



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 ?



Avenue de l'Espérance, 1
6220 Fleurus, Belgium

T.+32 (0)71 82 95 56
F.+32 (0)71 81 38 12

www.ire.eu
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