduling
- ⚗ Operating processing facilities
- ⚗ Regulatory consideration
- ⚗ Competitive and fair market price
- ⚗ And eventually Do what you say and say what you do

Is there a workable,
scalable and
(eventually...)
sustainable business
case ?

Find « extra » or « spare » capacity

Increase capacity from LEU fission process : Opt. 1 Dedicated target irradiation

- ⚙️ Adapt irradiation plan from LEU producers :
- ⚙️ Use same existing process
- ⚙️ Immediately scalable
- ⚙️ No main regulatory concern
- ⚙️ Set a fair selling/market price

Is there a
sustainable case ?

Find « extra » or « spare » capacity

Increase capacity from LEU fission process : Opt. 2 Get I-131 where it already exists

- ⚗ 2 Mo-99 producers do not extract I-131
- ⚗ The very low selling price is not worth the complexity and risk of the extraction process
- ⚗ If total or even part of this volume would be extracted, global demand would be likely covered for the next decade

Is there a workable and sustainable business case ?



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